Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-4

REGISTRATION STATEMENT Under

The Securities Act of 1933

CARA THERAPEUTICS, INC. (Exact name of Registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

2834 (Primary Standard Industrial Classification Code Number) 75-3175693 (I.R.S. Employer Identification Number)

400 Atlantic Street Suite 500

Stamford, CT 06901 (203) 406-3700

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Christopher Posner Chief Executive Officer Cara Therapeutics, Inc. 400 Atlantic Street Suite 500 Stamford, CT 06901 (203) 406-3700

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Please send copies of all communications to:

Daniel A. Bagliebter Jeffrey P. Schultz Kenneth R. Koch Mintz Levin Cohn Ferris Glovsky and Popeo, P.C. 919 Third Avenue New York, NY 10022 (212) 935-3000 Scott Terrillion General Counsel Cara Therapeutics, Inc. 400 Atlantic Street Suite 500 Stamford, CT 06901 (203) 406-3700 Divakar Gupta Carlos Ramirez Rama Padmanabhan Anitha Anne Cooley LLP 55 Hudson Yards New York, NY 10001 (212) 479-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effectiveness of this registration statement and the satisfaction or waiver of all other conditions under the Merger Agreement described herein.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, please check the following box. \Box

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. \Box

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. \Box

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer	
Non-accelerated filer	\boxtimes	Smaller reporting company	\times
		Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. \Box

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13(e)-4(i) (Cross-Border Issuer Tender Offer)

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

PRELIMINARY — SUBJECT TO COMPLETION — DATED DECEMBER 18, 2024

PROPOSED MERGER YOUR VOTE IS VERY IMPORTANT

To the Stockholders of Cara Therapeutics, Inc.:

Cara Therapeutics, Inc. (Cara) and Tvardi Therapeutics, Inc. (Tvardi) have entered into an Agreement and Plan of Merger and Reorganization, dated December 17, 2024, as may be amended from time to time (Merger Agreement), pursuant to which CT Convergence Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Cara (Merger Sub), will merge with and into Tvardi, with Tvardi surviving as a wholly owned subsidiary of Cara (Merger). The Merger will result in a clinical-stage biopharmaceutical company focused on the development of novel, oral small molecule therapies targeting STAT3 to treat fibrosis-driven diseases with significant unmet need.

The Merger will become effective at the time the Certificate of Merger has been duly filed with the Secretary of State of the State of Delaware or such other date and time as is agreed upon by Cara and Tvardi and specified in the Certificate of Merger in accordance with the General Corporation Law of the State of Delaware (DGCL) (such date, the Closing Date, and such time, the Effective Time). At the Effective Time, (i) each outstanding share of common stock of Tvardi, \$0.001 par value per share (Tvardi common stock) (after giving effect to the automatic conversion of all shares of preferred stock of Tvardi into common stock of Tvardi prior to the Merger (the Preferred Stock Conversion) and excluding shares held by stockholders who have exercised and perfected appraisal rights and excluding shares held as treasury stock by Cara or held or owned by Cara, Merger Sub or any subsidiary of Cara or Tvardi), will be converted into the right to receive approximately 4.8997 shares of common stock of Cara, \$0.001 par value per share (Cara common stock), based on an assumed exchange ratio of 4.8997 (Exchange Ratio), which is subject to certain adjustments as described below, and (ii) the outstanding Convertible Notes (as defined below) of Tvardi will be automatically converted into an aggregate of approximately 46,115,173 shares of Cara common stock, assuming (a) interest on the Convertible Notes is accrued through an anticipated Closing Date of March 31, 2025 and (b) the Convertible Notes are converted into shares of Cara common stock (Conversion Shares) at a conversion price equal to 80% of the implied value of the combined company. The assumed Exchange Ratio was calculated assuming, among other things, that Cara's net cash at closing will be between \$22.875 million and \$23.125 million and a number of Conversion Shares equal to approximately 46,115,173. Such assumed Exchange Ratio is subject to certain adjustments, including based on the amount of Cara net cash at closing and the final amount of Conversion Shares. Cara will assume outstanding and unexercised options to purchase shares of Tvardi common stock, and in connection with the Merger they will be converted into options to purchase shares of Cara common stock based on the Exchange Ratio. At the Effective Time, Cara's stockholders will continue to own and hold their then existing shares of Cara common stock, subject to adjustment for the reverse stock split proposed in connection with the Merger. All outstanding and unexercised options to purchase shares of Cara common stock and outstanding Cara restricted stock units (RSUs) will be accelerated, the RSUs will be net settled, and the options will remain outstanding in accordance with their terms, except that the post-termination exercise period shall not exceed 90 days and the number of shares underlying such options will be adjusted based on the reverse stock split proposed in connection with the Merger.

Immediately following the Merger, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock and the holders of the Convertible Notes are expected to hold approximately 12.54% of the shares of Cara common stock, in each case, on a fully diluted basis, and subject to certain assumptions described below. The expected post-Merger equity ownership split percentages are based on the assumed Exchange Ratio of 4.8997 and an amount of Conversion Shares equal to 46,115,173 and are subject to adjustments, including based on the final Exchange Ratio and final amount of Conversion Shares.

The shares of Cara common stock are currently listed on The Nasdaq Capital Market under the symbol "CARA". Tvardi will file an initial listing application with The Nasdaq Stock Market LLC (Nasdaq) pursuant to Nasdaq's "reverse merger" rules. Substantially concurrent with the completion of the Merger, Cara will be renamed "Tvardi Therapeutics, Inc." and expects to trade on The Nasdaq Capital Market under the symbol "TVRD". On December 17, 2024, the last trading day before the date of this proxy statement/prospectus, the closing sale price of Cara common stock was \$0.2497 per share.

Cara is holding a special meeting of stockholders (Cara special meeting) in order to obtain the stockholder approvals necessary to complete the Merger and other matters. At the Cara special meeting, which will be held exclusively online via live audio-only webcast on , 2025, at Eastern Time, unless postponed or adjourned to a later date, Cara will ask its stockholders, among other things, to (i) approve the issuance of shares of Cara common stock as consideration in the Merger and the change of control of Cara resulting from the Merger, as described in this proxy statement/prospectus (Stock Issuance Proposal), (ii) approve the adoption of a new 2025 Equity Incentive Plan (Equity Incentive Plan Proposal), (iii) approve the adoption of a new 2025 Employee Stock Purchase Plan (ESPP Proposal), (iv) approve an amendment to Cara's certificate of incorporation effecting a reverse stock split of Cara common stock at a ratio in the range from -for-1 to -for-1, with such specific ratio to be mutually agreed upon by the respective Cara and Tvardi boards of directors or, if the issuance of shares of Cara common stock as consideration in the Merger is not approved by Cara stockholders, at a ratio determined solely by the Cara board of directors (Cara's Board or the Cara Board) following the special meeting, each as described in this proxy statement/prospectus. (Reverse Stock Split Proposal), (v) approve an amendment to Cara's certificate of incorporation to increase the authorized number of shares of common stock from shares to shares (Authorized Share Proposal) and (vi) approve a postponement or adjournment of the Cara special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal, referred to as the Adjournment Proposal.

Please refer to the various provisions of this proxy statement/prospectus for further information with respect to the business to be transacted at the Cara special meeting. As described in this proxy statement/prospectus, certain of Tvardi's stockholders are parties to support agreements with Cara and certain of Cara's stockholders are parties to support agreements with Tvardi (collectively, Support Agreements), whereby such stockholders have agreed to vote their shares in favor of the adoption and approval, among other things, of the Merger Agreement and the approval of the transactions contemplated therein, including the Merger, and, with respect to Cara's stockholders, the issuance of shares of Cara common stock to Tvardi's stockholders and the change of control resulting from the Merger, subject to the terms of the Support Agreements.

In addition, once this registration statement on Form S-4 (Registration Statement), of which this proxy statement/prospectus is a part, is declared effective by the Securities and Exchange Commission (SEC) and pursuant to the conditions of the Merger Agreement and the Support Agreements, Tvardi's stockholders who are party to the Support Agreements will each execute an action by written consent of Tvardi's stockholders (Tvardi Written Consent) adopting and approving, among other things, the Merger Agreement, and the transactions contemplated therein, including the Merger. No meeting of Tvardi's stockholders will be held; all of Tvardi's stockholders will have the opportunity to elect to adopt and approve the Merger Agreement and the transactions contemplated therein, by signing and returning to Tvardi the Tvardi Written Consent.

After careful consideration, Cara's Board has unanimously: (i) determined that the Merger and the transactions and actions contemplated by the Merger Agreement are fair to, advisable and in the best interests of Cara and its stockholders; (ii) authorized, approved and declared advisable the Merger Agreement and the transactions contemplated therein, including the Merger, the issuance of shares of Cara common stock to the stockholders of Tvardi common stock pursuant to the terms of Merger Agreement and the change of control of Cara resulting from the Merger; and (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that the stockholders of Cara vote "FOR" each of the proposals set forth in this proxy statement/prospectus.

More information about Cara, Tvardi and the proposed transactions is contained in this proxy statement/prospectus. Cara urges you to read this proxy statement/prospectus carefully and in its entirety. In particular, you should carefully consider the matters discussed under "Risk Factors" beginning on page <u>25</u>.

Cara is excited about the opportunities the Merger brings to Cara's stockholders, and thank you for your consideration and continued support.

Christopher Posner President and Chief Executive Officer Cara Therapeutics, Inc.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this proxy statement/prospectus. Any representation to the contrary is a criminal offense.

This proxy statement/prospectus is dated or about , 2025.

, 2025 and is first being mailed to Cara's and Tvardi's stockholders on



400 Atlantic Street Suite 500 Stamford, CT 06901 NOTICE OF SPECIAL MEETING OF STOCKHOLDERS To Be Held On , 2025

Dear Stockholders of Cara:

The Cara Board is pleased to deliver this proxy statement/prospectus for the proposed Merger between a wholly owned subsidiary of Cara and Tvardi, for the purpose of, among other things, considering the approval of the issuance of Cara common stock pursuant to the Merger Agreement, among Cara, Merger Sub and Tvardi, pursuant to the Merger.

There will not be a physical meeting location. The Cara special meeting will be held exclusively online via live audio-only webcast on , 2025, at Eastern Time, and can be accessed by visiting where you will be able to attend the Cara special meeting via live audio-only webcast. You will be able to vote your shares and submit questions during the Cara special meeting webcast. Online check-in will begin at Eastern Time, and Cara encourages you to allow ample time for the online check-in procedures. Please note that you will not be able to attend the Cara special meeting in person. Cara is holding the Cara special meeting to consider the following proposals:

1. Approve (i) the issuance of shares of Cara common stock pursuant to the Merger, which will represent more than 20% of the shares of Cara common stock outstanding immediately prior to the Merger and (ii) the change of control of Cara, pursuant to Rules 5635(a) and 5635(b) of Nasdaq, respectively, referred to as the Stock Issuance Proposal;

2. Approve the Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan, referred to as the Equity Plan Proposal;

3. Approve the Tvardi Therapeutics, Inc. 2025 Employee Stock Purchase Plan, referred to as the ESPP Proposal;

4. Approve an amendment to the amended and restated certificate of incorporation of Cara to effect a reverse stock split of Cara common stock at a ratio within the range between -for-1 to

-for-1 (with such ratio to be mutually agreed upon by the Cara Board and the Tvardi Board prior to the effectiveness of the Merger or, if the Stock Issuance Proposal is not approved by Cara stockholders, determined solely by the Cara Board), referred to as the Reverse Stock Split Proposal;

5. Approve an amendment to the Cara amended and restated certificate of incorporation to increase the number of authorized shares of Cara common stock from shares to shares, referred to as the Authorized Share Proposal; and

6. Approve a postponement or adjournment of the Cara special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal, referred to as the Adjournment Proposal.

These six proposals are referred to collectively as the Cara Proposals.

Please read this proxy statement/prospectus for further information with respect to the business to be transacted at the Cara special meeting. The Cara Board has fixed as the record date for the determination of stockholders entitled to notice of, and to vote at, the Cara special meeting and any adjournment or postponement thereof. Only holders of record of shares of Cara common stock at the close of business on the record date are entitled to notice of, and to vote at, the Cara special meeting.

At the close of business on the record date, Cara had shares of common stock outstanding and entitled to vote. A complete list of such stockholders entitled to vote at the Cara special meeting will be

available for examination at the Cara offices in Stamford, Connecticut during normal business hours for a period of ten days prior to the Cara special meeting.

Your vote is important. Approval of each of the Stock Issuance Proposal, the Equity Plan Proposal, the ESPP Proposal, the Reverse Stock Split Proposal and the Authorized Share Proposal requires the affirmative vote of a majority of the voting power of the votes cast by the holders of shares present at the meeting (by virtual attendance) or represented by proxy at the Cara special meeting and entitled to vote on the matter. Approval of the Adjournment Proposal requires the affirmative vote of a majority of shares present in person (by virtual attendance) or represented by proxy at the meeting and entitled to vote on the matter. No Cara Proposal is conditioned upon any other Cara Proposal. However, each of the Stock Issuance Proposal, the Reverse Stock Split Proposal and the Authorized Share Proposal is a condition to the consummation of the Merger. Therefore, the Merger cannot be consummated without the approval of the Stock Issuance Proposal, the Reverse Stock Split Proposal and the Authorized Share Proposal. The Equity Plan Proposal and the ESPP Proposal are conditioned upon the consummation of the Merger.

You are cordially invited to attend the Cara special meeting. The Cara special meeting can be accessed by , where you will be able to attend the Cara special meeting via live audio-only webcast. visiting In order to attend you must pre-register at . You will be able to vote your shares and submit questions during the Cara special meeting webcast by logging in using the unique link and password provided upon registration. Whether or not you expect to attend the Cara special meeting, to ensure your representation at the Cara special meeting, Cara urges you to submit a proxy to vote your shares as promptly as possible by (1) visiting the Internet site listed on the enclosed Cara proxy card, (2) calling the toll-free number listed on the enclosed Cara proxy card or (3) submitting your enclosed Cara proxy card by mail by using the provided self-addressed, stamped envelope. Submitting a proxy will not prevent you from attending by means of remote communication the Cara special meeting and voting at the Cara special meeting, but it will help to ensure that a quorum is present and avoid added solicitation costs. Any holder of record of Cara common stock as of the record date who attends the Cara special meeting may vote at the Cara special meeting, thereby revoking any previous proxy. In addition, a proxy may also be revoked in writing before the Cara special meeting in the manner described in this proxy statement/prospectus. If your shares are held in the name of a bank, broker or other nominee, please follow the instructions on the voting instruction form furnished by your bank, broker or other nominee.

If you own shares in street name through an account with a bank, broker or other nominee and you decide to attend the Cara special meeting, you cannot vote at the Cara special meeting unless you present a "legal proxy," issued in your name from your bank, broker or other nominee. If your shares are held in a brokerage account or by a bank or other nominee, your ability to vote by telephone or the Internet depends on your broker's voting process. Please follow the directions provided to you by your broker, bank or nominee.

THE CARA BOARD HAS UNANIMOUSLY DETERMINED AND BELIEVES THAT EACH OF THE PROPOSALS OUTLINED ABOVE IS FAIR TO, ADVISABLE AND IN THE BEST INTERESTS OF, CARA AND ITS STOCKHOLDERS. THE CARA BOARD UNANIMOUSLY RECOMMENDS THAT CARA'S COMMON STOCKHOLDERS VOTE "FOR" THE STOCK ISSUANCE PROPOSAL, THE EQUITY PLAN PROPOSAL, THE ESPP PROPOSAL, THE REVERSE STOCK SPLIT PROPOSAL, THE AUTHORIZED SHARE PROPOSAL AND THE ADJOURNMENT PROPOSAL.

By Order of the Cara Board of Directors,

Scott M. Terrillion Corporate Secretary Stamford, CT , 2025

ABOUT THIS DOCUMENT

This document, which forms part of a registration statement on Form S-4 filed with the SEC by Cara, constitutes a prospectus of Cara under the Securities Act of 1933, as amended (Securities Act), with respect to the shares of Cara common stock to be issued to the equityholders of Tvardi pursuant to the Merger Agreement. This document also constitutes a notice of a meeting and a proxy statement of Cara under Section 14(a) of the Securities Exchange Act of 1934, as amended (Exchange Act), with respect to the Cara special meeting at which Cara stockholders will be asked to consider and vote on the Cara Proposals.

No one has been authorized to provide you with information that is different from that contained in or incorporated by reference into this proxy statement/prospectus. This proxy statement/prospectus is dated as of the date set forth on the cover hereof. You should not assume that the information contained in or incorporated by reference into this proxy statement/prospectus is accurate as of any date other than the date on the front cover of those documents. Neither the mailing of this proxy statement/prospectus to Tvardi stockholders nor the issuance by Cara of Cara common stock in connection with the proposed Merger will create any implication to the contrary.

This proxy statement/prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, any securities, or the solicitation of a proxy, in any jurisdiction in which or from any person to whom it is unlawful to make any such offer or solicitation in such jurisdiction.

Information contained in this proxy statement/prospectus (including the documents incorporated by reference into this proxy statement/prospectus) regarding Tvardi and its business, operations, management and other matters has been provided by Tvardi and information contained in or incorporated by reference into this proxy statement/prospectus regarding Cara and its business, operations, management and other matters has been provided by Cara.

If you would like additional copies of this proxy statement/prospectus or if you have questions about the proposed Merger or the proposals to be presented at the Cara special meeting, please contact Cara's proxy solicitor listed below. You will not be charged for any of the documents that you request.

You may also request additional copies from Cara's proxy solicitor using the following contact information:

ALLIANCE ADVISORS, LLC

Stockholders call toll-free: 844-876-6183

Email: CARA@allianceadvisors.com

To ensure timely delivery of these documents, any request should be made no later than , 2025 to receive them before the Cara special meeting.

Cara intends to mail this proxy statement/prospectus on or about , 2025 to all stockholders of record entitled to vote at the Cara special meeting.

ADDITIONAL INFORMATION

This proxy statement/prospectus incorporates important business and financial information about Cara from other documents that are not included in or delivered with this proxy statement/prospectus. For a listing of documents incorporated by reference into this proxy statement/prospectus, please see the section entitled "*Where You Can Find More Information*" beginning on page <u>284</u> of this proxy statement/prospectus. This information is available to you without charge upon your request.

You can obtain the documents incorporated by reference into this proxy statement/prospectus by requesting them in writing or by telephone at the following address and telephone number:

Cara Therapeutics, Inc. 400 Atlantic Street Suite 500 Stamford, CT 06901 (203) 406-3700 Attn: Investor Relations

Investors may also consult Cara's website for more information concerning the Merger described in this proxy statement/prospectus. Cara's website is *www.Caratherapeutics.com*. Information included on or accessible through Cara's website is not incorporated by reference into this proxy statement/prospectus.

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QUESTIONS AND ANSWERS ABOUT THE MERGER

Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus does not give effect to the proposed reverse stock split (Reverse Stock Split) of common stock of Cara, as described in Proposal No. 4 beginning on page <u>180</u> of this proxy statement/ prospectus. The following section provides answers to frequently asked questions about the proposed Merger and the Cara special meeting. This section, however, provides only summary information. For a more complete response to these questions and for additional information, please refer to the cross-referenced sections.

Q: What is the Merger?

A: Cara, Merger Sub, and Tvardi entered into the Merger Agreement on December 17, 2024. The Merger Agreement contains the terms and conditions of the proposed merger transaction among Cara, Merger Sub and Tvardi. Under the Merger Agreement, Merger Sub will merge with and into Tvardi, with Tvardi surviving as a wholly owned subsidiary of Cara. This transaction is referred to as the Merger.

The Merger will become effective at the time the Certificate of Merger has been duly filed with the Secretary of State of the State of Delaware or such other date and time as is agreed upon by Cara and Tvardi and specified in the Certificate of Merger in accordance with the DGCL. At the Effective Time, (i) each share of Tvardi common stock outstanding immediately prior to the Effective Time (after giving effect to the conversion of all shares of Tvardi preferred stock into shares of Tvardi common stock (the Preferred Stock Conversion) and excluding shares held by stockholders who have exercised and perfected appraisal rights as more fully described in the section titled "*The Merger Agreement* — *Appraisal Rights*" beginning on page <u>155</u> of this proxy statement/prospectus and excluding shares held as treasury stock by Cara or held or owned by Cara, Merger Sub or any subsidiary of Cara or Tvardi) will be automatically converted solely into the right to receive a number of shares of Cara common stock calculated using an exchange ratio formula described in the Merger Agreement and (ii) each Convertible Note that is outstanding immediately prior to the Effective Time will be automatically converted into the right to receive a number of Shares of Cara common stock calculated based on a conversion price equal to 80% of the implied value of the combined company (as more fully described in the Section titled "*Agreements Related to the Merger*" beginning on page <u>163</u>).

Immediately following the Merger, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock and the holders of the Convertible Notes are expected to hold approximately 12.54% of the shares of Cara common stock, in each case of Cara and Tvardi, on a fully diluted basis and subject to further adjustment as further described below. The expected post-Merger equity ownership split percentages are based on the assumed Exchange Ratio of 4.8997 and an assumed amount of Conversion Shares equal to approximately 46,115,173, and are subject to adjustments based on the final Exchange Ratio and final amount of Conversion Shares. The assumed Exchange Ratio was calculated assuming, among other things, that Cara Net Cash (as defined below) at the closing of the Merger (Closing) will be between \$22.875 million and \$23.125 million, and an amount of Conversion Shares equal to approximately 46,115,173. Such assumed Exchange Ratio is subject to certain adjustments, including based on the amount of Cara Net Cash at Closing, the final ratio for the Reverse Stock Split of Cara common stock and the final amount of Conversion Shares. The Exchange Ratio formula is based upon a Tvardi fixed valuation of \$210.0 million and a Cara valuation of \$43.0 million, subject to certain adjustments, including based upon Cara Net Cash at Closing, and an assumed implied value of the combined company of approximately \$282 million, subject to certain adjustments, as more fully described in the section titled "The Merger Agreement — Merger Consideration and Exchange Ratio" beginning on page 140 of this proxy statement/prospectus. An \$18.0 million Cara Net Cash threshold is a condition for Tvardi to be required to complete the Merger (Net Cash Condition).

Based on the assumed Exchange Ratio of 4.8997 and an assumed amount of Conversion Shares equal to approximately 46,115,173, if Cara Net Cash less than \$22.875 million at Closing, the equityholders of Cara (pre-Merger) are expected to hold less than 15.25% of the outstanding shares of Cara common

stock, on a fully diluted basis (subject to further adjustment as further described below), and if Cara Net Cash more than \$23.125 million at Closing, the equityholders of Cara (pre-Merger) are expected to hold more than 15.25% of the outstanding shares of Cara common stock on a fully diluted basis, as more fully described in the section titled "*The Merger Agreement* — *Merger Consideration and Exchange Ratio*" beginning on page <u>140</u> of this proxy statement/prospectus.

At the Effective Time, Cara's stockholders will continue to own and hold their existing shares of Cara common stock, subject to adjustment in connection with the Reverse Stock Split. All outstanding and unexercised options to purchase shares of Cara common stock and outstanding Cara RSUs will be accelerated, the RSUs will be net settled, and the options will remain outstanding in accordance with their terms, except that the post-termination exercise period shall not exceed 90 days and the number of shares underlying such options will be adjusted based on the Reverse Stock Split. Each option to purchase shares of Tvardi common stock that is outstanding and unexercised immediately prior to the Effective Time, whether or not vested, will be assumed and converted into an option to purchase shares of Cara common stock, with the number of shares of Cara common stock subject to such option and the exercise price being appropriately adjusted to reflect the Exchange Ratio. Substantially concurrently with the completion of the Merger, Cara will change its corporate name to "Tvardi Therapeutics, Inc." as required by the Merger Agreement.

Q: What will happen to Cara if, for any reason, the Merger does not close?

A: If, for any reason, the Merger does not close, the Cara Board may elect to, among other things, continue the business of Cara, attempt to continue to sell or otherwise dispose of the various assets of Cara, or dissolve and liquidate its assets. Additionally, if the Merger does not close, Cara will not issue shares of Cara common stock to the equityholders of Tvardi as merger consideration and the Convertible Notes will not be converted into shares of Cara common stock. Under certain circumstances, Cara may be obligated to pay Tvardi or Tvardi may be obligated to pay Cara a termination fee of \$2.25 million or reimburse certain expenses up to \$750,000, as more fully described in the section titled "*The Merger Agreement — Termination and Termination Fees*" beginning on page <u>158</u> of this proxy statement/prospectus. If Cara decides to dissolve and liquidate its assets, Cara would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims. There can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying the debts and other obligations of Cara and setting aside funds for reserves.

Q: Why are the two companies proposing to merge?

A: Cara believes that the Merger will result in a clinical-stage biopharmaceutical company advancing the development of Tvardi's novel, oral small molecule therapies targeting STAT3 to treat fibrosis-driven diseases with significant unmet need. For a discussion of Cara's reasons for the Merger, please see the section titled "*The Merger — Cara Reasons for the Merger*" beginning on page <u>111</u> of this proxy statement/prospectus.

Q: Why am I receiving this proxy statement/prospectus?

A: You are receiving this proxy statement/prospectus because you have been identified as a holder of Cara common stock as of the record date.

This document serves as: (x) a proxy statement of Cara used to solicit proxies for the Cara special meeting and (y) a prospectus of Cara used to offer shares of Cara common stock in exchange for shares of Tvardi common stock (after giving effect to the Preferred Stock Conversion) and the Convertible Notes in the Merger. Information about the Cara special meeting, the Merger, the Merger Agreement and the other business to be considered by Cara stockholders at the Cara special meeting is contained in this proxy statement/prospectus. Cara stockholders should read this information carefully and in its entirety. The enclosed voting materials allow Cara stockholders to vote their shares by proxy without attending the Cara special meeting.

Cara Stockholders

If you are a holder of Cara common stock as of the record date, you are entitled to vote at the Cara special meeting, which has been called for the purpose of approving the following proposals:

- Proposal 1 (i) the issuance of shares of Cara common stock pursuant to the Merger, which will
 represent more than 20% of the shares of Cara common stock outstanding immediately prior to the
 Merger and (ii) the change of control of Cara resulting from the Merger, pursuant to Rules 5635(a)
 and 5635(b) of Nasdaq, respectively, referred to as the Stock Issuance Proposal;
- 2. **Proposal 2** the Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan, referred to as the Equity Plan Proposal;
- 3. **Proposal 3** the Tvardi Therapeutics, Inc. 2025 Employee Stock Purchase Plan, referred to as the ESPP Proposal;
- 4. Proposal 4 an amendment to the amended and restated certificate of incorporation of Cara to effect a reverse stock split of Cara common stock at a ratio within the range between -for-1 to -for-1 (with such ratio to be mutually agreed upon by the Cara Board and the Tvardi Board prior to the effectiveness of the Merger or, if the Stock Issuance Proposal is not approved by Cara stockholders, determined solely by the Cara Board), referred to as the Reverse Stock Split Proposal;
- Proposal 5— an amendment to the Cara amended and restated certificate of incorporation to increase the number of authorized shares of Cara common stock from shares to shares, referred to as the Authorized Share Proposal; and
- 6. **Proposal 6** the postponement or adjournment of the Cara special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal, referred to as the Adjournment Proposal.

Cara does not expect that any matter other than these six proposals (the Cara Proposals) will be brought before the Cara special meeting.

Q: What is required to consummate the Merger?

A: To consummate the Merger, holders of Cara common stock must approve the Stock Issuance Proposal (Proposal No. 1 above), the Reverse Stock Split Proposal (Proposal No. 4 above) and the Authorized Share Proposal (Proposal No. 5 above) (collectively, the Required Cara Closing Stockholder Matters).

Certain of Tvardi's stockholders and certain of Cara's stockholders are parties to Support Agreements with Cara and Tvardi, respectively, whereby such stockholders have agreed to vote their shares in favor of the adoption and approval, among other things, of the Merger Agreement and the Contemplated Transactions, subject to the terms of the Support Agreements.

In addition to the requirement of obtaining stockholder approval of the Required Cara Closing Stockholder Matters and the Tvardi Stockholder Matters, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived. For a complete description of the closing conditions under the Merger Agreement, refer to the section titled "*The Merger Agreement* — *Conditions to the Completion of the Merger*" beginning on page <u>144</u> of this proxy statement/prospectus.

In the event of a waiver of a condition, the Cara Board will evaluate the materiality of any such waiver to determine whether amendment of this proxy statement/prospectus and resolicitation of stockholder approval is necessary. For more information, refer to the section titled "*Risk Factors Related to the Merger* — *Cara or Tvardi may waive one or more of the conditions to the Merger without recirculation of this proxy statement/prospectus or resoliciting stockholder approval*" beginning on page <u>29</u> of this proxy statement/prospectus.

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Q: What will Tvardi's stockholders, noteholders and option holders receive in the Merger?

A: Each share of Tvardi common stock outstanding (after giving effect to the Preferred Stock Conversion) will be converted into the right to receive a number of shares of Cara common stock calculated using the Exchange Ratio. The Convertible Notes (as defined below) will also be converted into the right to receive a number of shares of Cara common stock calculated based on a conversion price equal to 80% of the implied value of the combined company (as more fully described in the Section titled *"Agreements Related to the Merger"* beginning on page <u>163</u>). Cara will assume options to purchase shares of Tvardi common stock (each such option, a Tvardi Option), and in connection with the Merger such Tvardi Options will be converted into options to purchase shares of Cara common stock. For a more complete description of what Tvardi's stockholders and option holders will receive in the Merger, please see the section titled *"The Merger Agreement — Merger Consideration and Exchange Ratio"* beginning on page <u>140</u> of this proxy statement/prospectus.

Q: What will Cara's stockholders and option holders receive in the Merger?

A: At the Effective Time, Cara's stockholders and optionholders will continue to own and hold their existing shares, RSUs or options to purchase shares of Cara common stock, which outstanding options and RSUs will be accelerated. The RSUs will be net settled and the options will remain outstanding in accordance with their terms, except that the post-termination exercise period shall not exceed 90 days and the number of shares underlying such options will be adjusted based on the Reverse Stock Split.

Q: Who will be the directors of Cara following the Merger?

A: At the Effective Time, the board of directors of the combined company (Combined Company Board) will consist of seven directors and will be comprised of five members designated by Tvardi (Sujal Shah, Michael Wyzga, Wallace Hall, Shaheen Wirk and Imran Alibhai), one member to be designated by Cara prior to Closing and one vacancy, to be designated by Tvardi if prior to the closing of the Merger or by the combined company if following the consummation of the Merger. The Combined Company Board will have an audit committee, a compensation committee and a nominating and corporate governance committee, in accordance with the rules of Nasdaq. All of Cara's current directors other than the director to be designated by Cara prior to Closing are expected to resign from their positions as directors of Cara, effective upon the Effective Time. For a more complete description of the Combined Company Board, please see the section titled "Management Following the Merger" beginning on page <u>252</u> of this proxy statement/prospectus.

Q: Who will be the executive officers of Cara following the Merger?

A: Immediately following the Merger, the executive management team of the combined company is expected to comprise the following individuals with such additional officers as may be added by the combined company:

Name	Position with the Combined Company	Current Position at Tvardi
Imran Alibhai, Ph.D.	Chief Executive Officer and Director	Chief Executive Officer and Director
Dan Conn, J.D., M.B.A.	Chief Financial Officer	Chief Financial Officer
John Kauh, M.D.	Chief Medical Officer	Chief Medical Officer
Jeffrey Larson, Ph.D., DABT	Senior Vice President, Research &	Senior Vice President, Research &
	Development	Development
Yixin "Joseph" Chen, Ph.D.	Vice President, Chemistry, Manufacturing and Controls	Vice President, Chemistry, Manufacturing and Controls



Q: As a stockholder of Cara, how does the Cara Board recommend that I vote?

- A: After careful consideration, the Cara Board recommends that the holders of Cara common stock vote:
 - "FOR" Proposal 1 the Stock Issuance Proposal;
 - "FOR" Proposal 2 the Equity Plan Proposal;
 - "FOR" Proposal 3 the ESPP Proposal;
 - "FOR" Proposal 4 the Reverse Stock Split Proposal;
 - "FOR" Proposal 5 the Authorized Share Proposal; and
 - "FOR" Proposal 6 the Adjournment Proposal.

For more information on each proposal and the Cara Board's recommendations, please see the section titled "*Matters Being Submitted to a Vote of Cara's Stockholders*" beginning on page <u>166</u> of this proxy statement/prospectus.

Q: How many votes are needed to approve each Cara Proposal?

A: Approval of each of the Stock Issuance Proposal, the Equity Plan Proposal, the ESPP Proposal and the Authorized Share Proposal requires the affirmative vote from a majority of the votes cast by the holders of shares present at the meeting (by virtual attendance) or represented by proxy. Approval of the Adjournment Proposal requires votes from the majority of shares present in person (by virtual attendance) or represented by proxy at the meeting and entitled to vote on the matter.

Q: What risks should I consider in deciding whether to vote in favor of the Cara Proposals?

A: You should carefully review the section titled "*Risk Factors*," beginning on page <u>25</u> of this proxy statement/prospectus. You also should read and carefully consider the risk factors contained in the documents that are incorporated by reference into this proxy statement/prospectus.

Q: When do you expect the Merger to be consummated?

A: We anticipate that the Merger will be consummated during the first half of 2025, soon after the Cara special meeting to be held on , 2025, but we cannot predict the exact timing. For more information, please see the section titled "*The Merger Agreement* — *Conditions to the Completion of the Merger*" beginning on page <u>144</u> of this proxy statement/prospectus.

Q: What are the material U.S. Federal Income Tax consequences of the Merger to holders of Cara common stock?

A: Cara stockholders will not sell, exchange or dispose of any shares of Cara common stock as a result of the Merger. Thus, there will be no material U.S. federal income tax consequences to Cara stockholders as a result of the Merger.

Q: What are the material U.S. Federal Income Tax consequences of the Reverse Stock Split to U.S. holders of Cara shares?

A: Cara intends to treat the Reverse Stock Split as a "recapitalization" for U.S. Federal Income Tax purposes. If it so qualifies, a Cara stockholder who is a U.S. holder (as defined in the section titled "Matters Being Submitted to a Vote of Cara's Stockholders — Proposal No. 4: Approval of an Amendment to the Amended and Restated Certificate of Incorporation of Cara Effecting the Reverse Stock Split — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split" beginning on page <u>185</u> of this proxy statement/prospectus) should not recognize gain or loss upon the Reverse Stock Split (other than in respect of cash received in lieu of fractional shares). A U.S. holder's aggregate tax basis in the shares of Cara common stock received pursuant to the Reverse Stock Split should equal the aggregate tax basis of the shares of Cara common stock surrendered (excluding any portion of such basis that is allocated to any fractional share of Cara common stock), and such U.S. holder's holding

period in the shares of Cara common stock received should include the holding period in the shares of Cara common stock surrendered. Treasury Regulations provide detailed rules for allocating the tax basis and holding period of the shares of Cara common stock surrendered to the shares of Cara common stock received in a "recapitalization". U.S. holders of shares of Cara common stock acquired on different dates and at different prices should consult their tax advisors regarding the allocation of the tax basis and holding period of such shares.

Please review the information in the section titled "Matters Being Submitted to a Vote of Cara's Stockholders — Proposal No. 4: Approval of an Amendment to the Amended and Restated Certificate of Incorporation of Cara Effecting the Reverse Stock Split — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split" beginning on page <u>185</u> of this proxy statement/prospectus for a more complete description of the material U.S. Federal Income Tax consequences of the Reverse Stock Split U.S. Federal Income Tax consequences of the Reverse Stock Split.

Q: What are the Convertible Notes?

A: On December 3, 2024, Tvardi entered into a Note Purchase Agreement to issue and sell convertible promissory notes (Convertible Notes) in an aggregate amount of approximately \$28.3 million. The Convertible Notes accrue simple interest at 8% per annum and mature on December 31, 2026. Upon the Closing, the outstanding principal balance of such notes and all unpaid accrued interest will be automatically converted into shares of Cara common stock, at a conversion price equal to 80% of the implied valuation of the combined company in the Merger. The Conversion Shares shall be calculated by multiplying the Post-Closing Cara Shares (as defined below) by (a) the quotient obtained by dividing (i) the Implied Note Valuation (as defined below) by (ii) the Aggregate Post-Bridge Valuation (as defined below). The Post-Closing Shares means the quotient obtained by *dividing* the Cara Outstanding Shares (as defined below) by the Cara Allocation Percentage (as defined below). The Implied Note Valuation means the quotient obtained by dividing (a) the principal amount of the Convertible Notes plus all accrued and unpaid interest by (b) 80%. The Aggregate Post-Bridge Valuation means the sum of (i) the Tvardi Valuation (as defined below), plus (ii) the Cara Valuation (as defined below) plus (iii) the Implied Note Valuation. The Conversion Shares issued with respect to the 20% discount under the terms of the Convertible Notes (Note Conversion Discount Shares) shall dilute the pre-Merger equityholders of Tvardi as part of calculating the Exchange Ratio. The remaining Conversion Shares shall dilute the pre-Merger Cara equityholders and the pre-Merger Tvardi equityholders on a pro rata basis. Immediately following the conversion of the Convertible Notes, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock, and the holders of the Convertible Notes are expected to hold approximately 12.54% of the shares of Cara common stock, in each case of Cara and Tvardi, on a fully diluted basis and subject to further adjustment as further described below. The expected post-Merger equity ownership split percentages are based on the assumed Exchange Ratio of 4.8997 and an amount of Conversion Shares equal to approximately 46,115,173 and are subject to adjustments based on the final Exchange Ratio and final amount of Conversion Shares. For more information about the Convertible Notes, please see the section titled "Agreements Related to the Merger" beginning on page 163 of this proxy statement/ prospectus.

Q: What do I need to do now?

A: Cara urges you to read this proxy statement/prospectus carefully, including its annexes and information incorporated herein, and to consider how the Merger affects you.

If you are a common stockholder of Cara, please vote your shares as soon as possible so that your shares will be represented at the Cara special meeting. Please follow the instructions set forth on the enclosed Cara proxy card or on the voting instruction form provided by the record holder of your shares if your shares are held in the name of your bank, broker or other nominee.

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Q: When and where is the Cara special meeting? What must I do to attend the Cara special meeting?

A: The Cara special meeting will be held exclusively online via live audio-only webcast on , 2025 at Eastern Time. Online check-in will begin at Eastern Time, and Cara encourages you to allow ample time for the online check-in procedures. Please note that you will not be able to attend the Cara special meeting in person.

You or your authorized proxy may attend the Cara special meeting if you were a registered or beneficial stockholder of Cara common stock as of the record date.

You will be able to vote your shares and submit questions during the Cara special meeting webcast by logging in to the website listed above using the 16-digit control number included in your proxy card. If you wish to submit a question during the Cara special meeting, log into the Cara special meeting platform at ______, type your question into the "Ask a Question" field, and click "Submit." Cara will respond to as many properly submitted questions during the relevant portion of the Cara special meeting agenda as time allows.

If Cara experiences technical difficulties during the Cara special meeting (e.g., a temporary or prolonged power outage), Cara will determine whether the Cara special meeting can be promptly reconvened (if the technical difficulty is temporary) or whether the Cara special meeting will need to be reconvened on a later day (if the technical difficulty is more prolonged). In any situation, Cara will promptly notify stockholders of the decision via Cara will have technicians ready to assist you with any technical difficulties you may have accessing the Cara special meeting website. If you encounter any difficulties accessing the Cara special meeting website during the check-in or meeting time, please call the technical support number that will be posted on the Cara special meeting website log-in page at

If you own shares in street name through an account with a bank, broker or other nominee, please send proof of your Cara share ownership as of the record date (for example, a brokerage firm account statement or a "legal proxy" from your intermediary) along with your registration request. If you are not sure what proof to send, check with your intermediary.

If your shares are registered in your name with Cara's stock registrar and transfer agent, Equiniti Trust Company, LLC, no proof of ownership is necessary because Cara can verify your ownership.

Q: What is the quorum requirement?

A: A quorum of Cara stockholders is necessary to hold a valid meeting. The presence virtually or by proxy duly authorized, of the holders of one-third of the outstanding shares of common stock entitled to vote, as of the record date, shall constitute a quorum for the transaction of business at the Cara special meeting. As of the record date there were shares of Cara common stock outstanding and entitled to vote. Accordingly, the holders of at least shares of Cara common stock must be present virtually or by proxy at the Cara special meeting to establish a quorum.

Your shares will be counted towards the quorum if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other nominee) or if you attend the Cara special meeting and vote your shares during the Cara special meeting. Abstentions and broker non-votes, if applicable, will also be counted towards the quorum requirement. If there is no quorum, the person presiding over the Cara special meeting, or the holders of a majority of shares present at the Cara special meeting or represented by proxy, may adjourn the meeting to another date.

Q: How are votes with respect to the Cara Proposals counted?

A: Votes with respect to the Cara Proposals will be counted by the inspector of elections appointed for the meeting, who will separately count votes "FOR" and "AGAINST," abstentions and, if applicable, broker non-votes.

Cara does not expect that any matters other than the Cara Proposals will be brought before the Cara special meeting.

Q: What are "broker non-votes"?

A: Brokers who hold shares in street name for customers have the authority to vote on "routine" proposals when they have not received instructions from beneficial owners. However, brokers are precluded from exercising their voting discretion with respect to approval of non-routine matters, and, as a result, absent specific instructions from the beneficial owner of such shares, brokers are not empowered to vote those shares, referred to generally as "broker non-votes." Broker non-votes, if any, will be treated as shares that are present at the Cara special meeting for purposes of determining whether a quorum exists but will not have any effect for the purpose of voting on Proposal No. 1 (Stock Issuance Proposal), Proposal No. 2 (Equity Plan Proposal), Proposal No. 3 (ESPP Proposal), Proposal No. 4 (Reverse Stock Split Proposal), Proposal No. 5 (Authorized Share Proposal) or Proposal No. 6 (Adjournment Proposal).

Q: What will happen if I return my proxy form without indicating how to vote?

A: If you submit your proxy form without indicating how to vote your shares on any particular Cara Proposal, the common stock represented by your proxy will be voted as recommended by the Cara Board with respect to that proposal.

Q: May I change my vote after I have submitted a proxy or voting instruction form?

- A: Cara's common stockholders of record, other than those Cara stockholders who are parties to Support Agreements, may change their vote at any time before their proxy is voted at the Cara special meeting in one of following ways:
 - By sending a written notice to the Secretary of Cara stating that you would like to revoke your proxy;
 - By duly executing a subsequently dated proxy relating to the same shares of common stock and return it in the postage-paid envelope provided or similar means, which subsequent proxy is received before the prior proxy is exercised at the Cara special meeting;
 - Duly submitting a subsequently dated proxy relating to the same shares of common stock by telephone or via the Internet (i.e., your most recent duly submitted voting instructions will be followed) before Eastern Time on , 2025; and
 - By attending the Cara special meeting and voting such shares during the Cara special meeting.

If a stockholder who owns Cara shares in "street name" has instructed a broker to vote its shares of Cara common stock, the stockholder must follow directions received from its broker to change those instructions.

Q: Who is paying for this proxy solicitation?

- A: Cara and Tvardi will each pay 50% of the costs of printing and filing of this proxy statement/ prospectus and any amendments and supplements thereto and paid to a financial printer or to the SEC. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Cara common stock for the forwarding of solicitation materials to the beneficial owners of Cara common stock. Cara will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. In addition, Cara has engaged Alliance Advisors, LLC, a proxy solicitation firm, to solicit proxies from Cara's stockholders for a fee of up to approximately \$50,000 plus certain additional costs associated with solicitation campaigns, which fees and costs will be shared between Cara and Tvardi.
- Q: Should Cara's and Tvardi's stockholders send in their stock certificates now, to the extent they have any?
- A: No. After the Merger is consummated, Tvardi's stockholders will receive written instructions from the exchange agent for exchanging their certificates or book entry notations representing shares of Tvardi common stock (after giving effect to the Preferred Stock Conversion) for book entry notations

representing shares of Cara common stock. Each Tvardi stockholder who otherwise would be entitled to receive a fractional share of Cara common stock will be entitled to receive cash in lieu of fractional shares.

In addition, Cara's stockholders will receive written instructions, as applicable, from Cara's transfer agent, Equiniti Trust Company, LLC, for exchanging their certificates representing shares Cara common stock for new certificates giving effect to the Reverse Stock Split, if effected. Cara's stockholders will also receive a cash payment in lieu of any fractional shares, determined by multiplying such fraction by the average closing trading price of a share of Cara common stock on Nasdaq for the five consecutive trading days ending three trading days immediately prior to the date of the public announcement of the Merger Agreement, which is equal to \$0.276.

Q: Who can help answer my questions?

A: If you are a stockholder of Cara and would like additional copies, without charge, of this proxy statement/prospectus or if you have questions about the Merger, including the procedures for voting your shares, you should contact Alliance Advisors, LLC, Cara's proxy solicitor, by telephone, toll-free, at 844-876-6183 or by email at CARA@allianceadvisors.com.



PROSPECTUS SUMMARY

This summary highlights selected information from this proxy statement/prospectus and may not contain all of the information that is important to you. To better understand the Merger and the proposals being considered at the Cara special meeting, you should read this entire proxy statement/prospectus carefully, including the Merger Agreement attached as Annex A and the other annexes to which you are referred herein and the documents incorporated by reference into this proxy statement/prospectus. For more information, please see the section titled "Where You Can Find More Information" beginning on page <u>284</u> of this proxy statement/prospectus.

The Companies

Cara Therapeutics, Inc.

400 Atlantic Street, Suite 500 Stamford, Connecticut 06901 (203) 406-3700

Cara is a biopharmaceutical company that has been focused on leading a new treatment paradigm to improve the lives of patients suffering from chronic pruritus. On June 14, 2024, the Cara Board approved a streamlined operating plan exploring strategic alternatives focused on maximizing shareholder value after Cara announced its decision to discontinue the clinical program in notalgia paresthetica (NP) on June 12, 2024. Cara's decision to discontinue the clinical program in NP followed the outcome from the dose-finding Part A of the KOURAGE-1 study evaluating the efficacy and safety of oral difelikefalin for moderate-to-severe pruritus in adult patients with NP in which oral difelikefalin did not demonstrate a meaningful clinical benefit at any dose compared to placebo. The decision was not related to any safety or medical issues, or negative regulatory feedback related to the NP program.

Cara also developed an IV formulation of oral difelikefalin, which is approved for the treatment of moderate-to-severe pruritus associated with advanced chronic kidney disease in adults undergoing hemodialysis in the United States, the European Union (EU) and multiple other countries. The IV formulation is out-licensed worldwide.

On December 17, 2024, Cara and its subsidiary, Cara Royalty Sub, LLC (Royalty Sub, and together with Cara, each, a Seller and together, the Sellers), entered into an Asset Purchase Agreement (APA) with Vifor Fresenius Medical Care Renal Pharma, Ltd., a majority-owned, indirect subsidiary of CSL Limited (CSL Vifor), pursuant to which, at the consummation of the transaction, Sellers will sell to CSL Vifor and CSL Vifor will acquire from Sellers certain assets and rights for the development, manufacture and commercialization of difelikefalin as well as certain associated liabilities (Asset Disposition) for a purchase price of \$900,000 (subject to certain adjustments with respect to inventory). Pursuant to the APA, in connection with the consummation of the Asset Disposition, CSL Vifor and HCR (as defined below) have entered into a letter agreement with Cara providing that CSL Vifor and HCR will, subject to the satisfaction of conditions to closing under the APA, enter into an amended and restated purchase agreement to amend and replace the existing Purchase and Sale Agreement, dated as of November 1, 2023 (as amended, Original HCR Agreement), by and among Royalty Sub, HCRX Investments HoldCo, L.P. (HCRX) and HealthCare Royalty Partners IV, L.P. (HCR IV and together with HCRX, HCR). Upon entering into the amended and restated purchase agreement, effective as of the closing of the Asset Disposition: (i) CSL Vifor will be obligated to make certain payments to HCR from and after the date thereof relating to certain revenue and/or royalties from difelikefalin, (ii) each of the Contribution Agreement, the License Agreement and the Pledge Agreement (each as defined in the Original HCR Agreement) shall be terminated, and (iii) Sellers shall have no further payment or other obligations to HCR under the Original HCR Agreement. Additionally, pursuant to the APA, at the consummation of the Asset Disposition, Cara has agreed to pay CSL Vifor \$3.0 million to compensate CSL Vifor for the estimated incremental future expenses to be incurred by CSL Vifor as a result of the transfer of the assets to be acquired and the liabilities to be assumed by it in connection with the Asset Disposition. See "Asset Sale" beginning on page 165 of this proxy statement/prospectus.

This proxy statement/prospectus incorporates important business and financial information about Cara from other documents that are not included in or delivered with this proxy statement/prospectus. For

a list of the documents that are incorporated by reference, see "*Where You Can Find More Information*" beginning on page <u>284</u> of this proxy statement/prospectus.

Tvardi Therapeutics, Inc.

3 Sugar Creek Center Blvd., Suite 525 Sugarland, Texas 77478 (713) 489-8654

Tvardi is a clinical-stage biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting STAT3 to treat fibrosis-driven diseases with significant unmet need. Tvardi is leveraging its deep understanding of the transcription factor, STAT3, to develop a pipeline of oral small molecules with a differentiated mechanism of action to directly inhibit STAT3, a highly validated, yet historically undruggable target. Tvardi's lead product candidate, TTI-101, is in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), and hepatocellular carcinoma (HCC). Tvardi expects to report unblinded data from the Phase 2 IPF clinical trial in the second half of 2025 and anticipates preliminary topline data from the Phase 1b/2 HCC clinical trial in the second half of 2025. Its second product candidate, TTI-109, is structurally related to, yet chemically distinct from, TTI-101 and is designed to enhance the ability to target STAT3. Tvardi expects to submit an investigational new drug (IND), application for TTI-109 in the first half of 2025.

Tvardi's approach is rooted in the expertise around STAT3's functional composition and its critical role in disease pathogenesis, as well as other essential biological functions. Tvardi's co-founder, David J. Tweardy, M.D., was one of the first to identify that STAT3, when activated by phosphorylation on tyrosine (Y) residue 705, referred to herein as pY-STAT3, acts as a central catalyst across critical fibrotic signaling pathways and is key to the cellular processes associated with fibrosis-driven diseases. Persistent pY-STAT3 drives the development and progression of the pathogenic cascade of fibrosis. By targeting pY-STAT3, Tvardi's approach is designed to simultaneously modulate each of the key pathways of the fibrotic cascade, whereas, previous approaches only targeted single pathways. Beyond its role in fibrosis, STAT3 also has an essential role in cellular respiration in the mitochondria. Tvardi, therefore, leveraged the insights of its cofounder to design its product candidates to inhibit STAT3 activation which, it believes, will lead to disease modifying activity without impairing essential biological functions in the mitochondria.

Tvardi believes it has robust proof of concept to support the potential of STAT3 inhibitors to treat fibrosis-driven diseases. In preclinical models, TTI-101 administration resulted in statistically significant reductions in levels of well-known biomarkers of fibrosis, most notably collagen type I alpha1 chain (COL1A1) ($p \le 0.05$). In addition, TTI-101 administration decreased the amount of fibrotic tissue in the lungs in a statistically significant manner ($p \le 0.05$), as measured by histologic evaluation of fibrosis severity, and returned oxygen saturation (SO₂), to near normal levels versus animals treated with placebo where SO_2 levels continued to decline. Tyardi is currently enrolling patients in an ongoing Phase 2, randomized, double-blind, placebo-controlled clinical trial of TTI-101 as monotherapy or in addition to nintedanib, a standard of care (SoC), therapy, to evaluate its safety, tolerability and preliminary efficacy in patients suffering from IPF. It has also previously demonstrated, in a Phase 1 oncology clinical trial of TTI-101 as monotherapy enriched for patients with HCC, that TTI-101 was generally well-tolerated, targeted STAT3, lowering levels of pY-STAT3 in tumors as evidenced by biopsy sample, and demonstrated a disease control rate of 53% as measured by Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1), a standard way to measure the response of a tumor to treatment. Tvardi is currently enrolling patients in its Phase 1b/2 clinical trial to investigate TTI-101 as monotherapy and in combination with SoC, in patients with HCC. The ongoing Phase 1b/2 design allows Tvardi to transition from a dose-finding and safety evaluation in the Phase 1b portion of the clinical trial, to a larger, Phase 2 portion of the clinical trial with primary efficacy endpoints, including overall response rate using RECIST v.1.1.



The U.S. Food and Drug Administration (FDA), has granted orphan drug designation for TTI-101 in both IPF and HCC as well as Fast-Track Designation for TTI-101 in HCC.

TTI-101 for the Treatment of IPF

In the United States, approximately 150,000 individuals have IPF, while globally the number is estimated to be three million. Currently, approved anti-fibrotic therapies, Esbriet and Ofev, had collective peak sales of \$4.9 billion, yet their use is limited as they do not reverse fibrosis or improve lung function. Based on the well-established role of pY-STAT3 in the pathogenesis of fibrosis, Tvardi believes TTI-101's differentiated mechanism of action has the potential to address this unmet need in IPF, if approved. In preclinical models, Tvardi observed that TTI-101 led to a reduction of fibrotic tissue in the lungs and improved lung function. Tvardi also observed dose-dependent decreases in validated biomarkers associated with cell proliferation (resulting in reduced deposition) as well as increase in the modulation and activity of T cells (responsible for increased cellular and extracellular degradation). Additionally, Tvardi's completed Phase 1 healthy volunteer drug-drug interaction clinical trial with IPF SoC therapies showed TTI-101 to be generally well-tolerated. No severe adverse events were reported. The most frequent treatment emergent adverse events predominantly reported as mild in severity, resolved on study. This clinical data, including robust pharmacokinetic (PK), pharmacodynamic (PD), and tolerability data, has allowed Tvardi to rapidly progress into a Phase 2 clinical trial in IPF.

Tvardi is currently enrolling in a REVERT_{IPF} Phase 2, multicenter, randomized, double-blind, placebocontrolled clinical trial of TTI-101 to evaluate safety, tolerability and PK in patients suffering from IPF as monotherapy and in addition to nintedanib, a current SoC. Tvardi also plans to evaluate multiple efficacy measures, including the established Phase 3 efficacy endpoint of forced vital capacity (FVC). Approximately 75 patients are randomly assigned (1:1:1) to receive oral TTI-101 400 mg/day, TTI-101 800 mg/day or placebo for 12 weeks as monotherapy or in addition to SoC, nintedanib. The natural course of disease for patients suffering from IPF even when treated with SoC, is a decline in lung function as measured by FVC. Preliminary blinded data from the two dose levels of TTI-101 and placebo in 38 patients to date have reported approximately 50% of patients' FVC values near or above baseline. Tvardi expects to report unblinded data from this clinical trial in the second half of 2025.

TTI-101 for the Treatment of HCC

HCC, a fibrosis-driven cancer, is the third-leading cause of cancer-related mortality in the United States and globally, with an estimated survival of six to 20 months following diagnosis. Treatment with the current SoC in first line remains suboptimal with an overall response rate (ORR), of 10% to 27%. Following

progression on first-line therapies, response rates are further reduced (ORR of \leq 5%) for patients who go on to receive second-line therapies. Overall response rate is defined as the proportion of patients who have achieved a partial response (\geq 30% decrease in the sum of the diameters of target lesions, as compared with the baseline sum of diameters) or a complete response (disappearance of all target lesions). Similar to its role in IPF, pY-STAT3 in HCC serves an integral role in both the intrinsic cellular processes that drive aberrant proliferation, survival, deposition and extrinsic processes that induce immune suppression. Greater than 95% of patients with HCC have pY-STAT3 in their tumors, the presence of which correlates closely with tumor vascularity and aggressiveness of disease and is significantly associated with poor overall survival. In preclinical studies, TTI-101 demonstrated statistically significant changes in (1) microsteatosis score (abnormal liver fat accumulation) that was 89% lower in animals treated with TTI-101 versus placebo treated animals (p < 0.001), (2) fibrosis, measured by histologic staining, that was 65% lower in animals treated with TTI-101 versus placebo treated animals (p<0.001) and (3) tumor growth, measured by comparing the average tumor volume determined by MRI, that was 57% lower in animals treated with TTI-101 versus placebo treated animals (p=0.04). Additionally, in a separate study, combination of TTI-101 with anti-PD-1 and bevacizumab demonstrated a larger reduction in tumor weight compared to anti-PD-1 and bevacizumab or saline that was statistically significant (p < 0.01). Tvardi has completed a Phase 1 doseescalation and dose-expansion clinical trial for TTI-101 in advanced tumors, enriched for patients with HCC. TTI-101 was observed to lower levels of pY-STAT3 in tumors as evidenced by biopsy sample and demonstrated a disease control rate of 53% as measured by RECIST v1.1, leading to clinical responses in HCC and other tumor types. Tvardi believes that the results to date support TTI-101's differentiated mechanism of action to deliver therapeutic benefit as monotherapy and in combination with existing SoC agents, if approved. If approved, Tvardi does not believe that a commercial license, supply and/or collaboration agreement with the marketers of existing SoC treatments would be needed, as these commercial therapies are available in the market.

Tvardi is currently enrolling a REVERT_{LIVER CANCER} Phase 1b/2, multicenter, open-label clinical trial designed to investigate the safety and efficacy of TTI-101 across three cohorts of patients with HCC: as monotherapy and in combination with SoC treatments pembrolizumab or atezolizumab + bevacizumab. Tvardi plans to report preliminary topline data from this clinical trial in the second half of 2025.

TTI-109

Tvardi's second product candidate, TTI-109, is an oral, small-molecule, prodrug of, and mechanistically identical to, TTI-101. TTI-109 itself does not inhibit STAT3, but rapidly converts to TTI-101 in the blood. TTI-109 is designed to enhance the ability to target STAT3 as a more efficient delivery vehicle for TTI-101 with the potential to improve tolerability. In Tvardi's IND-enabling toxicology studies in rats and monkeys, TTI-109 has been observed to result in equivalent drug exposure as compared to TTI-101, with no toxicity observed. Tvardi has received pre-IND feedback from the FDA that the data package to date is sufficient to support a clinical trial of TTI-109 in oncology. To maximize the potential of TTI-109 in fibrosis-driven diseases, Tvardi is planning additional preclinical studies and a first-in-human IND submission for TTI-109 in the first half of 2025.

CT Convergence Merger Sub, Inc.

400 Atlantic Street, Suite 500 Stamford, Connecticut 06901 (203) 406-3700

Merger Sub is a wholly-owned subsidiary of Cara and was formed solely for the purposes of carrying out the Merger.

The Merger

On December 17, 2024, Cara, Merger Sub and Tvardi entered into the Merger Agreement, pursuant to which Merger Sub will merge with and into Tvardi, with Tvardi surviving as a wholly owned subsidiary of Cara. Cara common stock will be issued to the holders of Tvardi common stock at the Effective Time (after giving effect to the Preferred Stock Conversion) and holders of Convertible Notes at the Effective Time, and Cara will assume each Tvardi Option, which will become options to purchase Cara common stock at

the Effective Time. In connection with the Closing, Cara will change its name to "Tvardi Therapeutics, Inc." References to the combined company in this proxy statement/prospectus are references to Cara, its consolidated subsidiaries and Tvardi following the Merger.

Cara and Tvardi expect the Merger to be consummated during the first half of 2025, subject to satisfaction or waiver of certain conditions to the Closing, including, among other things, approval by Cara's stockholders of the Required Cara Closing Stockholder Matters.

Immediately following the Merger, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock, and the holders of the Convertible Notes are expected to hold approximately 15.54% of the shares of Cara common stock, in each case, on a fully diluted basis and subject to further adjustment as further described below. The expected post-Merger equity ownership split percentages are based on the assumed Exchange Ratio of 4.8997 and an assumed amount of Conversion Shares equal to approximately 46,115,173 and are subject to adjustments based on the final Exchange Ratio and final amount of Conversion Shares. The assumed Exchange Ratio was calculated assuming, among other things, that Cara Net Cash at the Closing will be between \$22.875 million and \$23.125 million and an amount of Conversion Shares equal to approximately 46,115,173. Such assumed Exchange Ratio is subject to certain adjustments, including based on the amount of Cara Net Cash at Closing, the final ratio for the reverse stock split of Cara common stock and the final amount of Conversion Shares. The Exchange Ratio formula is based upon a Tvardi fixed valuation of \$210.0 million and a Cara valuation of \$43.0 million, subject to certain adjustments, including based upon Cara Net Cash at Closing, and an assumed implied value of the combined company of \$282.0 million, subject to certain adjustments, as more fully described in the section titled "The Merger Agreement -Merger Consideration and Exchange Ratio" beginning on page 140 of this proxy statement/prospectus. An \$18.0 million Cara Net Cash threshold is a condition for Tvardi to be required to complete the Merger.

Reasons for the Merger

The Cara Board considered various reasons for the Merger, as described later in this proxy statement under the section titled "*The Merger — Cara Reasons for the Merger*."

Opinion of Cara's Financial Advisor

On December 17, 2024, Piper Sandler & Co. (Piper Sandler), rendered its oral opinion, which was subsequently confirmed by delivery of Piper Sandler's written opinion, dated December 17, 2024, to the Cara Board that, as of such date and based upon and subject to the various assumptions made, procedures followed, matters considered, and qualifications and limitations upon the review undertaken by Piper Sandler in preparing its opinion, the Exchange Ratio (without giving effect to the Reverse Stock Split) was fair, from a financial point of view, to Cara as of the date thereof (the Piper Sandler Opinion, as more fully described under the section titled "*The Merger — Opinion of Cara's Financial Advisor*" beginning on page <u>114</u>).

The full text of the written opinion is attached to this proxy statement/prospectus as Annex B and is incorporated into this proxy statement/prospectus by reference. The description of the Piper Sandler Opinion set forth in this proxy statement/prospectus is qualified in its entirety by reference to the full text of the written opinion. Cara stockholders are urged to read the written opinion carefully and in its entirety for a discussion of the assumptions made, procedures followed, matters considered, and qualifications and limitations upon the review undertaken by Piper Sandler in preparing the Piper Sandler Opinion. The Piper Sandler Opinion was prepared at the request of, and furnished solely to, the Cara Board (in the Cara Board members' individual capacities as directors and not in any other capacity) for its information and assistance in connection with its consideration of the financial terms of the Merger, and was only one of many factors considered by the Cara Board in its evaluation of the Merger. Further, the Piper Sandler Opinion only addresses the fairness, from a financial point of view as of the date thereof, to Cara of the Exchange Ratio (without giving effect to the Reverse Stock Split). The Piper Sandler Opinion did not address, among other things, (i) any other terms or agreements relating to the Merger or any other terms of the Merger Agreement, (ii) the relative merits of the Merger as compared to other transactions or strategies that might be available to Cara, or (iii) the underlying business decision of Cara to proceed with the Merger. The Piper Sandler Opinion was not intended to, and

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does not, constitute a recommendation to the Cara Board, Cara, any security holder of Cara, or any other party as to how to vote or otherwise act with respect to the Merger or any other matter relating thereto.

Merger Consideration and Exchange Ratio

At the Effective Time, each outstanding share of Tvardi common stock (after giving effect to the Preferred Stock Conversion and excluding shares held by stockholders who have exercised and perfected appraisal rights and excluding shares held as treasury stock by Cara or held or owned by Cara, Merger Sub or any subsidiary of Cara or Tvardi), will be converted into the right to receive a number of shares of Cara common stock equal to the Exchange Ratio. The Convertible Notes will also be converted into the right to receive a number of shares of Cara common stock calculated based on a conversion price equal to 80% of the implied value of the combined company (as more fully described in the Section titled "Agreements Related to the Merger" beginning on page <u>163</u>].

No fractional shares of Cara common stock will be issued in connection with the Merger, and Tvardi stockholders will receive cash in lieu of fractional shares. Based on an assumed Exchange Ratio of 4.8997 and an assumed amount of Conversion Shares of approximately 46,115,173, Cara expects that it will issue approximately 46,115,173 shares of Cara common stock in the Merger, excluding any shares that may be subsequently issued in connection with the exercise of options assumed by Cara or the assumption of the Tvardi Plan (as defined below) and assuming no stockholders of Tvardi exercise and perfect their appraisal rights.

The Merger Agreement does not include a price-based termination right, so there will be no adjustment to the total number of shares of Cara common stock that Tvardi stockholders will be entitled to receive for changes in the market price of Cara common stock.

The Exchange Ratio formula is derived based upon a Tvardi fixed valuation of \$210.0 million and a Cara valuation of \$43.0 million, subject to certain adjustments, including based upon Cara Net Cash at Closing, and an assumed implied value of the combined company of approximately \$282.0 million, subject to certain adjustments. The calculation of Cara Net Cash at Closing includes, among other things, a credit or reduction for net proceeds that Cara receives or pays from the Asset Disposition. The Net Cash Condition means that Cara Net Cash must be no less than \$18.0 million in order for Tvardi to be required to complete the Merger.

Immediately following the Merger, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock, and the holders of the Convertible Notes are expected to hold approximately 12.54% of the shares of Cara common stock, in each case, on a fully diluted basis (subject to further adjustment as further described below). The expected post-Merger equity ownership split percentages are based on the assumed Exchange Ratio of 4.8997 and an amount of Conversion Shares equal to approximately 46,115,173 and are subject to adjustments based on the final Exchange Ratio and final amount of Conversion Shares.

For a more complete description of the Merger, the potential adjustments in the Exchange Ratio and Conversion Shares and the calculation of Cara Net Cash, please see the section titled "*The Merger Agreement* — *Merger Consideration and Exchange Ratio*."

Treatment of Tvardi Stock Options

Under the terms of the Merger Agreement, each option to purchase shares of Tvardi common stock that is outstanding and unexercised immediately prior to the Effective Time, whether or not vested, will be converted into and become an option to purchase shares of Cara common stock. Cara will assume the Tvardi's 2018 Stock Incentive Plan (Tvardi Plan), and all rights with respect to each outstanding option to purchase Tvardi common stock in accordance with its terms and the terms of the stock option agreement by which such option is evidenced.

Accordingly, from and after the Effective Time: (i) each outstanding Tvardi stock option assumed by Cara may be exercised solely for shares of Cara common stock; (ii) the number of shares of Cara common stock subject to each outstanding Tvardi stock option assumed by Cara will be determined by multiplying

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(A) the number of shares of Tvardi common stock that were subject to such Tvardi stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Cara common stock; (iii) the per share exercise price for the Cara common stock issuable upon exercise of each Tvardi stock option assumed by Cara will be determined by dividing (A) the per share exercise price of Cara common stock subject to such Tvardi stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any Tvardi stock option assumed by Cara will continue in full force and effect and the term, exercisability, vesting schedule, accelerated vesting provisions, and any other provisions of such Tvardi stock option will otherwise remain unchanged; provided, however, that the Cara Board or a committee thereof will succeed to the authority and responsibility of the board of directors of Tvardi or any committee thereof with respect to each Tvardi stock option assumed by Cara.

Conditions to the Completion of the Merger

The obligations of Cara and Tvardi to consummate the Merger are subject to the satisfaction or waiver, on or prior to the Effective Time, of the conditions set forth in the section titled "*The Merger Agreement* — *Conditions to the Completion of the Merger*" below.

Non-Solicitation

Capitalized terms in this section are as defined in the section titled "*The Merger Agreement — Non-Solicitation*."

Cara and its subsidiaries and Tvardi are prohibited by the terms of the Merger Agreement, other than, in the case of Cara, with respect to the Asset Disposition, from, directly or indirectly, (i) soliciting, initiating or knowingly encouraging, inducing or facilitating the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or taking any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnishing any non-public information regarding Cara or Tvardi, respectively, to any person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engaging in discussions (other than to inform any person of the existence of these prohibitions) or negotiations with any person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approving, endorsing or recommending any Acquisition Proposal; (v) executing or entering into any letter of intent or any contract contemplating or otherwise relating to any Acquisition Transaction (other than, in the case of Cara, a confidentiality agreement permitted as described below); or (vi) publicly proposing to do any of the foregoing.

Subject to certain restrictions and prior to approval of the Required Cara Closing Stockholder Matters by the required Cara Stockholder Vote (as defined below), Cara and its subsidiaries may furnish non-public information regarding Cara or any of its subsidiaries to, and enter into discussions or negotiations with, any person in response to a bona fide Acquisition Proposal by such person, which the Cara Board determines in good faith, after consultation with its outside financial advisor and outside legal counsel, constitutes, or is reasonably likely to result in, a Superior Offer (and is not withdrawn) if: (A) none of Cara, any of its subsidiaries or any of their respective representatives shall have breached the non-solicitation restrictions in the Merger Agreement in any material respect, (B) the Cara Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of the Cara Board under applicable law, (C) Cara receives from such person an executed confidentiality agreement containing provisions (including nondisclosure provisions, use restrictions, non-solicitation provisions, no hire and "standstill" provisions), in the aggregate, at least as favorable to it as those contained in the confidentiality agreement entered into between Cara and Tvardi in connection with the Merger and (D) substantially contemporaneously with furnishing any such non-public information to such person, Cara gives Tvardi notice of Cara's intention to furnish non-public information to, or enter into discussions with, such person and furnishes such non-public information to Tvardi (to the extent such information has not been previously furnished by Cara to Tvardi).

For a more complete description of the non-solicitation provisions, please see the section titled "*The Merger Agreement* — *Non-Solicitation*."

Termination and Termination Fees

Capitalized terms are as defined in the section titled "*The Merger Agreement* — *Termination and Termination Fees*," except as otherwise noted below.

The Merger Agreement contains certain customary termination rights, including, among others as described in more detail below, (i) by mutual written consent, (ii) by either Cara or Tvardi if the Contemplated Transactions have not been consummated by June 30, 2025, which date may be extended by Cara for an additional 60 days if the SEC has not declared this Registration Statement effective by June 30, 2025, (iii) by Cara if the Required Tvardi Stockholder Vote has not been obtained within seven business days of the date of the Registration Statement becoming effective, (iv) by either Cara or Tvardi if the Cara Proposals were not approved by the Required Cara Stockholder Vote (as defined under "*Cara Stockholder Meeting*"), (v) by Tvardi if a Cara Triggering Event has occurred and (vi) by Cara if a Tvardi Triggering Event has occurred.

Cara must pay Tvardi a nonrefundable termination fee of \$2.25 million if (i) (A) the Merger Agreement is terminated in certain circumstances described in the section titled "*Merger Agreement — Termination and Termination Fees*," (B) an Acquisition Proposal with respect to Cara has been publicly announced, disclosed or otherwise communicated to Cara or the Cara Board at any time after the date of the Merger Agreement but prior to the termination of the Merger Agreement (which has not been withdrawn) and (C) within 12 months after the date of such termination, Cara enters into a definitive agreement with respect to a subsequent transaction or consummates a subsequent transaction in respect of any Acquisition Proposal; or (ii) the Merger Agreement is terminated, Tvardi has the right to terminate the Merger Agreement for an Cara Triggering Event).

Tvardi must pay Cara a nonrefundable termination fee of \$2.25 million if (i) (A) the Merger Agreement is terminated in certain circumstances described in the section titled "*The Merger Agreement — Termination and Termination Fees*," (B) an Acquisition Proposal with respect to Tvardi has been publicly announced, disclosed or otherwise communicated to Tvardi or the Tvardi Board at any time after the date of the Merger Agreement but prior to obtaining the Required Tvardi Stockholder Vote (which has not been withdrawn, (1) in the case of a termination in certain circumstances described in the section titled "*The Merger Agreement — Termination and Termination Fees*," at the time the Required Tvardi Stockholder Vote is obtained and (2) in the case of a termination in certain circumstances described in the section titled "*The Merger Agreement — Termination and Termination Fees*," at the time of such termination) and (C) within 12 months after the date of such termination, Tvardi enters into a definitive agreement with respect to a subsequent transaction or consummates a subsequent transaction in respect of any Acquisition Proposal; or (ii) the Merger Agreement is terminated by Cara for a Tvardi Triggering Event (or if at the time the Merger Agreement is terminated, Cara has the right to terminate the Merger Agreement for a Tvardi Triggering Event).

For a more complete description of the termination provisions and termination fees, please see the section titled "*The Merger Agreement* — *Termination and Termination Fees*."

Support Agreements

Concurrently with the execution of the Merger Agreement, the officers and directors of Cara, and their affiliated funds that hold Cara common stock and who collectively beneficially own approximately 1% of the Cara common stock, entered into support agreements (Cara Support Agreements) in favor of Tvardi relating to the Merger. The Cara Support Agreements provide, among other things, that such officers, directors and stockholders will vote all of their shares of Cara common stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the other Contemplated Transactions and the Cara Proposals, (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any Acquisition Proposal.

Concurrently with the execution of the Merger Agreement, the officers and directors of Tvardi and certain stockholders of Tvardi and who collectively hold approximately 97% of the Tvardi common stock entered into support agreements (Tvardi Support Agreements, and together with the Cara Support Agreements, the Support Agreements) in favor of Cara relating to the Merger. The Tvardi Support

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Agreements provide, among other things, that such executive officers, directors and stockholders vote all of their shares of Tvardi capital stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the other Contemplated Transactions and the Tvardi Stockholder Matters, (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any Acquisition Proposal.

Lock-Up Agreements

Concurrently with the execution of the Merger Agreement, (i) the officers, directors, certain stockholders of Tvardi and who collectively hold approximately 97% of the Tvardi common stock and (ii) the director of Cara expected to continue to serve on the Combined Company Board beneficially owning approximately 1% of the Cara common stock, entered into lock-up agreements (Lock-Up Agreements), pursuant to which such persons accepted certain restrictions on transfers of the shares of Cara common stock held by such persons for the 180-day period following the Effective Time.

Convertible Notes

On December 3, 2024, Tvardi entered into a Note Purchase Agreement to issue and sell Convertible Notes in an aggregate amount of approximately \$28.3 million, which accrue simple interest at 8% per annum and mature on December 31, 2026. Upon the Closing, the outstanding principal balance of such notes and all unpaid accrued interest will be automatically converted into shares of Cara common stock, at a conversion price equal to 80% of the implied valuation of the combined company in the Merger. The Conversion Shares shall be calculated by multiplying the Post-Closing Cara Shares by (a) the quotient obtained by dividing (i) the Implied Note Valuation by (ii) the Aggregate Post-Bridge Valuation. The Post-Closing Shares means the quotient obtained by *dividing* the Cara Outstanding Shares by the Cara Allocation Percentage. The Implied Note Valuation means the quotient obtained by dividing (a) the principal amount of the Convertible Notes plus all accrued and unpaid interest by (b) 80%. The Aggregate Post-Bridge Valuation means the sum of (i) the Tvardi Valuation, plus (ii) the Cara Valuation plus (iii) the Implied Note Valuation. The Conversion Shares issued with respect to the 20% discount under the terms of the Convertible Notes shall dilute the pre-Merger equityholders of Tvardi as part of calculating the Exchange Ratio. The remaining Conversion Shares shall dilute the pre-Merger Cara equityholders and the pre-Merger Tvardi equityholders on a pro rata basis. Immediately following the conversion of the Convertible Notes, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock, and the holders of the Convertible Notes are expected to hold approximately 12.54% of the shares of Cara common stock, in each case, on a fully diluted basis. The expected post-Merger equity ownership split percentages are based on the assumed Exchange Ratio of 4.8997 and an amount of Conversion Shares equal to approximately 46,115,173 and are subject to adjustments based on the final Exchange Ratio and final amount of Conversion Shares. For more information, please see the section titled "Agreements Related to the Merger" beginning on page 163 of this proxy statement/prospectus.

Appraisal Rights

Cara stockholders are not entitled to appraisal rights in connection with the Merger.

Tvardi stockholders are entitled to statutory appraisal rights in connection with the Merger under Section 262 of the DGCL. For more information about such rights, please see the provisions of Section 262 of the DGCL attached as Annex C and the section titled "*The Merger Agreement — Appraisal Rights*" beginning on page <u>155</u> of this proxy statement/prospectus.

Management Following the Merger

Immediately following the Merger, the executive management team of the combined company is expected to comprise the following individuals with such additional officers as may be added by the combined company:



Name	Position with the Combined Company	Current Position at Tvardi
Imran Alibhai, Ph.D.	Chief Executive Officer and Director	Chief Executive Officer and Director
Dan Conn, J.D., M.B.A.	Chief Financial Officer	Chief Financial Officer
John Kauh, M.D.	Chief Medical Officer	Chief Medical Officer
Jeffrey Larson, Ph.D., DABT	Senior Vice President, Research & Development	Senior Vice President, Research & Development
Yixin "Joseph" Chen, Ph.D.	Vice President, Chemistry, Manufacturing and Controls	Vice President, Chemistry, Manufacturing and Controls

Directors of the Combined Company Following the Merger

At the Effective Time, the combined company is expected to initially have a seven-member board of directors, comprised of five members designated by Tvardi (Sujal Shah, Michael Wyzga, Wallace Hall, Shaheen Wirk and Imran Alibhai), one member to be designated by Cara prior to Closing and one vacancy, to be designated by Tvardi if prior to the closing of the Merger or by the combined company if following the consummation of the Merger, until their respective successors are duly elected or appointed and qualified or their earlier death, resignation or removal. If the one remaining director is not identified prior to the Effective Time, the Combined Company Board anticipates reducing the size of the Combined Company Board to six directors.

The aforementioned Combined Company Board will have an audit committee, a compensation committee and a nominating and corporate governance committee, in accordance with the Nasdaq rules. All of Cara's current directors, other than the member to be designated by Cara prior to Closing, are expected to resign from their positions as directors of Cara, effective as of the Effective Time.

Interests of Certain Directors and Executive Officers of Cara and Tvardi in the Merger

In considering the recommendation of the Cara Board with respect to the issuance of Cara common stock pursuant to the Merger Agreement and the other matters to be acted upon by Cara's stockholders at the Cara special meeting, Cara's stockholders should be aware that certain members of the Cara Board and current and former executive officers of Cara have interests in the Merger that may be different from, or in addition to, interests they have as Cara's stockholders. The Cara Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the Merger Agreement, the Merger, and the Contemplated Transactions.

As of December 1, 2024, Cara's directors and executive officers (including affiliates) beneficially owned, in the aggregate, approximately 4.2% of the outstanding shares of Cara common stock. As of December 1, 2024, Cara's executive officers and directors collectively held unvested stock options to purchase 1,863,589 shares of Cara common stock and vested stock options to purchase 1,823,318 shares of Cara common stock, for a total of options to purchase 3,686,907 shares of Cara common stock. As of December 1, 2024, Cara's executive officers and directors collectively held 959,052 unvested RSUs. The vesting of all Cara options and RSUs will be accelerated upon consummation of the Merger; the RSUs will be net settled and the options will remain outstanding in accordance with their terms, except that the post-termination exercise period shall not exceed 90 days and the number of shares underlying such options will be adjusted based on the Reverse Stock Split.

The compensation arrangements with Cara's officers and directors are discussed in greater detail in the section titled "*The Merger*—*Interests of the Cara Directors and Executive Officers in the Merger*" beginning on page <u>128</u> of this proxy statement/prospectus. Additionally, as described elsewhere in this proxy statement/prospectus, including in the section captioned "*Management Following the Merger*" beginning on page <u>252</u> of this proxy statement/prospectus, one of Cara's directors is expected to remain a director of the combined company upon the closing of the Merger.

As described elsewhere in this proxy statement/prospectus, including in the section titled "*The Merger* — *Management Following the Merger*," certain of Tvardi's directors and executive officers are expected to become directors and executive officers of the combined company upon the closing of the Merger.

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Cara's executive officers and directors, and Tvardi's executive officers, directors and certain affiliated stockholders have entered into the Support Agreements, pursuant to which such directors, officers and certain stockholders, respectively, have agreed, solely in their capacity as stockholders of Cara and Tvardi, respectively, to vote all of their shares of Cara common stock or Tvardi capital stock in favor of, among other things, the adoption and approval, respectively, of the Merger Agreement and the Contemplated Transactions. The Support Agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger*" beginning on page <u>163</u> of this proxy statement/prospectus.

Risk Factors and Risk Factor Summary

Both Cara and Tvardi are subject to various risks associated with their businesses and their industries. In addition, the Merger, including the possibility that the Merger may not be completed, poses a number of risks to each company and its respective stockholders. You should carefully read this proxy statement/ prospectus, including the annexes, and the documents incorporated by reference into this proxy statement/ prospectus and especially consider the material risks discussed below and these and other risks discussed in greater detail under the section titled "*Risk Factors*" beginning on page 25 of this proxy statement/ prospectus. Cara and Tvardi encourage you to read and consider all of these risks carefully. In addition, you should read and consider the risks associated with the business of Cara because these risks may also affect the combined company. These risks can be found in Cara's Annual Report on Form 10-K, as updated by subsequent Quarterly Reports on Form 10-Q, all of which are filed with the SEC and incorporated by reference into this proxy statement/prospectus.

Risks Related to the Merger

- The Merger may not be completed on the terms or timeline currently contemplated, or at all;
- Cara's net cash may be less than \$22.875 million at the Closing, which would result in Cara's stockholders owning a smaller percentage of the combined company and, if Cara's net cash is less than \$18.0 million as of the End Date (as defined below), could even result in the termination of the Merger Agreement;
- The Exchange Ratio is fixed and will not be adjusted based on the market price of Cara common stock, so the consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed;
- Failure to complete the Merger may result in Cara or Tvardi paying a termination fee to the other party and could harm the common stock price of Cara;
- The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and/or other causes;
- Some executive officers and directors of Cara and Tvardi have interests in the Merger that are different from the respective stockholders of Cara and Tvardi and that may influence them to support or approve the Merger without regard to the interests of the respective stockholders of Cara and Tvardi;
- The market price of Cara common stock following the Merger may decline as a result of the Merger;
- Cara and Tvardi equityholders will have a materially reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the closing of the Merger as compared to their current ownership and voting interest in the respective companies;
- During the pendency of the Merger Agreement, Cara and Tvardi may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses;
- Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement;
- Because the lack of a public market for Tvardi's common stock makes it difficult to evaluate the fairness of the Merger, the stockholders of Tvardi may receive consideration in the Merger that is

less than the fair market value of Tvardi's common stock or Cara may pay more than the fair market value of Tvardi's common stock;

- The opinion delivered by Piper Sandler to the Cara Board prior to the entry into the Merger Agreement does not reflect changes in circumstances that may have occurred since the date of the opinion;
- The combined company may become involved in securities class action litigation that could divert management's attention and harm the combined company's business and insurance coverage may not be sufficient to cover all costs and damages;
- Cara or Tvardi may waive one or more of the conditions to the Merger without recirculation of this proxy statement/prospectus or resoliciting stockholder approval;
- Transfers of the combined company's securities utilizing Rule 144 of the Securities Act may be limited; and
- Cara's winddown of its historical operations, the suspension of development activities and the proposed Merger, resulting in the conversion of Tvardi into a public company, will make Cara subject to the SEC requirements applicable to reporting shell company business combinations. As a result, the combined company will be subject to more stringent reporting requirements, offering limitations and resale restrictions.

Risks Related to the Tvardi Business

- Tvardi has a limited operating history, which may make it difficult to evaluate its prospects and likelihood of success.
- Tvardi has not generated any revenue to date and may never become or remain profitable.
- Tvardi's financial condition raises substantial doubt as to its ability to continue as a going concern.
- Even if this Merger is successful, Tvardi will require substantial additional capital to fund its operations. If Tvardi is unable to raise such capital when needed, or on acceptable terms, it may be forced to delay, reduce and/or eliminate one or more of its research and drug development programs, future commercialization efforts or other operations.
- Tvardi's business is highly dependent on the success of its product candidates, TTI-101 and any other product candidates that it advances into the clinic. All of Tvardi's product candidates will require significant additional preclinical and clinical development before Tvardi may be able to seek regulatory approval for and launch a product commercially.
- Preclinical and clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.
- Tvardi's ongoing and future clinical trials may reveal significant adverse events or unexpected drugdrug interactions not seen in preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of Tvardi's product candidates.
- Interim, blinded and preliminary data from Tvardi's clinical trials that it announces or publishes from time to time may change as more patient data become available or as additional analyses are conducted and as the data are subject to audit and verification procedures that could result in material changes in the final data.
- Positive results from early preclinical studies and clinical trials of Tvardi's current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of Tvardi's current or future product candidates. If Tvardi cannot replicate the positive results from Tvardi's preclinical studies or early clinical trials of current or future product candidates in future clinical trials, it may be unable to successfully develop, obtain regulatory approval for and commercialize any current or future product candidates.
- Although Tvardi has received U.S. orphan drug designation for TTI-101 for IPF and HCC, it may be unable to obtain and maintain orphan drug designation for our other product candidates and, even

if Tvardi obtains such designation, it may not be able to realize the benefits of such designation, including potential marketing exclusivity of its product candidates, if approved.

- Although Tvardi has received a Fast Track designation from the U.S. Food and Drug Administration (FDA), for TTI-101 for HCC and intends to seek Fast Track designation for TTI-109 for HCC, it may not benefit from a faster development or regulatory review or approval process and a Fast Track designation does not increase the likelihood that its product candidates will receive marketing approval.
- The regulatory approval process is highly uncertain, and Tvardi may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize TTI-101, TTI-109 or any current or future product candidates. Even if we Tvardi believes that its current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.
- Tvardi does not currently own or in-license any composition of matter patent protection for the TTI-101 molecule. As such, it relies solely upon patents related to methods of use, manufacturing and pharmaceutical compositions.
- It is difficult and costly to protect Tvardi's intellectual property and its proprietary technologies, and Tvardi may not be able to ensure their protection.
- Tvardi relies on third parties to conduct certain aspects of its preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, Tvardi may not be able to obtain regulatory approval of or commercialize any potential product candidates.
- Tvardi has identified material weaknesses in its internal control over financial reporting. If Tvardi fails to remediate these material weaknesses, or if it experiences additional material weaknesses in the future or otherwise fails to maintain effective internal control over financial reporting in the future, Tvardi may not be able to accurately or timely report its financial condition or results of operations, which may adversely affect investor confidence in Tvardi and, as a result, the value of Tvardi's common stock following the completion of the Merger.

If Tvardi is unable to adequately address these and other risks it faces, its business may be harmed.

Risks Related to the Combined Company

- Following the Merger, Cara and Tvardi may be unable to successfully integrate their businesses and realize the anticipated benefits of the Merger;
- The combined company will need to raise additional financing in the future to fund its operations, which may not be available to it on favorable terms or at all;
- The market price of the combined company's common stock is expected to be volatile, and the market price of the common stock may drop following the Merger;
- The combined company will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies;
- Cara and Tvardi do not anticipate that the combined company will pay any cash dividends in the foreseeable future;
- An active trading market for the combined company's common stock may not develop and its stockholders may not be able to resell their shares of common stock for a profit, if at all;
- Future sales of shares by existing stockholders could cause the combined company's stock price to decline;
- If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the combined company, its business or its market, its stock price and trading volume could decline; and



• The unaudited pro forma condensed combined financial statements included in this proxy statement/ prospectus are presented for illustrative purposes only and may not be an indication of the combined company's financial condition or results of operations following the completion of the Merger.

Regulatory Approvals

In the United States, Cara must comply with applicable federal and state securities laws and the rules and regulations of Nasdaq in connection with (i) the issuance of shares of Cara common stock to Tvardi's stockholders in connection with the transactions contemplated by the Merger Agreement and the change of control resulting from the Merger and (ii) the filing of this proxy statement/prospectus with the SEC. Cara does not intend to seek any regulatory approval from antitrust authorities to consummate the Contemplated Transactions.

Nasdaq Stock Market Listing

Shares of Cara common stock are currently listed on The Nasdaq Capital Market under the symbol "CARA." Tvardi will file an initial listing application with Nasdaq pursuant to Nasdaq's "reverse merger" rules. Substantially concurrent with the completion of the Merger, Cara will be renamed "Tvardi Therapeutics, Inc." and expects to trade on The Nasdaq Capital Market under the symbol "TVRD". Under the Merger Agreement, each of Tvardi's and Cara's obligation to complete the Merger is subject to the satisfaction or waiver by each of the parties, at or prior to the Merger, of various conditions, including that the shares of Cara common stock to be issued in the Merger have been approved for listing (subject to official notice of issuance) on Nasdaq as of the closing of the Merger. The terms of the Merger Agreement permit that this condition may be waived by agreement among Tvardi, Cara and Merger Sub, without recirculation or resolicitation of this proxy statement/prospectus.

Anticipated Accounting Treatment

The Merger will be treated by Cara as a reverse recapitalization under accounting principles generally accepted in the United States of America (GAAP). For accounting purposes, Tvardi is considered to be the accounting acquirer in this transaction.

Description of Cara and Tvardi Common stock

Both Cara and Tvardi are incorporated under the laws of the State of Delaware and, accordingly, the rights of the stockholders of each are currently, and will continue to be, governed by the DGCL. If the Merger is completed, Tvardi stockholders will become Cara stockholders, and their rights will be governed by the DGCL, the amended and restated bylaws of Cara and the amended and restated certificate of incorporation of Cara, as may be amended by the Reverse Stock Split Proposal and the Authorized Share Proposal if approved by the Cara stockholders at the Cara special meeting. The rights of Cara stockholders contained in Cara's amended and restated certificate of incorporation, and amended and restated bylaws differ from the rights of Tvardi stockholders under Tvardi's current amended and restated certificate of incorporation and bylaws, as more fully described under the section titled "*Comparison of Rights of Holders of Cara Stock and Tvardi Stock*" beginning on page <u>269</u> of this proxy statement/prospectus.

Cara Stockholder Meeting

The Cara special meeting will be held exclusively online via audio-only webcast on , 2025 at Eastern Time, unless postponed or adjourned to a later date. The Cara special meeting can be accessed by visiting , where you will be able to vote your shares and submit questions during the Cara special meeting webcast by logging in to the website listed above using the 16-digit control number included in your proxy card. Online check-in will begin at Eastern Time, and Cara encourages you to allow ample time for the online check-in procedures. Please note that you will not be able to attend the Cara special meeting in person. For more information on the Cara special meeting, see the section titled "*The Special Meeting of Cara's Stockholders*" beginning on page <u>97</u> of this proxy statement/prospectus.

Market Price and Dividend Information

Cara's common stock is currently listed on The Nasdaq Capital Market under the symbol "CARA." Tvardi is a private company and its common stock and preferred stock are not publicly traded.

Cara Common Stock

The closing price of Cara common stock on December 17, 2024, the trading day immediately prior to the public announcement of the Merger on December 18, 2024, as reported on The Nasdaq Capital Market, was \$0.2497 per share.

Because the market price of Cara common stock is subject to fluctuation, the market value of the shares of Cara common stock that Tvardi stockholders will be entitled to receive in the Merger may increase or decrease.

Assuming successful application for initial listing with Nasdaq, following the consummation of the Merger, Cara anticipates that the Cara common stock will trade under Cara's new name "Tvardi Therapeutics, Inc." and the new trading symbol "TVRD" on The Nasdaq Capital Market.

As of , the record date for the Cara special meeting, there were approximately holders of record of the Cara common stock.

Dividends

Cara has never declared or paid any cash dividends on the Cara common stock and does not anticipate paying cash dividends on Cara common stock for the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends subsequent to the Merger will be at the discretion of the combined company's then-current board of directors and will depend upon a number of factors, including the combined company's results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the then-current board of directors deems relevant.

Tvardi has never declared or paid any cash dividends on shares of Tvardi common stock. Tvardi anticipates that the combined company will retain all of its future earnings to advance the preclinical studies and clinical trials for its product candidates, and does not anticipate paying any cash dividends on shares of its common stock in the foreseeable future. Any future determination to declare cash dividends on shares of the combined company's common stock will be made at the discretion of the Combined Company Board, subject to applicable law and contractual restrictions and will depend on its financial condition, results of operations, capital requirements, general business conditions and other factors that the Combined Company Board of directors may deem relevant.

RISK FACTORS

The combined company will be faced with a market environment that cannot be predicted and that involves significant risks, many of which will be beyond its control. In addition to the other information contained in and incorporated by reference into this proxy statement/prospectus, you should carefully consider the material risks described below before deciding how to vote your shares of Cara common stock. In addition, you should read and consider the risks associated with the business of Cara because these risks may also affect the combined company. These risks can be found in Cara's Annual Report on Form 10-K, as updated by subsequent Quarterly Reports on Form 10-Q, all of which are filed with the SEC and incorporated by reference into this proxy statement/prospectus. You should also read and consider the other information in this proxy statement/prospectus and the other documents incorporated by reference into this proxy statement/prospectus. Realization of any of the risks described below, any of the uncertainties described under "Cautionary Note Regarding Forward-Looking Statements" could have a material adverse effect on Cara's, Tvardi's or the combined company's businesses, financial condition, cash flows and results of operations. Please see the section titled "Where You Can Find More Information" beginning on page <u>284</u> of this proxy statement/prospectus.

Risks Related to the Merger

The Merger may not be completed on the terms or timeline currently contemplated, or at all.

The consummation of the Merger is subject to numerous conditions, including (1) the effectiveness of the Registration Statement, (2) the approval by Cara's stockholders of the Required Cara Closing Stockholder Matters, (3) the approval by Tvardi's stockholders of the Tvardi Stockholder Matters, and (4) other customary closing conditions and there can be no assurance that the Merger will be consummated. See the section "*The Merger Agreement — Conditions to the Completion of the Merger*" on page <u>144</u> of this proxy statement/prospectus.

If the Merger is not completed for any reason, the price of Cara's common stock may decline to the extent that the market price of Cara's common stock reflects or previously reflected positive market assumptions that the Merger would be completed and the related benefits would be realized. In addition, Cara and Tvardi have expended and will continue to expend significant management time and resources and have incurred and will continue to incur significant expenses due to legal, advisory, printing and financial services fees related to the Merger. These expenses must be paid regardless of whether the Merger is consummated.

The Exchange Ratio will not be adjusted based on the market price of Cara common stock, so the consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.

The Exchange Ratio will not change based on changes in the trading price of Cara common stock. Therefore, if before the completion of the Merger, the market price of Cara common stock increases from the market price on the date of the Merger Agreement, Tvardi stockholders could then receive merger consideration with substantially higher value for their shares of Tvardi common stock than the parties had negotiated when they established the Exchange Ratio. The Merger Agreement does not include a pricebased termination right. Immediately following the Merger, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock, and the holders of the Convertible Notes are expected to hold approximately 12.54% of the shares of Cara common stock, in each case, on a fully diluted basis (subject to further adjustment as further described below), subject to certain adjustments, including based upon Cara Net Cash at Closing. The calculation of Cara Net Cash at Closing includes, among other things, a credit or reduction for cash proceeds that Cara receives or pays from the Asset Disposition. The Net Cash Condition means that Cara Net Cash must be no less than \$18.0 million in order for Tvardi to be required to complete the Merger. For a more complete description of the Merger, please see the section titled "The Merger Agreement - Merger Consideration" beginning on page <u>140</u> of this proxy statement/prospectus.

Cara's net cash may be less than \$22.875 million at the Closing, which would result in Cara's stockholders owning a smaller percentage of the combined company and, if Cara's net cash is less than \$18.0 million as of the End Date, could even result in the termination of the Merger Agreement.

For purposes of the Merger Agreement, net cash is subject to certain reductions, including, without limitation, for payments made in connection with the sale, transfer, license, assignment or other divestiture of its intellectual property and other assets and technology in existence on the date of the Merger Agreement on or about the anticipated Closing, accounts payable, accrued expenses (except those related to the Merger), current liabilities payable in cash, unpaid expenses related to the Merger and certain other unpaid obligations. In the event the amount of Cara's cash is smaller or such reductions are greater than anticipated, Cara stockholders could hold a significantly smaller portion of the combined company.

Failure to complete the Merger may result in Cara or Tvardi paying a termination fee to the other party and could harm the common stock price of Cara.

If the Merger is not completed, each of Cara and Tvardi is subject to the following risks:

- upon termination of the Merger Agreement, Cara may be required to pay Tvardi a termination fee of \$2.25 million or up to \$750,000 in expense reimbursements; or Tvardi may be required to pay Cara a termination fee of \$2.25 million or up to \$750,000 in expense reimbursements;
- the parties have incurred, and will continue to incur, significant expenses related to the Merger, such as legal, financial advisor and accounting fees, which must be paid even if the Merger is not completed;
- the price of Cara's common stock may decline and remain volatile;
- · Cara may be forced to cease its operations, dissolve and liquidate its assets.

In addition, if the Merger Agreement is terminated and the Cara Board or Tvardi Board determines to seek another business combination, there can be no assurance that either Cara or Tvardi will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger or any partner at all. Please see "*The Merger Agreement* — *Termination and Termination Fee*" beginning on page <u>158</u> of this proxy statement/prospectus.

If the conditions to the closing of the Merger are not met, the Merger may not occur.

Even if the Required Cara Closing Stockholder Matters are approved by the stockholders of Cara, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in the section titled "*The Merger Agreement* — *Conditions to the Completion of the Merger*" beginning on page 144 of this proxy statement/prospectus. Cara and Tvardi cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or will be delayed, and Cara and Tvardi each may lose some or all the intended benefits of the Merger.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and/or other causes.

In general, either Cara or Tvardi can refuse to complete the Merger if there is a Tvardi Material Adverse Effect (as defined in the Merger Agreement) or a Cara Material Adverse Effect (as defined in the Merger Agreement), as applicable, between December 17, 2024, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on Cara or Tvardi, including:

- general business, political or economic conditions generally affecting the industry in which Tvardi or Cara operate;
- acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions;

- changes in financial, banking or securities markets;
- any change in the stock price or trading volume of Cara common stock (it being understood, however, that any effect causing or contributing to any change in stock price or trading volume of Cara common stock may be taken into account in determining whether a material adverse effect with respect to Cara has occurred, unless such effects are otherwise excepted from the definition of Cara material adverse effect);
- any failure by Cara to meet internal or analysts' expectations or projections or the results of
 operations of Cara (it being understood, however, that any effect causing or contributing to the
 failure of Cara to meet internal or analysts' expectations or projections or the results of operations of
 Cara may be taken into account in determining whether a material adverse effect with respect to Cara
 has occurred, unless such effects are otherwise excepted from the definition of Cara material adverse
 effect);
- any change in, or any compliance with or action taken for the purpose of complying with, any applicable law or GAAP (or interpretations of ay applicable law or GAAP);
- the announcement of the Merger Agreement or the pendency of the Contemplated Transactions; or
- the taking of any action required to be taken by the Merger Agreement.

If a material adverse change occurs with respect to either party or both parties and Cara and Tvardi still complete the Merger, the stock price of the combined company following the closing of the Merger may suffer and may reduce the value of the Merger to the stockholders of Cara, Tvardi or both.

Some executive officers and directors of Cara have interests in the Merger that are different from the respective stockholders of Cara and that may influence them to support or approve the Merger without regard to the interests of the stockholders of Cara.

Some officers and directors of Cara are parties to arrangements that provide them with interests in the Merger that are different from the stockholders of Cara, including some or all of service as an officer or director of the combined company following the closing of the Merger, severance and retention benefits, the acceleration of equity award vesting and continued indemnification. For more information regarding the interests of the Cara executive officers and directors in the Merger, see the section titled "*The Merger*— *Interests of the Cara Directors and Executive Officers in the Merger*" of this proxy statement/prospectus.

The market price of Cara common stock following the Merger may decline as a result of the Merger.

The market price of Cara common stock may decline as a result of the Merger for a number of reasons, including if:

- investors react negatively to the prospects of the combined company's business and prospects following the closing of the Merger;
- the effect of the Merger on the combined company's business and prospects following the closing of the Merger is not consistent with the expectations of financial or industry analysts; or
- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by stockholders or financial or industry analysts, or at all.

Cara and Tvardi equityholders will have a materially reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the closing of the Merger as compared to their current ownership and voting interest in the respective companies.

Immediately following the Merger, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the outstanding shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the outstanding shares of Cara common stock, and the holders of the Convertible Notes are expected to hold approximately 12.54% of the shares of Cara common stock, in each case, on a fully diluted basis (subject to further adjustment as further described below),

subject to certain adjustments, including based upon Cara Net Cash at Closing. The calculation of Cara Net Cash at Closing includes, among other things, a credit or reduction for cash proceeds that Cara receives or pays from the Asset Disposition. The Net Cash Condition means that Cara Net Cash must be no less than \$18 million in order for Tvardi to be required to complete the Merger. For a more complete description of the Merger, please see the section titled "*The Merger Agreement — Merger Consideration and Exchange Ratio*" beginning on page <u>140</u> of this proxy statement/prospectus.

Following the Closing, Sujal Shah will serve as Chairman and Imran Alibhai will serve as the Chief Executive Officer of Cara as the combined company. Additionally, following the closing, the Combined Company Board will consist of seven directors, and will be comprised of five members designated by Tvardi (Sujal Shah, Michael Wyzga, Wallace Hall, Shaheen Wirk and Imran Alibhai), one member to be designated by Cara prior to Closing and one vacancy, to be designated by Tvardi if prior to the closing of the Merger or by the combined company if following the consummation of the Merger.

During the pendency of the Merger Agreement, Cara and Tvardi may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede the ability of Cara and Tvardi to make acquisitions, subject to specified exceptions relating to fiduciary duties, or complete other mergers, sales of assets or other business combinations pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, encouraging or entering into specified extraordinary transactions, such as a merger, sale of assets or other business combination, with any third party, subject to specified exceptions, even if any such transaction could be favorable to such party's stockholders. For a more complete description of the restrictions on pursuing alternative transactions please see the section titled "*The Merger Agreement*" beginning on page <u>140</u> of this proxy statement/prospectus.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of Cara and Tvardi from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances for Cara when the Cara Board determines in good faith, after consultation with its outside financial advisor and outside legal counsel, that an unsolicited competing proposal constitutes, or is reasonably likely to result in, a superior competing proposal and, after consultation with its outside legal counsel, that failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of the Cara Board. Even in such circumstances, while the Cara Board may change its recommendation to Cara stockholders, Cara will remain obligated to hold a stockholder vote on the Required Cara Closing Stockholder Matters and may not terminate the Merger Agreement in order to enter into an agreement with respect to a Superior Offer. In addition, if Cara or Tvardi terminate the Merger Agreement under specified circumstances, including terminating because of a decision of the Cara Board to recommend a superior competing proposal, Cara may be required to pay Tvardi a termination fee of \$2.25 million and/or up to \$750,000 in expense reimbursements or Tvardi may be required to pay Cara a termination fee of \$2.25 million, and/or up to \$750,000 in expense reimbursements, as defined and described under "The Merger Agreement — Termination and Termination Fee." This termination fee may discourage third parties from submitting competing proposals to Cara or its stockholders and may cause the Cara Board or the Tvardi Board, as the case may be, to be less inclined to recommend a competing proposal.

Because the lack of a public market for Tvardi's common stock makes it difficult to evaluate the fairness of the Merger, the stockholders of Tvardi may receive consideration in the Merger that is less than the fair market value of Tvardi's common stock or Cara may pay more than the fair market value of Tvardi's common stock.

The outstanding common stock of Tvardi is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Tvardi's common stock. Because the percentage of Cara equity to be issued to Tvardi stockholders was determined based on

negotiations between the parties, it is possible that the value of the Cara common stock to be received by Tvardi stockholders will be less than the fair market value of Tvardi's common stock, or Cara may pay more than the aggregate fair market value for Tvardi's common stock.

The Piper Sandler Opinion delivered by Piper Sandler to the Cara Board prior to the entry into the Merger Agreement does not reflect changes in circumstances that may occur after the date thereof.

The Cara Board has not obtained an updated opinion either as of the date of this proxy statement/ prospectus or as of any other date subsequent to the date of the Piper Sandler Opinion from Piper Sandler, Cara's financial advisor. Changes in circumstances, including without limitation the operations and prospects of Cara or Tvardi, stock prices, general market and economic conditions and other factors, some or all of which may be beyond the control of Cara and Tvardi, are not reflected in the Piper Sandler Opinion. The Piper Sandler Opinion does not speak as of any date other than the date thereof.

The combined company may become involved in securities litigation that could divert management's attention and harm the combined company's business and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action or stockholder derivative litigation often follows certain significant business transactions, such as the sale of a business division or announcement of a merger. The combined company may become involved in this type of litigation in the future in connection with the Merger and the other Contemplated Transactions. Responding to these demands and litigation often is expensive and diverts management's attention and resources, which could adversely affect the combined company's business.

Cara or Tvardi may waive one or more of the conditions to the Merger without recirculation of this proxy statement/prospectus or resoliciting stockholder approval.

Conditions to Cara's or Tvardi's obligations to complete the Merger may be waived, in whole or in part, to the extent permitted by law, in certain circumstances unilaterally or by agreement of Cara and Tvardi. In the event of a waiver of a condition, the Cara Board will evaluate the materiality of any such waiver to determine whether amendment of this proxy statement/prospectus and resolicitation of stockholder approval is necessary.

In the event that the Cara Board, in its own reasonable discretion, determines any such waiver is not significant enough to require recirculation of this proxy statement/prospectus and re-solicitation of its stockholders, it will have the discretion to complete the Merger without seeking further stockholder approval, which decision may have a material adverse effect on the Cara stockholders. For example, if Cara and Tvardi agree to waive the requirement that the shares of Cara common stock to be issued in the Merger have been approved for listing (subject to official notice of issuance) on Nasdaq as of the closing of the Merger, and their respective boards of directors elect to proceed with the closing of the Merger, Nasdaq may notify the combined company of its determination to delist the company's securities based upon the failure to satisfy the initial inclusion criteria in the Nasdaq application. The combined company may appeal the determination to a hearings panel but such appeal will not stay the suspension and delisting action and Nasdaq may notify the combined company that its common stock will be immediately suspended from trading and delisted.

In addition, in order to meet the initial listing requirements of Nasdaq, Cara may release Tvardi stockholders from their Lock-Up Agreements and waive the requirement that such Lock-Up Agreements be in full force and effect immediately following the Effective Time. Such release would increase the number of shares that may be sold in the public market immediately after the Merger and any such sales could cause the combined company's stock price to decline.

Transfers of the combined company's securities utilizing Rule 144 of the Securities Act may be limited.

A significant portion of the combined company's securities will be restricted from immediate resale. Holders should be aware that transfers of Cara's securities pursuant to Rule 144 under the Securities Act (Rule 144) may be limited as Rule 144 is not available, subject to certain exceptions, for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers

that have previously been a shell company. Cara's winddown of its historical operations, the suspension of development activities and the proposed Merger will make Cara subject to the SEC requirements applicable to reporting shell company business combinations. Cara anticipates that following the consummation of the proposed transaction, the combined company will no longer be a shell company. As a result, Cara anticipates that holders will not be able to sell their restricted combined company securities pursuant to Rule 144 without registration until one year after the combined company files the Current Report on Form 8-K following the closing that includes the required Form 10 type information that reflects that the combined company is no longer a shell company. For more information, see the section entitled "Securities Act Restrictions on Resale of Combined Company Common Stock — Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies" beginning on page <u>277</u> of this proxy statement/prospectus.

Cara's winddown of its historical operations, the sale of assets, the suspension of development activities and the proposed Merger, resulting in the conversion of Tvardi into a public company, will make Cara subject to the SEC requirements applicable to reporting shell company business combinations. As a result, the combined company will be subject to more stringent reporting requirements, offering limitations and resale restrictions.

According to SEC guidance, the requirements applicable to reporting shell company business combinations apply to any company that sells or otherwise disposes of its historical assets or operations in connection with or as part of a plan to combine with a non-shell private company in order to convert the private company into a public one. Cara has suspended its development activities and, as such, Cara's plan to merge with Tvardi, resulting in the conversion of Tvardi into a public company, will be subject to the SEC requirements applicable to reporting shell company business combinations, which are as follows:

- the combined company will need to file a Current Report on Form 8-K to report the Form 10 type information (Super 8-K) after Closing reflecting its status as an entity that is not a shell company;
- the combined company will not be eligible to use a Form S-3 until 12 full calendar months after Closing;
- the combined company will need to wait at least 60 calendar days after the filing of the Super 8-K to file a Form S-8 for any equity plans or awards, such as the 2025 Equity Plan and the 2025 Employee Stock Purchase Plan;
- the combined company will be an "ineligible issuer" for three years following the Closing, which will prevent the combined company from (i) incorporating by reference in its Form S-1 filings, (ii) using a free writing prospectus or (iii) taking advantage of the well-known seasoned issuer (WKSI) status despite its public float;
- investors who (i) were affiliates of Tvardi at the time the Merger was submitted for the vote or consent of Tvardi's stockholders, (ii) receive securities of the combined company in the Merger and (iii) publicly offer or sell such securities will be deemed to be engaged in a distribution of such securities, and therefore would be underwriters with respect to resales of those securities, and accordingly such securities may not be included in the any resale shelf registration statement unless such securities are sold only in a fixed price offering in which such investors are named as underwriters in the prospectus; and
- Rule 144(i)(2) will limit the ability of holders of restricted securities and any affiliates of the public company to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other "restricted" or "control" securities of the combined company per Rule 144, until one year after the Form 10 information is filed with the SEC. Non-affiliate Cara Stockholders prior the Mergers will not be subject to such restrictions on public resales of their shares.

The foregoing SEC requirements will increase the combined company's time and cost of raising capital, offering stock under equity plans, and complying with securities laws. Furthermore, such requirements will add burdensome restrictions on the resale of the combined company common stock by affiliates of Tvardi and any holders of "restricted" or "control" securities of the combined company.

For more information about the conditions to the completion of the Merger, see the section titled "*The* Merger Agreement — Conditions to the Completion of the Merger."



Nasdaq may delist the combined company's securities from trading on its exchange, which could limit investors' ability to make transactions in its securities and subject the combined company to additional trading restrictions.

Currently, Cara's common stock is publicly traded on The Nasdaq Capital Market. In connection with the proposed Merger, Tvardi will file an initial listing application with Nasdaq pursuant to Nasdaq's "reverse merger" rules. The combined company will be required to meet the initial listing requirements for its securities to be listed on Nasdaq.

If Cara and Tvardi fail to meet the Nasdaq listing requirements and their respective boards choose to close the merger without Nasdaq's approval, then Nasdaq may notify the combined company of its determination to delist the company's securities based upon the failure to satisfy the criteria in the Nasdaq application. For more information, refer to the section titled "*Risk Factors Related to the Merger* — *Cara or Tvardi may waive one or more of the conditions to the Merger without recirculation of this proxy statement/ prospectus or resoliciting stockholder approval*" beginning on page 29 of this proxy statement/prospectus.

We cannot assure you that the combined company will be able to meet those initial listing requirements. Even if the combined company's securities are so listed, the combined company may be unable to maintain the listing of its securities in the future. In order to continue listing its securities on Nasdaq following the proposed Merger, the combined company will be required to maintain certain financial, distribution and stock price levels. If Nasdaq delists the combined company's securities from trading on its exchange at closing of the Merger (or thereafter) and the combined company is not able to list its securities on another national securities exchange or regain compliance with Nasdaq, the combined company's securities could be quoted on an over-the-counter market. If this were to occur, the combined company could face significant material adverse consequences, including:

- a limited availability of market quotations for its securities;
- reduced liquidity for its securities;
- a determination that the combined company's common stock is a "penny stock" which will require brokers trading in the combined company's common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- · a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts states from regulating the sale of certain securities, which are referred to as "covered securities." Since Cara's common stock is listed on Nasdaq, they are covered securities. Although states are preempted from regulating the sale of covered securities, the federal statute does allow states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then states can regulate or bar the sale of covered securities and it would be subject to regulation in each state in which it offers its securities, including in connection with the Merger.

Risks Related to Tvardi

Risks Related to Tvardi's Financial Position and Need for Additional Capital

Tvardi has incurred significant net losses since inception, and expects to continue to incur significant net losses for the foreseeable future.

Development of biopharmaceutical product candidates is a highly speculative undertaking and involves a substantial degree of risk. Tvardi is still in the early stages of development of its product candidates and its lead product candidate, TTI-101, is only in Phase 2 clinical trials for idiopathic pulmonary fibrosis (IPF), and hepatocellular carcinoma (HCC). Tvardi has no products approved for commercial sale and has not generated any revenue to date. Tvardi has incurred significant net losses since its inception and has financed operations principally through equity and debt financing. Tvardi continues to incur significant

research and development and other expenses related to its ongoing operations. Tvardi's net loss was \$16.7 million and \$13.0 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, it had an accumulated deficit of \$79.5 million. Tvardi has devoted substantially all of its resources and efforts to research and development, and expects that it will be at several years, if ever, before Tvardi has a commercialized product candidate and generates revenue from sales. Even if Tvardi receives marketing approval for and commercializes one or more of its product candidates, Tvardi expects that it will continue to incur substantial research and development and other expenses in order to further develop and, if approved, market additional potential product candidates.

Tvardi expects to continue to incur significant losses for the foreseeable future, and anticipates that its expenses will increase substantially if, and as, it:

- advances TTI-101, TTI-109 and its other product candidates through clinical development, and, if successful, later-stage clinical trials;
- · discovers and develops additional product candidates;
- · advances its preclinical development programs into clinical development;
- experiences delays or interruptions to preclinical studies, clinical trials, receipt of services from its third-party service providers on whom Tvardi relies or its supply chain;
- seeks and maintains regulatory approvals for any product candidates that successfully complete clinical trials;
- commercializes TTI-101, TTI-109, any other product candidates and any future product candidates, if approved;
- increases the amount of research and development activities to identify and develop product candidates;
- hires additional clinical development, quality control, scientific and management personnel;
- expands its operational, financial and management systems and increases personnel, including personnel to support its clinical development and manufacturing efforts and operations as a public company;
- establishes a sales, marketing, medical affairs and distribution infrastructure to commercialize any
 products for which it may obtain marketing approval and intends to commercialize on its own or
 jointly with third parties;
- maintains, expands and protects its intellectual property portfolio;
- · invests in or in-licenses other technologies or product candidates;
- · continues to build out its organization to engage in such activities; and
- incurs additional legal, accounting, investor relations and other general and administrative expenses associated with operating as a public company.

Tvardi has a limited operating history, which may make it difficult to evaluate its prospects and likelihood of success.

Tvardi is a clinical-stage biopharmaceutical company with a limited operating history. Tvardi was incorporated in 2017, has no products approved for commercial sale and has not generated any revenue to date. Tvardi's operations to date have been limited to organizing and staffing its company, business planning, raising capital, establishing its intellectual property portfolio and performing research and development of its product candidates, signaling and biology, medicinal chemistry and clinical insights to discover and develop novel therapies for the treatment of fibrosis-driven diseases, including IPF and certain cancers. Tvardi's most advanced product candidate, TTI-101, is in clinical development for the treatment of IPF and HCC, and in preclinical development for the treatment of certain solid tumors. Tvardi's second product candidate, TTI-109, is still in preclinical development. Both programs will require substantial additional development and clinical research time and resources before Tvardi would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. All of Tvardi's product candidates are still in

preclinical and early clinical development and may be unable to obtain regulatory approval, manufacture a commercial scale product or arrange for a third party to do so on Tvardi's behalf, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, Tvardi may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. Consequently, Tvardi has no meaningful history of operations upon which to evaluate its business, and predictions about any future success or viability may not be as accurate as they could be if Tvardi had a longer operating history or a history of successfully developing and commercializing drug products.

Tvardi has not generated any revenue to date and may never become or remain profitable.

Tvardi's ability to become profitable depends upon its ability to generate revenue. To date, Tvardi has not generated any revenue. Tvardi does not expect to generate significant product revenue unless or until it successfully completes clinical development and obtains regulatory approval of, and then successfully commercializes, at least one of its product candidates. All of its product candidates will require additional preclinical studies or clinical development as well as regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before it can generate any revenue from product sales. Tvardi will face significant development risk as its product candidate advances through clinical development. Tvardi's ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of its preclinical studies and current and future clinical trials, which may be significantly slower or more costly than currently anticipated and will depend substantially upon the performance of third-party contractors;
- Tvardi's ability to complete IND application-enabling studies and successfully submit INDs or comparable applications to allow it to initiate clinical trials for current or any future product candidates;
- whether Tvardi is required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of its product candidates or any future product candidates;
- Tvardi's ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety, potency, purity and acceptable risk-to-benefit profile of its product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with its product candidates or future product candidates;
- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of Tvardi's product candidates or future product candidates as potential cancer treatments;
- Tvardi's ability and the ability of third parties with whom it contracts to manufacture adequate clinical and commercial supplies of its product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMPs);
- Tvardi's ability to successfully develop a commercial strategy and thereafter commercialize its product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and
- Tvardi's ability to establish and enforce intellectual property rights in and to its product candidates or any future product candidates.



To become and remain profitable, Tvardi must develop and eventually commercialize products with significant market potential. This will require it to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which it may obtain marketing approval and satisfying any post-marketing requirements. Tvardi may never succeed in any or all of these activities and, even if it does, it may never generate revenue that is significant enough to achieve profitability. If Tvardi does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Tvardi's failure to become and remain profitable would decrease the value of the company and could impair its ability to raise capital, maintain research and development efforts, expand its business or continue its operations.

Tvardi's financial condition raises substantial doubt as to its ability to continue as a going concern.

As of September 30, 2024, Tvardi had approximately \$9.4 million in cash and cash equivalents and an accumulated deficit of \$79.5 million, and Tvardi has incurred and expects to continue to incur significant costs in developing its product candidates. In light of certain factors, including that Tvardi has suffered recurring losses from operations and has an accumulated deficit of \$79.5 million, there is substantial doubt as to its ability to continue as a going concern. To date, Tvardi has not generated product revenues from its activities and has incurred substantial operating losses. Tvardi expects that it will continue to generate substantial operating losses for the foreseeable future until it completes development and approval of its product candidates. It will continue to fund its operations primarily through utilization of its current financial resources and additional raises of capital.

These conditions raise substantial doubt about its ability to continue as a going concern. Tvardi plans to address these conditions by raising funds from this Merger, a public offering, from subsequent public or private offerings of equity or debt securities, and other funding sources. However, there can be no assurance that such funding will be available to Tvardi, will be obtained on terms favorable to Tvardi, or will provide Tvardi with sufficient funds to meet its objectives. The reaction of investors to the inclusion of a going concern statement by its auditors and the potential inability to continue as a going concern may materially adversely affect Tvardi's ability to raise new capital or enter into partnerships.

Even if this Merger is successful, Tvardi will require substantial additional capital to fund its operations. If Tvardi is unable to raise such capital when needed, or on acceptable terms, it may be forced to delay, reduce and/or eliminate one or more of its research and drug development programs, future commercialization efforts or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Tvardi's operations have consumed substantial amounts of cash since inception. Tvardi expects its expenses to increase in connection with its ongoing activities, particularly as it conducts its planned clinical trials of TTI-101, TTI-109 and any future product candidates that it may develop, seek regulatory approvals for its product candidates and launch and commercialize any products for which it receives regulatory approval. Following this Merger, it also expects to incur additional costs associated with operating as a public company. Accordingly, it will need to obtain substantial additional funding in order to maintain its continuing operations. If Tvardi is unable to raise capital when needed or on acceptable terms, it may be forced to delay, reduce or eliminate one or more of its research and drug development programs or future commercialization efforts.

As of September 30, 2024, Tvardi had approximately \$9.4 million in cash and cash equivalents and Tvardi will require additional capital in order to complete clinical development of any of its current programs. Tvardi's monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of its product candidates is highly uncertain, Tvardi is unable to estimate the actual funds it will require for development, marketing and commercialization activities. Tvardi's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

• the initiation, progress, timing, costs and results of preclinical studies and clinical trials for its product candidates;



- · the clinical development plans Tvardi establishes for its product candidates;
- the timelines of its clinical trials and the overall costs to conduct and complete the clinical trials, including any increased costs due to disruptions caused by marketplace conditions, including the effects of health epidemics, or other geopolitical and macroeconomic conditions;
- the cost and capital commitments required for manufacturing its product candidates at clinical and, if approved, commercial scales;
- the number and characteristics of product candidates that Tvardi develops;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- whether Tvardi is able to enter into future collaboration agreements and the terms of any such agreements;
- the ability to achieve and timing of achieving a favorable pricing and reimbursement decision by the pricing authorities in the markets of interest;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, including patent infringement actions brought by third parties against Tvardi or its product candidates;
- the effect of competing technological and market developments;
- · the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which Tvardi may receive regulatory approval in regions where it chooses to commercialize its products on its own.

Tvardi does not have any committed external source of funds or other support for its development efforts and cannot be certain that additional funding will be available on acceptable terms, or at all. Until Tyardi can generate sufficient revenue to finance its cash requirements, which it may never do, it expects to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If Tvardi raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of its common stockholders. Further, to the extent that Tvardi raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject Tvardi to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Tvardi raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, Tvardi may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to Tvardi. Tvardi also may be required to seek collaborators for any of its product candidates at an earlier stage than otherwise would be desirable or relinquish its rights to product candidates or technologies that it otherwise would seek to develop or commercialize alone. Market volatility resulting from challenging financial markets factors, including the effects of health epidemics and geopolitical conflicts or other factors, could also adversely impact Tvardi's ability to access capital when and in the amounts needed. If Tvardi is unable to raise additional capital in sufficient amounts or on terms acceptable to it, it may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its product candidates or one or more of its other research and development initiatives. Any of the above events could significantly harm its business, prospects, financial condition and results of operations and cause the price of its common stock to decline.

The amount of Tvardi's future losses is uncertain, and its quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause its stock price to fluctuate or decline.

Tvardi's quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of its control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for its product candidates or competing product candidates;
- Tvardi's ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- Tvardi's ability to obtain marketing approval for its product candidates, and the timing and scope of any such approvals it may receive;
- the timing and cost of, and level of investment in, research and development activities relating to its product candidates, which may change from time to time;
- the cost of manufacturing its product candidates, which may vary depending on the difficulty of manufacturing, quantity of production and the terms of its agreements with manufacturers;
- Tvardi's ability to attract, hire and retain qualified personnel;
- expenditures that Tvardi will or may incur to develop additional product candidates;
- the level of demand for its product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to its product candidates, if approved;
- existing and potential future therapeutics that compete with its product candidates;
- changes in the competitive landscape of Tvardi's industry, including consolidation among competitors or partners;
- general market conditions or extraordinary external events, such as recessions or the effects of health epidemics;
- the changing and volatile U.S. and global economic and political environments; and
- future accounting pronouncements or changes in its accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in Tvardi's quarterly and annual operating results. As a result, comparing Tvardi's operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in it failing to meet the expectations of industry or financial analysts or investors for any period. If Tvardi's revenue or operating results fall below the expectations of analysts or investors or below any forecasts Tvardi may provide to the market, or if the forecasts Tvardi provides to the market are below the expectations of analysts or investors, the price of its common stock could decline substantially. Such a stock price decline could occur even when Tvardi has met any previously publicly stated guidance it may provide.

Risks Related to Research and Development and the Biopharmaceutical Industry

Tvardi's business is highly dependent on the success of its product candidates, TTI-101 and any other product candidates that it advances into the clinic. All of Tvardi's product candidates will require significant additional preclinical and clinical development before Tvardi may be able to seek regulatory approval for and launch a product commercially.

Tvardi is currently conducting Phase 2 clinical trials of TTI-101 in IPF and HCC, has no products that are approved for commercial sale and may never be able to develop marketable products. Tvardi is early in its development efforts and has only one product candidate, TTI-101, in early clinical development and one product candidate, TTI-109, in preclinical development. If TTI-101, TTI-109 or any of its other product candidates encounter safety or efficacy problems, development delays, regulatory issues or other problems, Tvardi's development plans and business would be significantly harmed.

Before Tvardi can generate any revenue from sales of its product candidates, TTI-101, TTI-109 or any of its other product candidates, it must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of its product candidates are

approved, it must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and Tvardi may not have the financial resources to continue development of its product candidates.

Tvardi may experience setbacks that could delay or prevent regulatory approval of the extent of regulatory protection for or its ability to commercialize, its product candidates, including:

- negative or inconclusive results from preclinical studies or clinical trials or the clinical trials of others for product candidates similar to Tvardi's, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- undesirable product-related side effects experienced by subjects in Tvardi's clinical trials or by individuals using drugs or therapeutics similar to its product candidates;
- poor efficacy of Tvardi's product candidates during clinical trials;
- delays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from FDA or other comparable foreign regulatory authorities to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of Tvardi's clinical trials;
- delays in enrolling subjects in clinical trials, including due to operational challenges or competition with other clinical trials;
- high drop-out rates or screening failures of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of Tvardi's clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- failure to secure or maintain orphan designation in some jurisdictions;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of its third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to Tvardi's technology in particular; or
- varying interpretations of Tvardi's clinical and preclinical data by the FDA and other comparable foreign regulatory authorities.

In addition, because Tvardi's other product candidates, in particular TTI-109, are based on similar mechanisms of action, if TTI-101 encounters safety or efficacy problems, manufacturing or supply interruptions, developmental delays, regulatory issues or other problems, its development plans and business related to those other indications for TTI-101 as well as other product candidates could be significantly harmed. Tvardi does not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to its intellectual property rights and its manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

Preclinical and clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.

To obtain the requisite regulatory approvals to commercialize any product candidates, Tvardi must demonstrate through extensive preclinical studies and clinical trials that its product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive

data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or earlier stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A large number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier clinical trials. Most product candidates that commence clinical trials will ultimately be successful or support further clinical development of TTI-101, TTI-109 or any of Tvardi's other product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- later stage clinical trials may show the product candidates to be less effective than expected or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- development of competing products in the same indication;
- manufacturing costs, formulation issues, pricing or reimbursement issues or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of Tvardi's product candidates from being commercialized.

Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, some of Tvardi's clinical trials are open-label, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an "investigator bias," where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label clinical trials will not be replicated in later placebo-controlled clinical trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating Tvardi require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although Tvardi is initially focusing its efforts on development of small molecule drug products, it may in the future pursue development of other products, which could make it subject to additional regulatory requirements. Any analysis Tvardi performs of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Tvardi may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on Tvardi's ability to obtain approval of any product candidates that it develops.

Successful completion of clinical trials is a prerequisite to submitting a new drug application (NDA), to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate, and, consequently, the ultimate approval and commercial marketing of any product candidates. Tvardi may experience negative or inconclusive results, which may result in it deciding, or being required by regulators, to conduct additional preclinical studies or clinical trials or abandon some or all of its product development programs, which could have a material adverse effect on its business.

Tvardi's ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of its product candidates.

To obtain the requisite regulatory approvals to market and sell TTI-101 or TTI-109 for any indication, or any of Tvardi's future product candidates, it must demonstrate through clinical trials that such product candidates are safe and effective for use in each targeted indication. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. Unforeseen side effects could arise either during clinical development, or, if such side effects are more rare, after Tvardi's products have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients than if such side effect had arisen during a clinical trial. Further, Tvardi may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.

Tvardi completed clinical trials of its lead product candidate, TTI-101, in healthy volunteers and in patients with advanced malignancies, where TTI-101 was observed to be generally well-tolerated. However, if significant adverse events or other side effects are observed in any of its ongoing or future clinical trials, Tvardi may have difficulty recruiting patients to its clinical trials, patients may drop out of its clinical trials or it may be required to abandon the clinical trials or development efforts altogether. In addition, in Tvardi's ongoing Phase 2 clinical trials, Tvardi is evaluating TTI-101 administered alone or in addition to SoC IPF and HCC agents. Tvardi may encounter unexpected drug-drug interactions in planned clinical trials and may be required to further test these product candidates, including additional drug-drug interaction studies, which may be expensive and time-consuming and result in delays to Tvardi's programs.

For example, in Tvardi's Phase 1b/2 clinical trial in HCC, Tvardi explored escalating dosages of TTI-101 up to 1200 mg/day and determined 800 mg/day as the recommended monotherapy Phase 2 dose (RP2D). Based upon the HCC RP2D determination as well as other early data, Tvardi requested that the Safety Monitoring Committee of the Phase 2 clinical trial in IPF convene to consider discontinuation of enrollment to 1200 mg/day arm. The Safety Monitoring Committee agreed with Tvardi's recommendation to discontinue enrollment to the 1200 mg/day arm. In addition, after reviewing the benefit-risk of the remaining arms of the clinical trial, they recommended to continue enrollment to the 400 mg/day, 800 mg/day and placebo arms of the clinical trial.

Separately, early safety data from the combination arms (TTI-101 + pembrolizumab or TTI-101 + atezolizumab + bevacizumab) of the Phase 1b/2 clinical trial in HCC revealed a higher-than-expected incidence of pulmonary-related treatment-emergent adverse events, which are known side effects of treatment with standard of care. Based upon this information, and after consultations with thought leaders and investigators, the protocol was modified to explore lower dosages and intermittent schedules of TTI-101 in combination with pembrolizumab or atezolizumab + bevacizumab.

Clinical trials of Tvardi's product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that Tvardi's clinical trials, or those of any potential future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of Tvardi's product candidates receives marketing approval and Tvardi, or others, discover that it is less effective than previously believed or causes undesirable side effects that were not previously identified, including during any long-term follow-up observation period recommended or required for patients who receive treatment using Tvardi's products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product, seize the product or seek an
 injunction against its manufacture or distribution;
- Tvardi, or any future collaborators, may be required to recall the product, change the way such product is administered to patients or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication, or impose distribution or use restrictions;
- Tvardi, or any future collaborators, may be required to create a Risk Evaluation and Mitigation Strategy (REMS), which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- Tvardi, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- Tvardi, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- Tvardi's reputation may suffer.

Any of the foregoing could prevent Tvardi from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm its business, results of operations and prospects, and could adversely impact Tvardi's financial condition, results of operations or the market price of its common stock.

Tvardi may be subject to additional risks because it intends to evaluate its product candidates in combination with the standard of care for the indications that Tvardi is pursuing.

Tvardi intends to evaluate its product candidates in combination with other compounds, specifically the standard of care for the indications that Tvardi is pursuing. The use of Tvardi's product candidates in combination with such other compounds may subject it to risks that Tvardi would not face if its product candidates were being administered as monotherapy. The outcome and cost of developing a product candidate to be used with other compounds is difficult to predict and dependent on a number of factors that are outside its control. If Tvardi experiences efficacy or safety issues in its clinical trials in which its product candidates are being administered with other compounds, Tvardi may not receive regulatory approval for its product candidates, which could prevent it from ever generating revenue or achieving profitability.

Tvardi may experience delays in initiating, completing or ultimately be unable to complete, the development and commercialization of TTI-101, TTI-109 or any other product candidates.

Tvardi may experience delays in initiating or completing clinical trials. Tvardi also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent its ability to receive marketing approval or commercialize TTI-101, TTI-109 or any other product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize Tvardi its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with Tvardi's clinical trial design, including with respect to dosing levels administered in its planned clinical trials, which may delay or prevent Tvardi from initiating its clinical trials with its originally intended trial design;
- Tvardi may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (CROs), which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- patient enrollment in Tvardi's clinical trials may be slower than anticipated;

- the number of subjects required for clinical trials of any product candidates may be larger than Tvardi anticipates, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than Tvardi anticipates;
- Tvardi's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to Tvardi in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the clinical trial, which may require that Tvardi add new clinical trial sites or investigators;
- Tvardi may experience delays or interruptions to its manufacturing supply chain, or it could suffer delays in reaching, or may fail to reach, agreement on acceptable terms with third-party service providers on whom it relies;
- additional delays and interruptions to Tvardi's clinical trials could extend the duration of the clinical trials and increase the overall costs to finish the clinical trials as its fixed costs are not substantially reduced during delays;
- Tvardi may elect to, or regulators, IRBs, Data Safety Monitoring Boards (DSMBs), or ethics committees may require that it or its investigators suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- Tvardi may not have the financial resources available to begin and complete the planned clinical trials, or the cost of clinical trials of any product candidates may be greater than it anticipates;
- the supply or quality of its product candidates or other materials necessary to conduct clinical trials of its product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and
- the FDA or other comparable foreign regulatory authorities may require Tvardi to submit additional data such as long-term toxicology studies or impose other requirements before permitting it to initiate a clinical trial.

Tvardi's product development costs will increase if it experiences additional delays in clinical testing or in obtaining marketing approvals. Tvardi does not know whether any of its clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If Tvardi does not achieve product development goals in the timeframes it announces and expects, the approval and commercialization of its product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which it may have the exclusive right to commercialize product candidates and may allow competitors to bring products to market before Tvardi does, potentially impairing its ability to successfully commercialize product candidates and harming its business and results of operations. Any delays in Tvardi's clinical development programs may harm its business, financial condition and results of operations significantly.

Interim, blinded and preliminary data from Tvardi's clinical trials that it announces or publishes from time to time may change as more patient data become available or as additional analyses are conducted and as the data are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, Tvardi may publish interim, blinded or preliminary data from clinical trials. Interim data from clinical trials that it may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more or longer-term patient data become available. For example, the only Phase 2 clinical data in IPF Tvardi has from the preliminary, blinded safety data review of 45 patients in its Phase 2 clinical trial in patients suffering from IPF, which represents a small sample size relative to Tvardi's targeted enrollment for the overall clinical trial, and may not be indicative of the clinical trial's final results. The purpose of this blinded data review was to enable an assessment of the overall management and conduct of the clinical trial, without unblinding any individual patient data. Tvardi cannot make any determinations regarding the safety or efficacy of TTI-101 from this blinded data and it must wait for final unblinded data to make assessments about the safety or efficacy of TTI-101 in IPF. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim and preliminary

blinded data should be viewed with caution until the final data are available, as initial clinical trial results as necessarily indicative of results that will be obtained in subsequent clinical trials or clinical practice. Differences between preliminary or interim data and final data could significantly harm Tvardi's business prospects.

Positive results from early preclinical studies and clinical trials of Tvardi's current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of Tvardi's current or future product candidates. If Tvardi cannot replicate the positive results from preclinical studies or early clinical trials of its current or future product candidates in future clinical trials, Tvardi may be unable to successfully develop, obtain regulatory approval for and commercialize current or future product candidates.

Positive results from Tvardi's preclinical studies of current or future product candidates, and any positive results it may obtain from early clinical trials of its current or future product candidates, including the ongoing and future clinical trials of TTI-101, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if Tvardi is able to complete its planned preclinical studies or clinical trials of current or future product candidates according to its current development timeline, the positive results from such preclinical studies and/or clinical trials of current or future product candidates, including TTI-101 and TTI-109, may not be replicated in subsequent preclinical studies or clinical trials. In particular, while Tvardi has conducted certain preclinical studies of TTI-109 and Phase 1 clinical trials of TTI-101, it does not know whether either of these product candidates will perform in planned clinical trials as it has performed in these prior preclinical studies or early clinical trials.

There is no guarantee that preclinical results or early clinical results will be replicated in later clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and Tvardi cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from the FDA or comparable foreign regulatory authority. If Tvardi fails to produce positive results in planned preclinical studies or clinical trials of any of its current or future product candidates, the development timeline and regulatory approval and commercialization prospects for its current or future product candidates, and, correspondingly, its business and financial prospects, would be materially adversely affected.

If Tvardi encounters difficulties enrolling patients in clinical trials, its clinical development activities could be delayed or otherwise adversely affected.

Tvardi may experience difficulties in patient enrollment in clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on Tvardi's ability to enroll a sufficient number of patients who remain in the clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in Tvardi's clinical trials;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- Tvardi's ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications Tvardi is investigating or other preclinical studies or clinical trials enrolling for similar diseases;

- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- · Tvardi's ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

For example, Tvardi is initially developing TTI-101 for the treatment of IPF and HCC. In the United States, IPF is estimated to only affect approximately 150,000 patients in the United States. As a result, Tvardi may encounter difficulties enrolling subjects in its clinical trials of TTI-101 due, in part, to the small size of these patient populations. Tvardi's clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as its product candidates, and this competition will reduce the number and types of patients available to Tvardi, because some patients who might have opted to enroll in Tvardi's clinical trials may instead opt to enroll in a clinical trial being conducted by one of its competitors. Since the number of qualified clinical investigators is limited, Tvardi expects to conduct some of its clinical trials at the same clinical trial sites that some of its competitors use, which will reduce the number of patients who are available for Tvardi's clinical trials in such clinical trial site. Certain of Tvardi's planned clinical trials may also involve invasive procedures such as bronchoscopy and broncho-alveolar lavage, which may lead some patients to drop out of clinical trials to avoid these follow-up procedures.

Additionally, the FDA may modify or enhance clinical trial requirements, which may affect enrollment. For example, in August 2023, the FDA published a guidance document, "Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors," which supersedes past guidance and finalizes draft guidance on informed consent. The FDA's new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program.

The design or execution of Tvardi's ongoing and future clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. Tvardi is currently recruiting two Phase 2 clinical trials of TTI-101, one in IPF as monotherapy and in addition to SoC therapy and another in HCC as monotherapy and combination with SoC therapy. In some instances, there can be significant variability in safety or efficacy results between different clinical trials with the same product candidate due to numerous factors, including differences in clinical trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. Tvardi does not know whether any clinical trials it conducts will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market its product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of Tvardi's product candidates. Tvardi's product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with Tvardi's clinical trial designs and its interpretation of data from preclinical studies or clinical trials. Further, requirements regarding clinical trial data may evolve. Changes to data requirements may cause the FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies.

In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than Tvardi requests or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that Tvardi believes would be necessary or desirable for the successful commercialization of its product candidates, if approved.

Tvardi may not be successful in its efforts to identify or discover additional product candidates in the future.

Tvardi's research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- Tvardi's inability to design such product candidates with the pharmacological properties that it desires or attractive PK; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial, and human resources. If Tvardi is unable to identify suitable compounds for preclinical and clinical development, it will not be able to obtain product revenue in future periods, which likely would result in significant harm to it financial position and adversely impact its stock price.

Due to Tvardi's limited resources and access to capital, it must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect its business.

Tvardi has limited financial and human resources and intends to initially focus on research programs and product candidates for a limited set of indications. As a result, it may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, Tvardi seeks to accelerate its development timelines, including by initiating certain clinical trials of its product candidates before earlierstage studies have been completed. This approach may cause Tvardi to commit significant resources to prepare for and conduct later-stage clinical trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, resource allocation decisions may cause Tvardi to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on product candidates that are not viable.

There can be no assurance that Tvardi will ever be able to identify additional therapeutic opportunities for its product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect its future growth and prospects. Tvardi may focus its efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Tvardi may in the future conduct clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such clinical trials.

Tvardi may in the future choose to conduct one or more clinical trials outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the clinical trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which could be costly and time-consuming, and which may result in current or future product candidates that Tvardi may develop not receiving approval for commercialization in the applicable jurisdiction.

Although Tvardi has received U.S. orphan drug designation for TTI-101 for IPF and HCC, it may be unable to obtain and maintain orphan drug designation for other product candidates and, even if Tvardi obtains such designation, it may not be able to realize the benefits of such designation, including potential marketing exclusivity of its product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA, may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Although Tvardi has received U.S. orphan drug designation for TTI-101 for IPF and HCC, the designation of any of its product candidates as an orphan drug does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as Tvardi's product candidates.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities from approving another marketing application for a product that constitutes a similar medicinal product treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Although Tvardi received orphan drug designation for TTI-101 for IPF and HCC, that exclusivity may not effectively protect the product candidate from competition because different drugs with different active moieties can be approved for the same condition in the United States. Even after an orphan drug is approved, the FDA may subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the latter drug is not a similar medicinal product or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Any legislative changes to the orphan drug provisions could change Tvardi's opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect Tvardi's business, results of operations, financial condition and prospects.

Although Tvardi has received a Fast Track designation from the FDA for TTI-101 for HCC and intends to seek Fast Track designation for TTI-109 for HCC, it may not benefit from a faster development or regulatory review or approval process, and a Fast Track designation does not increase the likelihood that its product candidates will receive marketing approval.

If a drug product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. Tvardi has received Fast Track designation for TTI-101 for the treatment of relapsed/refractory locally advanced, unresectable or metastatic HCC but may never receive Fast Track designation for TTI-109. Marketing applications submitted by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing licensure by the FDA. Although Tvardi received Fast Track designation for TTI-101, it may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways, and receiving a Fast Track designation does not provide assurance of ultimate FDA licensure. In addition, the FDA may withdraw any Fast Track designation granted to Tvardi if it believes that the designation is no longer supported by data from Tvardi's clinical development program. The FDA may also withdraw any Fast Track designation at any time.

Even if a product candidate Tvardi develops receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if TTI-101, TTI-109 or any other product candidate Tvardi develops receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future healthcare reform measures designed to reduce the cost of health care. If the product candidates Tvardi develops do not achieve an adequate level of acceptance, Tvardi may not generate significant product revenues and Tvardi may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer Tvardi's products, if approved, for sale at competitive prices;
- · convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the recommendations with respect to Tvardi's product candidates in guidelines published by various scientific organizations applicable to Tvardi and its product candidates;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products Tvardi commercializes, market acceptance and commercial success would be reduced.

Tvardi faces substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than Tvardi.

The development and commercialization of new drug products is highly competitive. Tvardi may face competition with respect to any product candidates that it seeks to develop or commercialize in the future from major biopharmaceutical companies, specialty biopharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a number of biopharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of IPF and HCC. Companies that Tvardi is aware of that are targeting the treatment of various fibrosis indications include companies with significantly more financial resources such as AbbVie Inc., AstraZeneca plc, Bristol Myers Squibb Co., Corbus Pharmaceutical, Merck & Co., Inc., Morphic Therapeutics Inc., Novartis AG, Pliant Therapeutics Inc., Scholar Rock Inc. and Takeda Pharmaceutical Company. Companies that Tvardi is aware of that are targeting the treatment of the HCC indication include large companies such as Novartis AG, Bristol Myers Squibb Co., Roche AG, AstraZeneca plc, AbbVie Inc. and Bayer AG.

Many of Tvardi's current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Tvardi does.

Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of competitors. Smaller or early-stage companies



may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with Tvardi in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, its programs. Tvardi's commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that Tvardi may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of fibrosis as well, which could give such products significant regulatory and market timing advantages over TTI-101, TTI-109 or other product candidates that Tvardi may identify. Tvardi's competitors also may obtain FDA or other regulatory approval for their products more rapidly than Tvardi may obtain approval for its product candidates, which could result in Tvardi's competitors establishing a strong market position before Tvardi is able to enter the market. Additionally, products or technologies developed by Tvardi's competitors may render its potential product candidates uneconomical or obsolete, and Tvardi may not be successful in marketing any product candidates it may develop against competitors. The availability of competitive products could limit the demand, and the price Tvardi is able to charge, for any products that it may develop and commercialize.

Compliance with governmental regulations regarding the treatment of animals used in research could increase Tvardi's operating costs, which would adversely affect the commercialization of its products.

The Animal Welfare Act (AWA), is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size and feeding, watering and shipping conditions. Third parties with whom Tvardi contracts are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anticruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations and/or obligations exist in many foreign jurisdictions. If Tvardi or its contractors fail to comply with regulations concerning the treatment of animals used in research, Tvardi may be subject to fines and penalties and adverse publicity, and its operations could be adversely affected.

If product liability lawsuits are brought against Tvardi, it may incur substantial financial or other liabilities and may be required to limit commercialization of its product candidates.

Tvardi faces an inherent risk of product liability as a result of testing TTI-101, TTI-109 and any of its other product candidates in clinical trials and will face an even greater risk if it commercializes any products. For example, Tvardi may be sued if its product candidates cause, or are perceived to cause, injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If Tvardi cannot successfully defend itself against product liability claims, it may incur substantial liabilities or be required to limit commercialization of its product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- · decreased demand for Tvardi products;
- injury to Tvardi's reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- · initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- · diversion of management's time and its resources;

- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and Tvardi's capital resources;
- · the inability to commercialize any product candidate, if approved; and
- decline in Tvardi's share price.

Tvardi's inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products it develops. Tvardi will need to obtain additional insurance for clinical trials as TTI-101 continues clinical development and as additional product candidates, including TTI-109, enter the clinic. However, Tvardi may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of its clinical trials. Tvardi's insurance policies may also have various exclusions, and Tvardi may be subject to a product liability claim for which it has no coverage. Tvardi may have to pay any amounts awarded by a court or negotiated in a settlement that exceed its coverage limitations or that are not covered by its insurance, and Tvardi may not have, or be able to obtain, sufficient capital to pay such amounts. Even if Tvardi's agreements with any future corporate collaborators entitle it to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Marketing, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

The regulatory approval process is highly uncertain, and Tvardi may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize TTI-101, TTI-109 or any current or future product candidates. Even if Tvardi believes its current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

TTI-101, TTI-109 and any other current or future product candidates Tvardi develops are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of products. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of Tvardi's product candidates will obtain the regulatory approvals necessary for Tvardi to begin selling them.

As a company, Tvardi has no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating Tvardi require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis Tvardi performs of data from preclinical studies and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Tvardi may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. Any elongation or de-prioritization of preclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could adversely affect the development and clinical testing of TTI-101, TTI-109 or other current or future product candidates.

Further, the FDA and its foreign counterparts may respond to any NDA that Tvardi may file by defining requirements that Tvardi does not anticipate. Such responses could delay clinical development of TTI-101, TTI-109 or any other current or future product candidates.



Any delay or failure in obtaining required approvals could adversely affect Tvardi's ability to generate revenue from the particular product candidate for which Tvardi is seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which Tvardi may market the product or on the labeling or other restrictions.

Tvardi is also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on Tvardi's business, financial condition, results of operations and prospects.

Even if Tvardi receives regulatory approval for its product candidates, it will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, Tvardi's product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Tvardi may be subject to penalties if it fails to comply with regulatory requirements or experience unanticipated problems with its product candidates.

Any regulatory approvals that Tvardi or its future collaborators obtain for its product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA, the European Medicines Agency (EMA), or a comparable foreign regulatory authority approves Tvardi's product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and AE reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities Tvardi uses to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMPs requirements. The discovery of any new or previously unknown problems with Tvardi's third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacture or facility, including withdrawal of the product from the market. As Tvardi expects to rely on third-party manufacturers, it will not have control over compliance with applicable rules and regulations by such manufacturers.

Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. Although clinicians may prescribe products for off-label uses as the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, Tvardi's ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. In addition, as Tvardi does not intend to conduct head-to-head comparative clinical trials for its product candidates, it will be unable to make comparative claims regarding any other products in the promotional materials for its product candidates.

If Tvardi promotes its approved products in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, it may be subject to significant liability and enforcement

action. If Tvardi or its collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which Tvardi seeks to market its product candidates, Tvardi or its collaborators, manufacturers or service providers may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or comparable foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If Tvardi cannot successfully manage the promotion any product candidates, if approved, it could become subject to significant liability, which would materially adversely affect its business and financial condition.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with Tvardi's third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the Medicines and Healthcare Products Regulatory Agency or the FDA to approve pending applications or supplements to approved applications filed by Tvardi or its strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Tvardi also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Coverage and reimbursement may be limited or unavailable or pricing unfavorable in certain market segments for Tvardi's product candidates, if approved, which could make it difficult for Tvardi to sell any product candidates profitably.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which Tvardi may obtain regulatory approval. In the United States, sales of any products for which Tvardi may receive regulatory marketing approval will depend, in part, on the availability of coverage and adequacy of reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use Tvardi's product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. Tvardi cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, its product candidates or assure that coverage and adequate reimbursement will be available for any product that Tvardi may develop and, if reimbursement is available, what the level of reimbursement will be.

Government authorities and other third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- · cost-effective; and
- neither experimental nor investigational.

In the United States, as well as foreign jurisdictions, no uniform policy of coverage and reimbursement for products exists among third-party payors.

Coverage and reimbursement for products may vary depending on the payor, the insurance plan and other factors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require Tvardi to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of Tvardi products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if Tvardi obtains coverage for a given product, the resulting reimbursement payment rates might not be adequate for it to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for Tvardi's product candidates, if approved.

A primary trend in the United States and European healthcare industries is toward cost containment, as legislative bodies, government authorities, third-party payors, and others have attempted to control costs by limiting coverage, pricing and the amount of reimbursement available for certain treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge or seek to lower the prices charged for medical products, and many third-party payors limit coverage and reimbursement for newly approved health care products. Moreover, reimbursement, if available, may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers or by future laws, regulations or guidance seeking to limit prescription drug prices. If Tvardi is unable to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payers for any approved products that Tvardi develops, or if net prices are reduced by mandatory discounts or rebates effect on Tvardi's operating results, its ability to raise capital needed to commercialize products and overall financial condition.

Changes to current healthcare laws and state and federal healthcare reform measures that may be adopted in the future that impact coverage and reimbursement for drug or biologic products may result in additional payment reductions in Medicare and other healthcare funding and otherwise affect the prices Tvardi may obtain for any product candidates for which it may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for Tvardi to obtain marketing approval for and commercialize product candidates and may affect the prices Tvardi may set.

In the United States and some foreign jurisdictions, there have been, and Tvardi expects there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect Tvardi's ability to profitably sell any product candidates for which it obtains marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), was enacted in the United States, which resulted in delays in the implementation of, and action taken to repeal or replace, certain aspects of the

ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA), into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges in the future. Moreover, the American Taxpayer Relief Act of 2021, effective January 1, 2024, would eliminate the statutory cap on rebate amounts owed by drug manufacturers under the MDRP, which is currently capped at 100% of the Average Manufacturer Price for a covered outpatient drug.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the IRA, among other things, (1) directs the Department of Health & Human Services (HHS), to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to 15 additional drugs covered under Part D for price negotiation in 2025. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Patent and Trademark Law Amendments Act (the Bayh-Dole Act). On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Tvardi's ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of another company's drug continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product, which was originally approved in 2000, and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, Tvardi's ability to develop TTI-101, TTI-109 or future product candidates Tvardi may develop may be at risk and could be delayed, undermined or subject to protracted litigation. Finally, Tvardi could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In Loper Bright Enterprises v. Raimondo, for example, the court overruled Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as FDA acted within its statutory authority under the

Administrative Procedure Act (the APA). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the Centers for Medicare & Medicaid Services that Tvardi relies on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact Tvardi's business and operations.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints. Tvardi expects that the ACA, the IRA, and any other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that Tvardi receives for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent Tvardi from being able to generate revenue, attain profitability or commercialize its product candidates, if approved.

Tvardi's operations and relationships with healthcare providers, healthcare organizations, customers and thirdparty payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose Tvardi to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Tvardi's future arrangements with healthcare providers, healthcare organizations, third-party payors and customers will expose Tvardi to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Tvardi researches, markets, sells and distributes its products, if approved. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from
 knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or
 indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual
 for, or the purchase, order or recommendation of, any good or service, for which payment may be
 made, in whole or in part, under a federal and state healthcare program such as Medicare and
 Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent
 to violate it in order to have committed a violation;
- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- Health Insurance Portability and Accountability Act (HIPAA), which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information for or on behalf of a covered entity and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS), information on certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals and certain other health care providers (such as physician assistants and nurse practitioners), as well as ownership and investment interests held by physicians and their immediate family members;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

If Tvardi or its collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, it could be subject to enforcement actions, which could affect Tvardi's ability to develop, market and sell its product candidates successfully and could harm its reputation and lead to reduced acceptance of its products, if approved by the market.

Efforts to ensure that Tvardi's current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that Tvardi's business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Tvardi's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations or reputational harm, any of which could adversely affect its financial results. These risks cannot be entirely eliminated. Any action against Tvardi for an alleged or suspected violation could cause it to incur significant legal expenses and could divert management's attention from the operation of its business, even if the defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to Tvardi in terms of money, time and resources.

If Tvardi fails to comply with environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of its business.

Tvardi is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Tvardi's research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. Tvardi generally contracts with third parties for the disposal of these materials and wastes. Tvardi cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of its commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although Tvardi believes that the safety procedures utilized by its third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, it cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, Tvardi may be held liable for any resulting damages and such liability could exceed its resources and state or federal or other applicable authorities may curtail its use of certain materials and/or interrupt its business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. Tvardi cannot predict the impact of such changes and cannot be certain of its future compliance. In addition, Tvardi may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair its research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although Tvardi maintain workers' compensation insurance to cover costs and expenses it may incur due to injuries to its employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. Tvardi does not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Tvardi's future growth may depend, in part, on its ability to penetrate foreign markets, where it would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect its business.

Tvardi is not permitted to market or promote any of its current or future product candidates before it receives regulatory approval from the applicable regulatory authority in that foreign market, and Tvardi may never receive such regulatory approval for any of its current or future product candidates. To obtain separate regulatory approval in many other countries, Tvardi must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of its current or future product candidates, and Tvardi cannot predict success in these jurisdictions. If it obtains approval of its current or future product candidates and ultimately commercialize its current or future product candidates in foreign markets, Tvardi would be subject to additional risks and uncertainties, including:

- differing regulatory requirements in foreign countries, such that obtaining regulatory approvals outside of the United States may take longer and be more costly than obtaining approval in the United States;
- Tvardi's customers' ability to obtain reimbursement for current or future product candidates in foreign markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- · different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- 55

- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

Foreign sales of current or future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Governments outside the United States tend to impose strict price controls, which may adversely affect Tvardi's revenue, if any.

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, Tvardi may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. In addition, many countries outside the United States have limited government support programs that provide for reimbursement of drugs such as Tvardi's product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of Tvardi's products, if approved, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, Tvardi's business could be materially harmed.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of Tvardi's business may rely, which could negatively impact its business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA and other government agencies on which Tvardi's operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect Tvardi's

business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process Tvardi's regulatory submissions, which could have a material adverse effect on Tvardi's business. Further, in Tvardi's operations as a public company, future government shutdowns could impact its ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

Tvardi is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. Tvardi can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, contract research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Tvardi has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Tvardi also expects its non-U.S. activities to increase in time. Tvardi plans to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and it can be held liable for the corrupt or other illegal activities of its personnel, agents or partners, even if Tvardi does not explicitly authorize or have prior knowledge of such activities.

Risks Related to Tvardi's Intellectual Property

Tvardi's commercial success depends in part on its and its current or future licensors', including Baylor College of Medicine (BCM), ability to obtain, maintain, enforce, and otherwise protect its intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, Tvardi's competitors or other third parties could develop and commercialize similar products and product candidates and Tvardi's ability to successfully develop and commercialize its product candidates may be adversely affected.

Tvardi's commercial success depends, in large part, on its ability and the ability of its current and future licensors to obtain and maintain intellectual property rights protection through patents, trademarks and trade secrets in the United States and other countries with respect to its product candidates. If Tvardi and its current and future licensor do not adequately protect Tvardi's intellectual property rights, competitors or other third parties may be able to erode, negate or preempt any competitive advantage Tvardi may have, which could harm its business and ability to achieve profitability.

If the scope of the patent protection Tvardi obtains is not sufficiently broad, it may not be able to prevent others from developing and commercializing technology and products similar or identical to Tvardi's product candidates. The degree of patent protection Tvardi requires to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect its rights or permit Tvardi to gain or keep any competitive advantage. Tvardi cannot provide any assurances that any of its own or its licensor's patents have, or that any of its own or its licensor's pending patent applications that mature into issued patents will include claims with a scope sufficient to protect its product candidates or otherwise provide any competitive advantage. Other parties may develop technologies that may be related or competitive with Tvardi's approach and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with Tvardi's patent portfolio, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate its patent position. In addition, the laws of foreign countries may not protect its rights to the same extent as the laws of the United States.

Tvardi's patent portfolio may not provide it with any meaningful protection or prevent competitors from designing around its patent claims, enabling its competitors to circumvent Tvardi's patent portfolio by

developing similar or alternative pharmaceutical products in a non-infringing manner. For example, a third party may develop a pharmaceutical product that provides benefits similar to Tvardi's pharmaceutical products but falls outside the scope of its patent protection or licensed rights. If the patent protection provided by the patent and patent applications Tvardi holds or pursues with respect to its product candidates is not sufficiently broad to impede such competition, its ability to successfully commercialize its product candidates could be negatively affected, which would harm its business.

It is possible that defects of form in the preparation or filing of Tvardi's patent portfolio may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for patent term adjustments. If Tvardi or its future partners or collaborators fail to establish, maintain or protect Tvardi's patents and other intellectual property rights, such rights may be reduced or eliminated. In addition, while Tvardi has the right to provide input, it does not have the right to control prosecution or maintain certain patents and patent applications that Tyardi has in-licensed from BCM. If BCM is not fully cooperative or disagrees with Tvardi as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution or enforcement of Tvardi's patent portfolio, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the U.S. Patent and Trademark Office (USPTO), and various government patent agencies outside of the United States over the lifetime of Tvardi's owned or licensed patents and patent applications. Tvardi currently relies on its outside counsel and BCM to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. Any of these outcomes could impair Tvardi's ability to prevent competition from third parties, which may have an adverse impact on its business.

The patent position of biotechnology and pharmaceutical companies carries uncertainty. In addition, the determination of patent rights with respect to pharmaceutical products commonly involves complex legal and factual questions, which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals. As a result, the issuance, scope, validity, enforceability and commercial value of Tvardi's patent rights are characterized by uncertainty.

Tvardi's competitors may seek approval to market their own products similar to or otherwise competitive with Tvardi's products. In these circumstances, Tvardi may need to defend or assert its own and in-licensed patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find Tvardi's patents invalid or unenforceable, or that Tvardi's competitors do not infringe its own and licensed patents. As such, even if Tvardi has valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve its business objectives.

Tvardi also maintains certain information as company trade secrets. This information may relate to inventions that are not patentable or not optimally protected with patents. Tvardi uses commercially acceptable practices to protect this information, including, for example, limiting access to the information and requiring passwords for its computers. Additionally, Tvardi executes confidentiality agreements with any third parties to whom Tvardi may provide access to the information and with its employees, consultants, scientific advisors, collaborators, vendors, contractors and advisors. Tvardi cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. It is possible that technology relevant to Tvardi's business will be independently developed by a person who is not a party to such a confidentiality or invention assignment agreement. If any of Tvardi's trade secrets were to be independently developed by a competitor or other third party, Tvardi would have no right to prevent such competitor or third party, or those to whom they communicate such independently developed information, from using that information to compete with Tvardi. Tvardi may not be able to prevent the unauthorized disclosure or use of its technical knowledge or trade secrets by contract manufacturers, consultants, collaborators, vendors, advisors, former employees and current employees. Monitoring unauthorized uses and disclosures is difficult and Tvardi does not know whether the steps Tvardi has taken to protect its proprietary technologies will be effective. Furthermore, if the parties to Tvardi's confidentiality agreements breach or violate the terms of these agreements, Tvardi may

not have adequate remedies for any such breach or violation, and it could lose its trade secrets as a consequence of such breaches or violations. Tvardi's trade secrets could otherwise become known or be independently discovered by its competitors. Additionally, if the steps taken to maintain its trade secrets are deemed inadequate, Tvardi may have insufficient recourse against third parties for misappropriating its trade secrets. If any of these events occurs or if Tvardi otherwise loses protection for its trade secrets, its business, financial condition, results of operation and prospects may be materially and adversely harmed.

Pending patent applications cannot be enforced against third parties unless and until a patent issues. Even if Tvardi obtains any patents covering its product candidates or its technology, they could nonetheless be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, Tvardi cannot be certain that it or its licensor were the first to make the inventions claimed in its own or in-licensed patents and patent applications, or that Tvardi or its licensor were the first to file for patent protection of such inventions. If third parties have filed prior patent applications on inventions claimed in Tvardi's patent portfolio that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by Tvardi's patent portfolio. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether Tvardi's invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, the patents of Tvardi's patent portfolio may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all the potentially relevant prior art relating to Tyardi's patent portfolio has been found. If such prior art exists, it may be used to invalidate a patent or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the USPTO, or to other patent offices around the world. There also may be prior art of which Tvardi is aware, but which it does not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Alternately or additionally, Tvardi may become involved in post-grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter partes review, supplemental examinations or interference proceedings or challenges before the USPTO or in district court in the United States, or similar proceedings in various foreign jurisdictions, including both national and regional, challenging patents or patent applications in which Tvardi has rights, including patents on which Tvardi relies to protect its business. An adverse determination in any such challenges may result in loss of the patent or claims in the patent portfolio being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent portfolio, any of which could limit Tvardi's ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of Tvardi's technology and products.

Pending and future patent applications may not result in patents being issued that protect Tvardi's business, in whole or in part, or which effectively prevent others from commercializing competitive products. Competitors may also be able to design around Tvardi's own and in-licensed patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of Tvardi's own and in-licensed patents or narrow the scope of its own and in-licensed patent protection. In addition, the laws of foreign countries may not protect Tvardi's rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including jurisdiction covering significant commercial markets, such as the European Patent Office, China and Japan, restrict the patentability of methods of treatment of the human body more than U.S. law does. If these developments were to occur, they could have a material adverse effect on Tvardi's ability to generate revenue.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that Tvardi, its licensor or any future collaborators or partners will be successful in protecting Tvardi's product candidates by obtaining and defending patents.

The patent application process is subject to numerous risks and uncertainties, including that:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance, whether intentional or not, can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- Tvardi's own or in-licensed patents that have been issued or may be issued in the future may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- Tvardi's competitors, many of whom may have substantially greater resources and many of whom may have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate Tvardi's ability to make, use and sell its product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products;
- countries other than the United States may, under certain circumstances, force Tvardi to grant a license under its patents to a competitor, allowing the competitor to compete with Tvardi in that jurisdiction or forcing it to lower the price of its drug in that jurisdiction; and
- Tvardi, its licensor, and any future partners or collaborators, as the case may be, may fail to meet Tvardi's obligations to the U.S. government in regards to any co-owned or in-licensed patents and patent applications that are funded or may be funded by U.S. government grants, leading to the loss of patent rights.

Tvardi does not currently own or in-license any composition of matter patent protection for the TTI-101 molecule. As such, Tvardi relies solely upon patents related to methods of use, manufacturing and pharmaceutical compositions.

Composition-of-matter patents on the active pharmaceutical ingredient (API), in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. Tvardi does not own or in-license any patents or patent applications in the United States or any other jurisdiction with respect to the TTI-101 molecule. As the compound was made public before a patent application could be filed, Tvardi will not be able to obtain patents or patent applications in the United States or any other jurisdiction with respect to TTI-101 molecule.

Instead, Tvardi has filed patent applications and in-licensed patents and patent applications covering methods-of-use of TTI-101 and pharmaceutical composition of TTI-101. Method-of-use patents protect the use of a compound for the specified method. Pharmaceutical composition patents protect the compositions of TTI-101 with other components. Method-of-use patents do not prevent a competitor or other third party from developing or marketing TTI-101 for an indication that is outside the scope of Tvardi's patented methods of use. Pharmaceutical composition patents do not prevent a competitor or other third party from developing or marketing a different formulation of TTI-101 that is outside the scope of Tvardi's patented formulations. Moreover, with respect to method-of-use patents, even if competitors or other

third parties do not actively promote their product for Tvardi's targeted indications or uses for which Tvardi may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute.

There may be publications and other prior art that may be relevant to Tvardi's patent portfolio and may be used to challenge the validity of these owned or in-licensed patents and patent applications in litigation or other intellectual property-related proceedings. If these types of challenges are successful, the scope of Tvardi's patent portfolio may be narrowed or found to be invalid, and Tvardi may lose valuable intellectual property rights. Any of the foregoing could have a material adverse effect on Tvardi's business, financial conditions, prospects and results of operations.

It is difficult and costly to protect Tvardi's intellectual property and Tvardi's proprietary technologies, and Tvardi may not be able to ensure their protection.

Tvardi's commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for its product candidates, as well as on its ability to successfully defend these patents against potential third-party challenges. Tvardi's ability to protect its product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which Tvardi has rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and have in recent years been the subject of much litigation. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of Tvardi's intellectual property. Over the past decade, U.S. federal courts have increasingly invalidated pharmaceutical and biotechnology patents during litigation often based on changing interpretations of patent law. Further, the determination that a patent application or patent claim meets all the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although Tvardi has conducted searches for third-party publications, patents and other information that may affect the patentability of certain claims in Tvardi's patent portfolio, it cannot be certain that all relevant information has been identified. Accordingly, Tvardi cannot predict the breadth of claims that may be allowed or enforced in its own patent portfolio.

Tvardi cannot provide assurances that any of the patent applications in its patent portfolio will be found to be patentable, including over its own prior art publications or patent literature, or will issue as patents. Neither can Tvardi make assurances as to the scope of any claims that may issue from the patent applications of its patent portfolio, nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of its patent portfolio in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for its product candidates and/or materially harm its business.

In addition to challenges during litigation, third parties can challenge the validity of Tvardi's and its licensor's patents in the United States using post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent filed March 16, 2013, or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013, or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and use a lower burden of proof than used in litigation in U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any

of Tvardi's own or in-licensed patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that Tvardi will be successful in defending the patent, which may result in a loss of the challenged patent right to Tvardi.

The degree of future protection for Tvardi's proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect its rights or permit Tvardi to gain or keep its competitive advantage. For example:

- Tvardi may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of Tvardi's programs;
- it is possible that one or more of the patent applications in Tvardi's patent portfolio will not become an issued patent or, if issued, that the patent(s) claims will have sufficient scope to protect its technology, provide Tvardi with commercially viable patent protection or provide it with any competitive advantages;
- if the pending applications in Tvardi's patent portfolio issue as patents, they may be challenged by third parties as invalid or unenforceable under United States or foreign laws;
- Tvardi may not successfully commercialize its product candidates, if approved, before the relevant patents in its patent portfolio expire;
- Tvardi may not be the first to make the inventions covered by its patent portfolio;
- Tvardi may not develop additional proprietary technologies or inventions on its product candidates that are separately patentable; or
- it is possible that there are unpublished patent applications maintained in secrecy that may later issue with claims related to its product candidates or products or technology similar to Tvardi's.

In addition, to the extent that Tvardi is unable to obtain and maintain patent protection for its product candidates, or in the event that such patent protection expires, it may no longer be cost-effective to extend Tvardi's portfolio by pursuing additional development of any of its product candidates for follow-on indications.

Tvardi's intellectual property licensed from third parties may be subject to retained rights.

Tvardi's licensors may retain certain rights under the relevant agreements with Tvardi, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates. For example, Tvardi depends on its license agreements with the BCM for the development of its product candidates, pursuant to which Tvardi has an exclusive, worldwide, sublicensable license under BCM's rights to certain patents and patent applications related to STAT3 inhibitors in various indications. BCM has retained rights under the license agreements to grant a non-exclusive license to other academic or research institutions for non-commercial research purposes, and, if required by law, to grant a non-exclusive license to the U.S. government or to a foreign state pursuant to a treaty with the United States; BCM's rights to make or use the licensed patents and technology for non-commercial research, patient care and educational purposes; and additional rights reserved by the government of the United States. BCM has retained rights under the license agreements to the extent necessary to carry out its obligations for manufacturing under the license agreements with BCM. It is difficult to monitor whether BCM will limit its use of the intellectual property exclusively licensed to Tvardi for these permitted uses, and Tvardi could incur substantial expenses to enforce its rights to its licensed product candidates in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The U.S. federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. Tvardi may at times choose to collaborate with academic institutions to accelerate

its preclinical research or development. If Tvardi engages with university partners in projects where there is a risk that federal funds may be commingled, it cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If the federal government chooses to exercise its march-in rights with respect to any patents or technology Tvardi in-licensed and which is critical to its business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, Tvardi's ability to enforce or otherwise exploit patents covering such patents or technology may be adversely affected.

Patent terms may be inadequate to protect Tvardi's competitive position on its products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new pharmaceutical products, patents protecting such pharmaceutical products might expire before or shortly after such pharmaceutical products are commercialized.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension (PTE), of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication — in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. Tvardi anticipates applying for PTE in the United States. Similar extensions may be available in other countries where Tvardi is prosecuting patents, and Tvardi likewise anticipates applying for such extensions.

In the United States, Tvardi's broadest patent, Tvardi 8,779,001, which protects the use of TTI-101 for inhibiting STAT3, is set to expire on November 13, 2030. Tvardi may potentially apply PTE and Orphan Drug Exclusivity to the 8,779,001 patent, extending the patent term of the 8,779,001 patent by up to seven years. After expiration of the 8,779,001 patent, Tvardi's commercial use of TTI-101 will be protected by formulation patents and manufacturing patents that Tvardi owns; however these patents provide narrower protection than the 8,779,001 patent. If a competitor designs a formulation of TTI-101 that is not covered by any of Tvardi's formulation or manufacturing patents, then Tvardi may not be able to prevent them from selling their formulation of TTI-101 to inhibit STAT3.

The granting of patent term extensions is not guaranteed and is subject to numerous requirements. Tvardi might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. In addition, to the extent Tvardi wishes to pursue patent term extension based on a patent that it has in-licensed from BCM or another third party, Tvardi would need the cooperation of BCM or the other third party. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with Tvardi's assessment of whether such extensions are available, and may refuse to grant extensions to its patents, or may grant more limited extensions than Tvardi requests. If this occurs, Tvardi's competitors may be able to obtain approval of competing products following the patent expiration by referencing Tvardi's clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on Tvardi's ability to generate revenue.

In the context of the European Union, the Court of Justice of the European Union has recently restricted grant of supplementary protection certificate (SPC), for new medical uses of existing products, thus narrowing the availability of patent term extension for second medical uses. Therefore, any development of Tvardi's product candidates with respect to second medical uses may be adversely affected in the European Union. In addition, within the European Union, regulatory protections afforded to medicinal

products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extensions are currently under review and may likely be curtailed in future years. On April 26, 2023, the European Commission adopted a proposal for a new Regulation set to replace Regulation (EC) No 726/2004 and a new Directive replacing Directive 2001/83 on the Community Code relating to medicinal products for human use. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation and will affect the existing period of regulatory protection afforded to medicinal products in the European Union and Northern Ireland. If Tvardi is unable to obtain patent term extension or the term of any such extension is less than it requests, or if data exclusivity or other regulatory protections are reduced, Tvardi's competitors may obtain approval of competing products following Tvardi's patent expiration, and its business, financial condition, results of operations and prospects could be materially harmed.

Changes in the interpretation of patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing Tvardi's ability to protect its products.

The United States Congress is responsible for passing laws establishing patentability standards. As with any laws, implementation is left to federal agencies and the federal courts based on their interpretations of the laws. Interpretation of patent standards can vary significantly within the USPTO, and across the various federal courts, including the U.S. Supreme Court. Recently, the U.S. Supreme Court has ruled on several patent cases, generally limiting the types of inventions that can be patented. Further, there are open questions regarding interpretation of patentability standards that the Supreme Court has yet to decisively address. Absent clear guidance from the Supreme Court, the USPTO has become increasingly conservative in its interpretation of patent laws and standards.

In addition to increasing uncertainty with regard to Tvardi's ability to obtain patents in the future, the legal landscape in the U.S. has created uncertainty with respect to the value of patents. Depending on any actions by Congress, and future decisions by the lower federal courts and the U.S. Supreme Court, along with interpretations by the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken Tvardi's ability to obtain new patents or to enforce its existing patents and patents that it might obtain in the future.

The U.S. Supreme Court has ruled on several patent cases in recent years; these cases often narrow the scope of patent protection available to inventions in the biotechnology and pharmaceutical spaces. For example, in *Amgen Inc. v. Sanofi* (Amgen), the U.S. Supreme Court held that certain of Amgen's patent claims defined a class of antibodies by their function of binding to a particular antigen. The U.S. Supreme Court further wrote that because the patent claims defined the claimed class of antibodies only by their function of binding to a particular antigen, a skilled artisan would have to use significant trial and error to identify and make all of the molecules in that class. The U.S. Supreme Court ultimately held that Amgen failed to properly enable its patent claims. Tvardi's patent portfolio does not relate to any broad class of antibodies as in Amgen; however, Tvardi has claimed broad classes of compounds related to its lead products. To the extent that a court finds that the skilled artisan would need significant trial and error to identify all of the compounds covered by any of its claims, the court may find the claims invalid under Amgen. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken its ability to obtain new patents or to enforce its existing patents and patents that it might obtain in the future.

Further, a new court system recently became operational in the European Union. The Unified Patent Court (UPC), began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the European Union. The broad geographic reach of the UPC could enable third parties to seek revocation of any of Tvardi's European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on Tvardi's business and its ability to

commercialize its technology and product candidates and, resultantly, on its business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and Tvardi cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect Tvardi's ability to enforce or defend the validity of its European patents. Patent owners have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. Tvardi has decided to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, its European patents and patent applications could be subject to the jurisdiction of the UPC. Tvardi cannot be certain that its European patents and patent applications will avoid falling under the jurisdiction of the UPC, if it decides to opt out of the UPC.

Tvardi may not be able to seek or obtain patent protection throughout the world or enforce such patent protection once obtained.

Filing, prosecuting, enforcing and defending patents protecting Tvardi's product candidates in all countries throughout the world would be prohibitively expensive, and its intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where it does pursue patent protection, there can be no assurance that any patents will issue with claims that cover its products.

Moreover, Tvardi's ability to protect and enforce its own and in-licensed intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for Tvardi to stop the infringement of its patents or the misappropriation of its other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, Tvardi may not be able to prevent third parties from practicing its inventions in certain countries outside the United States and Europe or from selling or importing products made from its inventions in and into the United States or other jurisdictions. Competitors may use its technologies in jurisdictions where Tvardi has not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where Tvardi has patent protection, if its ability to enforce its patents to stop infringing activities is inadequate. These products may compete with Tvardi's products, and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, Tvardi does not know the degree of future protection that it will have on its product candidates. While Tvardi will endeavor to try to protect its product candidates with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

Proceedings to enforce Tvardi's own or in-licensed patent rights, whether successful or not, could result in substantial costs and divert its efforts and resources from other aspects of its business. Further, such proceedings could put its own and in-licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly; put its own or in-licensed pending patent applications at risk of not issuing; and provoke third parties to assert claims against Tvardi. Tvardi may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while Tvardi intends to protect its intellectual property rights in major markets for its products, it cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which Tvardi may wish to market its products, if approved. Accordingly, its efforts to protect its intellectual property rights in such countries may be inadequate.

In addition, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of Tvardi's patent applications or those of any current or future licensors and the maintenance, enforcement or defense of its issued patents or those of any current or future licensors. For example, the United States and foreign government actions

related to Russia's conflict in Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of Tvardi's patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on Tvardi's business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, Tvardi would not be able to prevent third parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia. Accordingly, Tvardi's competitive position may be impaired, and its business, financial condition, results of operations and prospects may be adversely affected.

In order to protect Tvardi's competitive position around its product candidates, Tvardi may become involved in lawsuits to enforce its patents or other intellectual property, which could be expensive, time consuming and unsuccessful and which may result in its own or in-licensed patents being found invalid or unenforceable.

Competitors may seek to commercialize competitive products to Tvardi's product candidates. In order to protect its competitive position, Tvardi may become involved in lawsuits asserting infringement of its own or in-licensed patents, or misappropriation or other violations of other of its intellectual property rights. Litigation is expensive and time consuming and would likely divert the time and attention of its management and scientific personnel. There can be no assurance that Tvardi will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if Tvardi ultimately prevails in such claims, the monetary cost of such litigation and the diversion of the attention of its management and scientific personnel could outweigh any benefit it receives as a result of the proceedings.

If Tvardi files a patent infringement lawsuit against a perceived infringer, such a lawsuit could provoke the defendant to counterclaim that it infringes their patents and/or that its own or in-licensed patents are invalid and/or unenforceable. In patent litigation in the United States, it is commonplace for a defendant to counterclaim alleging invalidity and/or unenforceability. In any patent litigation there is a risk that a court will decide that the asserted patents are invalid or unenforceable, in whole or in part, and that Tvardi does not have the right to stop the defendant from using the invention at issue. With respect to a counterclaim of invalidity, Tvardi cannot be certain that there is no invalidating prior art of which it and the patent examiner were unaware during prosecution. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent claims narrowly or decide that Tvardi does not have the right to stop the other party from using the invention at issue on the grounds that its patent claims do not cover the invention. If any of Tvardi's own or in-licensed patents are found invalid or unenforceable, or construed narrowly, its ability to stop the other party from launching a competitive product would be materially impaired. Further, such adverse outcomes could limit Tvardi's ability to assert those patents against future competitors. Loss of patent protection would have a material adverse impact on its business.

Even if Tvardi establishes infringement of any of its own or in-licensed patents by a competitive product, a court may decide not to grant an injunction against further infringing activity, thus allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay Tvardi a "reasonable royalty" as determined by the court, and/or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity and/or competition from a related product would have a material adverse impact on its business.

Litigation often involves significant amounts of public disclosures. Such disclosures could have a materially adverse impact on Tvardi's competitive position or its stock prices. During any litigation Tvardi would be required to produce voluminous records related to its patents and its research and development activities in a process called discovery. The discovery process may result in the disclosure of some of its confidential information. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of its common shares.

Litigation is inherently expensive, and the outcome is often uncertain. Any litigation likely would substantially increase Tvardi's operating losses and reduce its resources available for development activities.

Further, Tvardi may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of its competitors may be able to sustain the costs of such litigation or proceedings more effectively than Tvardi can because of their substantially greater financial resources. As a result, Tvardi may conclude that even if a competitor is infringing any of its patents, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of it or its stockholders. In such cases, Tvardi may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

For any in-licensed patent rights, Tvardi may not have the right to file a lawsuit for infringement and may have to rely on its licensor to enforce these rights for Tvardi. If Tvardi is not able to directly assert its licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on its behalf, Tvardi may have difficulty competing in certain markets where such potential infringers conduct their business, and Tvardi's commercialization efforts may suffer as a result.

Concurrently with an infringement litigation, third parties may also be able to challenge the validity of Tvardi's patents before administrative bodies in the United States or abroad. Such mechanisms include reexamination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of Tvardi's patents in such a way that they no longer cover its products, potentially negatively impacting any concurrent litigation.

If Tvardi is sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay Tvardi from developing or commercializing its product candidates.

Tvardi's commercial success depends in part on its ability to develop, manufacture, market and sell its product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. However, Tvardi's research, development and commercialization activities may be subject to claims that it infringes, misappropriates or otherwise violates patents or other intellectual property rights owned or controlled by third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compositions, formulations, methods of manufacturing compounds or formulations and/or methods of use for the treatment of the disease indications for which Tvardi is developing. If any third-party patents or patent applications are found to cover its product candidates, their compositions, formulations or their methods of use or manufacture, Tvardi may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and Tvardi may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to its product candidates, including patent infringement lawsuits in the U.S. or abroad. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the compositions or formulations and use or manufacture of Tvardi's product candidates. Third parties may assert infringement claims against Tvardi based on existing patents that they own or in-license or patents that may grant to them (or which they may in-license) in the future, regardless of the merit of such patents or infringement claims. If Tvardi's defenses to such assertions of infringement were unsuccessful, it could be liable for a court-determined reasonable royalty on its existing sales and further damages to the patent owner (or licensee), such as lost profits. Such royalties and damages could be significant. If Tvardi is found to have willfully infringed the claims of a third party's patent, the third party could be awarded treble damages and attorney's fees. Further, unless Tvardi obtains a license to such patent, it may be precluded from commercializing the infringing product candidate. Any of the aforementioned could have a material adverse effect on its business, financial condition, results of operations and prospects.

Tvardi cannot guarantee the completeness or thoroughness of any of its patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, nor can it be certain that it has identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of any of its product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that any of Tvardi's product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and

claim that use of Tvardi's technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against Tvardi based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including Tvardi, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If Tvardi were sued for patent infringement, it would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and Tvardi may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if Tvardi is successful in these proceedings, Tvardi may incur substantial costs and the time and attention of its management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm its business and operating results. In addition, parties making claims against Tvardi may be able to sustain the costs of complex patent litigation more effectively than it can because they have substantially greater resources, and Tvardi may not have sufficient resources to bring these actions to a successful conclusion.

If Tvardi is found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, it could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product. Alternatively, Tvardi may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. If Tvardi were required to obtain a license to continue to manufacture or market the affected product, Tvardi may be required to pay substantial royalties or grant cross-licenses to its patents. Even if Tvardi were able to obtain a license, it could be nonexclusive, thereby giving its competitors and other third parties access to the same technologies licensed to Tvardi. Tvardi cannot make assurances that any such license will be available on acceptable terms, if at all. Ultimately, Tvardi could be prevented from commercializing a product, or be forced to cease some aspect of its business operations as a result of claims of patent infringement or violation of other intellectual property rights, Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, Tvardi may not be able to obtain any required license on commercially reasonable terms or at all. Even if Tvardi were able to obtain a license, it could be nonexclusive, thereby giving its competitors access to the same technologies licensed to it; alternatively or additionally it could include terms that impede or destroy its ability to compete successfully in the commercial marketplace. A finding of infringement could prevent Tvardi from commercializing a product or force Tvardi to cease some of its business operations, which could harm its business. Claims that Tvardi has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of Tvardi's confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on its ability to raise additional funds or otherwise have a material adverse effect on its business, results of operations, financial condition and prospects.

Others may challenge inventorship or claim an ownership interest in Tvardi's intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

Determinations of inventorship can be subjective. While Tvardi undertakes to accurately identify correct inventorship of inventions made on its behalf by its employees, consultants and contractors, an employee, consultant or contractor may disagree with its determination of inventorship and assert a claim of inventorship. Any disagreement over inventorship could result in Tvardi being forced to defend its determination of inventorship in a legal action which could result in substantial costs and be a distraction to its senior management and scientific personnel.

While Tvardi typically requires employees, consultants and contractors who may develop intellectual property on its behalf to execute agreements assigning such intellectual property to Tvardi, Tvardi may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that it regards as its own. Moreover, even when Tvardi obtains agreements assigning intellectual property to it, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. In either case, Tvardi may be forced to bring claims against third parties, or defend claims that they may bring against Tvardi, to determine the ownership of what it regards as its intellectual property. Furthermore, individuals executing agreements with Tvardi may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with Tvardi may be ineffective in perfecting ownership of inventions developed by that individual. If Tvardi is unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on its behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in Tvardi losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and/or being enjoined from clinical testing, manufacturing and marketing of the affected product candidate(s). Even if Tvardi is successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to its senior management and scientific personnel.

Tvardi may be subject to claims by third parties asserting that its employees or it has misappropriated their intellectual property or claiming ownership of what it regards as its own intellectual property.

Many of Tvardi's current and former employees, including its senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although Tvardi takes commercially reasonable steps to ensure that its employees do not use the proprietary information, know-how or trade secrets of others in their work for Tvardi, including incorporating such intellectual property into its product candidates, Tvardi may be subject to claims that it or these employees have misappropriated the intellectual property of a third party.

If Tvardi or any of its employees are accused of misappropriating the proprietary information, knowhow or trade secrets of a third party, Tvardi may be forced to defend such claims in litigation. If Tvardi is found to have misappropriated the intellectual property rights of a third party, Tvardi may be forced to pay monetary damages, sustain reputational damage, lose key personnel or lose valuable intellectual property rights. Further, it may become necessary for Tvardi to obtain a license from such third party to commercialize its product candidates. Such a license may not be available on commercially reasonable terms or at all. Any of the aforementioned could materially affect the commercialization of Tvardi's product candidates. Even if Tvardi is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If Tvardi is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.

Tvardi considers proprietary trade secrets or confidential know-how and unpatented know-how to be important to its business. Tvardi may rely on trade secrets or confidential know-how to protect its technology, especially where patent protection is believed by Tvardi to be of limited value. Tvardi expects to rely on third parties for future manufacturing of its product candidates. Tvardi also expects to collaborate with third parties on the development of its product candidates. As a result of the aforementioned collaborations, Tvardi must, at times, share trade secrets with its collaborators. Tvardi may also conduct joint research and development programs that may require Tvardi to share trade secrets under the terms of its research and development partnerships or similar agreements.

Trade secrets or confidential know-how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, Tvardi's policy is to require its employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with Tvardi prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose Tvardi's confidential information, including its trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose

Tvardi's confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by Tvardi's competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that Tvardi's proprietary position is based, in part, on its know-how and trade secrets, a competitor's discovery of its trade secrets or other unauthorized use or disclosure would impair its competitive position and may have an adverse effect on its business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction.

In addition, these agreements typically restrict the ability of Tvardi's advisors, employees, third-party contractors and consultants to publish data potentially relating to its trade secrets, although its agreements may contain certain limited publication rights. Despite Tvardi's efforts to protect its trade secrets, its competitors may discover its trade secrets, either through breach of its agreements with third parties, independent development or publication of information by any of its third-party collaborators. A competitor's discovery of Tvardi's trade secrets would impair its competitive position and have an adverse impact on its business.

Furthermore, courts outside the United States are sometimes less willing to protect trade secrets. If Tvardi chooses to go to court to stop a third party from using any of its trade secrets, Tvardi may incur substantial costs. These lawsuits may consume Tvardi's time and other resources even if Tvardi is successful. Although Tvardi takes steps to protect its proprietary information and trade secrets, including through contractual means with its employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to Tvardi's trade secrets or disclose its technology.

Tvardi may need to acquire or license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of Tvardi's product candidates. It may be necessary for Tvardi to use the patented or proprietary technology of one or more third parties to commercialize its current and future product candidates.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that Tvardi may consider attractive. These established companies may have a competitive advantage over Tvardi due to their size, cash resources and greater clinical development. If Tvardi is unable to acquire such intellectual property outright or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, its ability to commercialize its product candidates, if approved, would likely be delayed or Tvardi may have to abandon development of that product candidate or program and its business and financial condition could suffer.

If Tvardi in-licenses additional product candidates in the future, it might become dependent on proprietary rights from third parties with respect to those product candidates. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to Tvardi's ability to develop and commercialize any product candidate subject to such licenses. Even if Tvardi is able to in-license any such necessary intellectual property, it could be on nonexclusive terms, including with respect to the use, field or territory of the licensed intellectual property, thereby giving Tvardi's competitors and other third parties access to the same intellectual property licensed to Tvardi. In-licensing intellectual property rights could require Tvardi to make substantial licensing and royalty payments. For example, upon commercialization of certain of its product candidates, if ever, Tvardi is obligated to make certain royalty payments to each of BCM and certain of its founders. Patents licensed to Tvardi's licensors or another licensee or in administrative proceedings. If any in-licensed patents are invalidated or held unenforceable, Tvardi may not be able to prevent competitors or other third parties from developing and commercializing competitive products.

Disputes may also arise between Tvardi and its current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- Tvardi's financial or other obligations under the license agreement;
- whether and the extent to which Tvardi's technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- Tvardi's right to sublicense patent and other rights to third parties under collaborative development relationships;
- Tvardi's diligence obligations with respect to the use of licensed technology in relation to its development and commercialization of its product candidates and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Tvardi's licensors and Tvardi and its partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that Tvardi has licensed or in the future have licensed prevent or impair Tvardi's ability to maintain its current licensing arrangements on acceptable terms, Tvardi may be unable to successfully develop and commercialize the affected product candidates.

The risks described elsewhere pertaining to Tvardi's intellectual property rights also apply to the intellectual property rights that Tvardi may own or in-license now or in the future, and any failure by Tvardi or its licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on its business. In some cases Tvardi may not have control over the prosecution, maintenance or enforcement of the patents that it licenses, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and potential future licensors may fail to take the steps that it believes are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

If Tvardi's trademarks and trade names are not adequately protected, then Tvardi may not be able to build name recognition in its trademarks of interest and its business may be adversely affected.

Tvardi's trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Tvardi relies on both registration and common law protection for its trademarks. As a means to enforce its trademark rights and prevent infringement, Tvardi may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of Tvardi's size. Tvardi may not be able to protect its rights to these trademarks and trade names or may be forced to stop using these names, which it needs for name recognition by potential partners or customers in its markets of interest. At times, competitors may adopt trade names or trademarks similar to Tvardi's, thereby impeding its ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of Tvardi's registered or unregistered trademarks or trade names. Over the long term, if Tvardi is unable to establish name recognition based on its trademarks and trade names, then Tvardi may not be able to compete effectively, and its business may be adversely affected. During trademark registration proceedings, Tvardi may receive rejections. Although Tvardi would be given an opportunity to respond to those rejections, Tvardi may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against Tvardi's trademarks, and its trademarks may not survive such proceedings. Moreover, any name Tvardi proposes to use for its products in the United States must be approved by the FDA, regardless of whether Tvardi has registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of Tvardi's proposed product names, Tvardi may be

required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If Tvardi is unable to establish name recognition based on its trademarks and trade names, Tvardi may not be able to compete effectively, and its business may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to its business.

The degree of future protection afforded by Tvardi's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect its business, or permit Tvardi to maintain its competitive advantage. The following examples are illustrative:

- others may be able to make products that are competitive to Tvardi's product candidates or any of its product candidates but that are not covered by the claims of its patent portfolio;
- others may independently develop similar or alternative technologies or otherwise circumvent any of Tvardi's technologies without infringing its patent portfolio;
- Tvardi or any of its collaborators might not have been the first to invent the inventions covered by its patent portfolio;
- Tvardi or any of its collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that it or they own or have obtained a license, or will own or will have obtained a license;
- it is possible that Tvardi's own and in-licensed pending patent applications or those that Tvardi may file in the future will not lead to issued patents;
- others may have access to the same intellectual property rights licensed to Tvardi on a non-exclusive basis in the future;
- issued patents that Tvardi owns or in-licensed may not provide Tvardi with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by its competitors;
- Tvardi's competitors might conduct research and development activities in countries where it does
 not have patent rights, or in countries where research and development safe harbor laws exist, and
 then use the information learned from such activities to develop competitive products for sale in its
 major commercial markets;
- ownership of Tvardi's patent portfolio may be challenged by third parties;
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on its business;
- patent enforcement is expensive and time-consuming and difficult to predict; thus, Tvardi may not be able to enforce any of its patents against a competitor; and
- Tvardi may choose not to file a patent application for certain inventions, instead choosing to rely on trade secret protection, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm Tvardi's business, financial condition, results of operations and prospects.

Risks Related to Tvardi's Reliance on Third Parties

Tvardi relies on third parties to conduct certain aspects of its preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, Tvardi may not be able to obtain regulatory approval of or commercialize any potential product candidates.

Tvardi depends upon third parties to conduct certain aspects of its preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. Tvardi

expects to have to negotiate budgets and contracts with such third parties, which may result in delays to its development timelines and increased costs.

Tvardi will rely especially heavily on third parties over the course of its clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, Tvardi is responsible for ensuring that each of its clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and Tvardi's reliance on third parties does not relieve Tvardi of its regulatory responsibilities. Tvardi and these third parties are required to comply with Good Clinical Practice (GCP), requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, clinical investigators and clinical trial sites. If Tvardi or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in its clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Tvardi to suspend or terminate these clinical trials or perform additional preclinical studies or clinical trials before approving its marketing applications. Tvardi cannot be certain that, upon inspection, such regulatory authorities will determine that any of its clinical trials comply with the GCP requirements.

Tvardi's failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require Tvardi to repeat clinical trials, which would delay the regulatory approval process. Moreover, Tvardi's business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of Tvardi's preclinical studies or clinical trials will not be its employees and, except for remedies that may be available to Tvardi under its agreements with such third parties, it cannot control whether or not they devote sufficient time and resources to its preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including Tvardi's competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on its behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to Tvardi's protocols or regulatory requirements or for other reasons or if due to federal or state orders or absenteeism due to global conditions, including health epidemics and pandemics, they are unable to meet their contractual and regulatory obligations, Tvardi's development timelines, including clinical development timelines, may be extended, delayed or terminated and Tvardi may not be able to complete development of, obtain regulatory approval of or successfully commercialize its product candidates. As a result, Tvardi's financial results and the commercial prospects for its product candidates would be harmed, its costs could increase and its ability to generate revenue could be delayed.

If any of Tvardi's relationships with these third-party CROs or others terminate, Tvardi may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact Tvardi's ability to meet its desired development timelines. Though Tvardi carefully manages its relationships with its CROs, there can be no assurance that it will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on its business, financial condition and prospects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause Tvardi's product candidates to perform

differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Tvardi's product candidates and jeopardize Tvardi's ability to commercialize its product candidates and generate revenue.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if Tvardi obtains marketing approval for any of its product candidates, there is no assurance that its manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If Tvardi's manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, its development and commercialization efforts would be impaired, which would have an adverse effect on its business, financial condition, results of operations and growth prospects.

Because Tvardi relies on third-party manufacturing and supply vendors, including single-source vendors and vendors in foreign jurisdictions, its supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

Tvardi relies on third-party contract manufacturers to manufacture its product candidates for preclinical studies and clinical trials. Tvardi does not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that its preclinical and clinical development product supplies will not be limited, interrupted or of satisfactory quality or continue to be available at acceptable prices, including due to challenging macroeconomic conditions. Because Tvardi is dependent on limited third-party suppliers and manufacturers for the manufacturing of its product candidates, so long as it remains dependent on them, the loss of any of these suppliers and manufacturers, or any difficulties encountered by these suppliers and manufacturers in the production of its product candidates, could materially delay the conduct of its clinical trials and adversely impact its business.

In addition, Tvardi relies on vendors in foreign jurisdictions for its clinical drug supply for TTI-101, TTI-109 and future drug formulations. If this supply is interrupted for business or geopolitical reasons, the development of TTI-101 or TTI-109 could be materially delayed. In particular, any replacement of Tvardi's manufacturers could require significant time, effort and expertise because there may be a limited number of qualified replacements and the process to transfer technology and initiate manufacturing is complex and time consuming. Moreover, there is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. It is possible further tariffs may be imposed that could affect imports of APIs used in Tvardi's product candidates or any other potential future product candidates, or its business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in its current or any other potential future product candidates.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of Tvardi's manufacturers fails to comply with such requirements or to perform its obligations to Tvardi in relation to quality, timing or otherwise, or if its supply of components or other materials becomes limited or interrupted for other reasons, Tvardi may be forced to manufacture the materials itself, for which it currently does not have the capabilities or resources, or enter into an agreement with another third party, which Tvardi may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture Tvardi's product candidates may be unique or proprietary to the original manufacturer and Tvardi may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase Tvardi's reliance on such manufacturer or require Tvardi to obtain a license from such manufacturer in order to have another third party manufacture its product candidates. If Tvardi is required to change manufacturers for any reason, it will be required to verify that the new manufacturer maintains

facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect Tvardi's ability to develop product candidates in a timely manner or within budget.

Tvardi expects to continue to rely on third-party manufacturers for commercial supply of drug product, if it receives regulatory approval for TTI-101, TTI-109 or any other product candidate. To the extent that Tvardi has existing, or enters into future, manufacturing arrangements with third parties, it will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If Tvardi is unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, Tvardi may not be able to develop and commercialize its product candidates successfully. Tvardi's or a third party's failure to execute on its manufacturing requirements and comply with cGMP could adversely affect its business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or Tvardi's manufacturing facilities to additional inspections by regulatory authorities;
- · requirements to cease distribution or to recall batches of Tvardi's product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for Tvardi's products.

Failure to maintain cGMP can result in a contractor receiving FDA sanctions, which can impact Tvardi's ability to operate or lead to delays in any clinical development programs. Tvardi believes that its current fill and finish contractor is operating in accordance with cGMP, but it can give no assurance that FDA or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect its business.

If Tvardi is unable to enter into new collaborations, or if these collaborations are not successful, its business could be adversely affected.

A part of Tvardi's strategy is to selectively evaluate partnerships in indications and geographies where it believes partners can add significant commercial and/or development capabilities. Further, Tvardi has limited capabilities for product development and does not yet have any capability for commercialization. Accordingly, Tvardi may in the future enter into collaborations with other companies to provide Tvardi with important technologies and funding for its programs and technology.

Any future collaborations Tvardi enters into may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Tvardi's products and product candidates if the collaborators believe that

the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than Tvardi's;

- product candidates discovered in collaboration with Tvardi may be viewed by its collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of Tvardi's product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of Tvardi's product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide Tvardi with timely and accurate information regarding development
 progress and activity under any future license agreement, which could adversely impact Tvardi's
 ability to report progress to Tvardi's investors and otherwise plan development of Tvardi's product
 candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract
 interpretation or the preferred course of development, might cause delays or terminations of the
 research, development or commercialization of product candidates, might lead to additional
 responsibilities for Tvardi with respect to product candidates, or might result in litigation or
 arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend Tvardi's intellectual property rights or may use Tvardi's proprietary information in such a way as to invite litigation that could jeopardize or invalidate Tvardi's intellectual property or proprietary information or expose Tvardi to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose Tvardi to litigation and potential liability;
- if a collaborator of Tvardi is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by Tvardi; and
- collaborations may be terminated by the collaborator, and, if terminated, Tvardi could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If collaborations Tvardi enters into do not result in the successful discovery, development and commercialization of product candidates or if a future collaborator terminates its agreement with Tvardi, Tvardi may not receive any research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Report also apply to the activities of Tvardi's therapeutic collaborators.

Tvardi faces significant competition in seeking appropriate collaborators for its product candidates, and the negotiation process is time-consuming and complex. In order for Tvardi to successfully establish a collaboration for one or more of its product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that Tvardi is seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Tvardi's ability to reach a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If Tvardi is unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, Tvardi may have to curtail the development of a product candidate, reduce or delay its development program or one or more of Tvardi's other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase Tvardi's expenditures and undertake development or commercialization activities at Tvardi's own expense. If Tvardi elects to increase its expenditures to fund development or commercialization activities on its own, Tvardi may need to obtain additional expertise and additional capital, which may not be available to Tvardi on acceptable terms, or at all. If Tvardi fails to enter into future collaborations or does not have sufficient funds or expertise to undertake the necessary development and commercialization activities, Tvardi may not be able to further develop its product candidates, bring them to market and generate revenue from sales of drugs or continue to develop its technology, and its business may be materially and adversely affected. Even if Tvardi is successful in its efforts to establish new strategic collaborations, the terms that it agrees upon may not be favorable to it, and it may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to Tvardi's product candidates could delay the development and commercialization of its product candidates and reduce their competitiveness even if they reach the market.

The operations of Tvardi's suppliers, some of which are located outside of the United States, are subject to additional risks that are beyond Tvardi's control and that could harm its business, financial condition, results of operations and prospects.

Currently, some of Tvardi's suppliers are located outside of the United States. As a result of its global suppliers, Tvardi is subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which Tvardi's products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where Tvardi's suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing Tvardi's suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA, EMA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional or local public health crises or other emergencies or natural disasters;
- · disruptions or delays in shipments; and
- changes in local economic conditions in countries where Tvardi's manufacturers or suppliers are located.

These and other factors beyond Tvardi's control could interrupt Tvardi's suppliers' production, influence the ability of Tvardi's suppliers to export its clinical supplies cost-effectively or at all, and inhibit Tvardi's suppliers' ability to procure certain materials, any of which could harm its business, financial condition, results of operations and prospects.

Tvardi's suppliers and any future collaborators may need assurances that its financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with Tvardi.

Tvardi's suppliers and any future collaborators may need assurances that its financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with Tvardi. If these parties are not satisfied with its financial resources and stability, it could have a material adverse effect on Tvardi's ability to develop its drug candidates, enter into licenses or other agreements and on its business, financial condition or results of operations.

Risks Related to Managing Tvardi's Business and Operations

Tvardi may encounter difficulties in managing its growth, which could adversely affect its operations.

As of September 30, 2024, Tvardi had 12 full-time employees. As Tvardi's clinical development and commercialization plans and strategies develop, it will need to expand its managerial, clinical, regulatory,



sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for Tvardi. As Tvardi's operations expand, Tvardi expects that it will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Tvardi's future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing Tvardi's development and commercialization efforts effectively, including the clinical and FDA review process for TTI-101, TTI-109 and any other product candidates, while complying with Tvardi's contractual obligations to contractors and other third parties; and
- improving Tvardi's operational, financial and management controls, reporting systems and procedures.

Tvardi's ability to continue to develop and, if approved, commercialize its product candidates will depend, in part, on its ability to effectively manage its future growth. Tvardi's management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If Tvardi is not able to effectively expand its organization by hiring new employees and expanding its groups of consultants and contractors, Tvardi may not be able to successfully implement the tasks necessary to further develop and commercialize TTI-101, TTI-109 or any other product candidates and, accordingly, may not achieve its research, development and commercialization goals.

Tvardi may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm its business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either its business or the acquired businesses.

Tvardi currently has no marketing and sales organization and has no experience as a company in commercializing products, and Tvardi may have to invest significant resources to develop these capabilities. If Tvardi is unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell its products, Tvardi may not be able to generate product revenue.

Tyardi has no internal sales, marketing or distribution capabilities, nor has it commercialized a product. If any of Tvardi's product candidates ultimately receives regulatory approval, Tvardi expects to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. Tvardi has no prior experience as a company in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including its ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of Tvardi's internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. Tvardi may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment its own sales force and distribution systems or in lieu of its own sales force and distribution systems. Tvardi may not be able to enter into collaborations or hire consultants or external service providers to assist Tvardi in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, its product revenues and its profitability, if any, may be lower if it relies on third parties for these functions than if it were to market, sell and distribute any products that it develops itself. Tvardi likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market its products effectively. If Tvardi is not successful in commercializing its products, either on its own or through arrangements with one or more third parties, Tvardi may not be able to generate any future product revenue and it would incur significant additional losses.

If Tvardi loses key management personnel, or if Tvardi fails to recruit additional highly skilled personnel, its ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make Tvardi less competitive.

Tvardi's ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel.

Tvardi is highly dependent on its management, scientific and medical personnel, including key members of its senior management and executive team. Although Tvardi has employment agreements with its key employees, these employment agreements provide for at-will employment, which means that any of its employees could leave its employment at any time, with or without notice. Tvardi does not maintain "key person" insurance for any of its executives or other employees. The loss of the services of any of Tvardi's executive officers, other key employees and other scientific and medical advisors, and its inability to find suitable replacements could result in delays in product development and harm its business. Competition for skilled personnel in its market is intense and may limit its ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain in Tvardi, in addition to salary and cash incentives, Tvardi has provided equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in its stock price that are beyond its control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite Tvardi's efforts to retain valuable employees, members of its management, scientific and development teams may terminate their employment with Tvardi on short notice. Tvardi's key employees are at-will employees, which means that any of its employees could leave its employment at any time, with or without notice. Tvardi does not maintain "key person" insurance policies on the lives of these individuals or the lives of any of its other employees. Tvardi's success also depends on its ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel.

Tvardi's employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Tvardi is exposed to the risk of employee fraud or other illegal activity by its employees, independent contractors, consultants, commercial partners, collaborators and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards Tvardi has established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to Tvardi. If Tvardi obtains FDA approval of any of its product candidates and begins commercializing those products in the United States, its potential exposure under such laws will increase significantly, and its costs associated with compliance with such laws will also increase. These laws may impact, among other things, its current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. It is not always possible to identify and deter misconduct by Tvardi's employees, independent contractors, consultants, commercial partners and vendors, and the precautions Tvardi takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Tvardi from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against Tvardi and Tvardi is not successful in defending itself or asserting its rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if Tvardi becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of its operations.

Tvardi or the third parties upon whom it depends may be adversely affected by natural disasters, and its business continuity and disaster recovery plans may not adequately protect Tvardi from a serious disaster.

Tvardi's operations are located in its facilities in Sugar Land, Texas and it works with third-party CROs and CDMOs globally. Any unplanned event, such as flood, fire, explosion, tornadoes, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in Tvardi being unable to fully utilize its facilities, or the manufacturing facilities of its third-party contract manufacturers, may have a material and adverse effect on its ability to operate its business and have significant negative consequences on its financial and operating conditions. Loss



of access to these facilities may result in increased costs, delays in the development of Tvardi's product candidates or interruption of its business operations. Natural disasters could further disrupt its operations and have a material and adverse effect on its business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented Tvardi from using all or a significant portion of its headquarters, that damaged critical infrastructure, such as its research facilities or the manufacturing facilities of its third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for Tvardi to continue its business for a substantial period of time.

As part of its risk management policy, Tvardi maintains insurance coverage at levels that it believes are appropriate for its business. However, in the event of an accident or incident at these facilities, Tvardi cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If Tvardi's facilities, or the manufacturing facilities of Tvardi's third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of Tvardi's research and development programs may be harmed.

General Risk Factors

Tvardi has identified material weaknesses in its internal control over financial reporting. If it fails to remediate these material weaknesses, or if it experiences additional material weaknesses in the future or otherwise fails to maintain effective internal control over financial reporting in the future, Tvardi may not be able to accurately or timely report its financial condition or results of operations, which may adversely affect investor confidence in Tvardi and, as a result, the value of its common stock following the completion of the Merger.

As of December 31, 2023 and 2022, Tvardi had limited accounting personnel and other resources to address its internal control over financial reporting. In connection with the preparation of Tvardi's financial statements for the years ended December 31, 2023 and 2022, material weaknesses were identified in the design and operating effectiveness of Tvardi's internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

These material weaknesses are related to the fact that Tvardi lacked a sufficient number of professionals to consistently establish appropriate authorities and responsibilities in pursuit of Tvardi's financial reporting objectives. The lack of sufficient number of finance and accounting professionals contributed to the inadequate design and Tvardi's inability to maintain effective controls over the segregation of duties related to journal entries. In addition, Tvardi identified a material weakness in its financial reporting related to inadequate review of financial statements and disclosures.

However, these material weaknesses could result in a misstatement of substantially all of Tvardi's accounts or disclosures that would result in a material misstatement of its annual or interim financial statements that would not be prevented or detected.

To remediate the material weaknesses, Tvardi plans to implement formal risk assessment processes and procedures and design sufficient controls to remediate these weaknesses. Tvardi intends to hire additional experienced accounting and financial reporting personnel, formalize design and implementation of internal controls over the financial reporting process, including general controls over information systems. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures Tvardi has taken to date, and is continuing to design and implement, may not be sufficient to remediate the material weaknesses Tvardi has identified or avoid potential future material weaknesses. If the steps Tvardi takes do not correct these material weaknesses in a timely manner, Tvardi will be unable to conclude that it maintains effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of Tvardi's financial statements would not be prevented or detected on a timely basis.

If Tvardi fails to remediate its existing material weaknesses or identify new material weaknesses in its internal control over financial reporting, if Tvardi is unable to comply with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if Tvardi is unable to conclude that its internal control over financial reporting is effective, or if its independent registered public accounting firm is unable to conclude that its internal control over financial report its financial control over financial, which may adversely affect investor confidence in Tvardi and the market price of its common stock following the completion of the Merger could be negatively affected. As a result, Tvardi could also become subject to investigations by the Nasdaq Capital Market, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm its reputation and financial condition or divert financial and management resources from its regular business activities.

Tvardi's disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public reporting company post-Merger, Tvardi will be subject to certain reporting requirements of the Exchange Act. Tvardi's disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by Tvardi in reports Tvardi files or submits under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Tvardi believes that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in Tvardi's control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Tvardi's issuance of additional capital stock in connection with financings, acquisitions, investments, its stock incentive plans or otherwise will dilute all other stockholders.

Tvardi expects to issue additional capital stock in the future that will result in dilution to all other stockholders. Tvardi expects to grant equity awards to employees, directors, and consultants under its stock incentive plans. As part of its business strategy, Tvardi may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of Tvardi's common stock to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about Tvardi's business, its stock price and trading volume could decline.

The trading market for Tvardi's common stock will depend in part on the research and reports that securities or industry analysts publish about Tvardi or its business. If one or more of the analysts who covers Tvardi downgrades its stock or publishes inaccurate or unfavorable research about its business, its stock price may decline. If one or more of these analysts ceases coverage of its company or fails to publish reports on Tvardi regularly, demand for its stock could decrease, which might cause its stock price and trading volume to decline.

Tvardi will incur significant increased costs as a result of operating as a public company, and its management is required to devote substantial time to new compliance initiatives.

As a public company post-Merger, Tvardi will incur significant legal, accounting and other expenses. Tvardi will be subject to the reporting requirements of the Exchange Act, which requires, among other things, that Tvardi file with the SEC annual, quarterly and current reports with respect to its business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Stock Market (Nasdaq), to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which Tvardi operates its business in ways it cannot currently anticipate.

Tvardi expects the rules and regulations applicable to public companies to substantially increase its legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of Tvardi's management and personnel from other business concerns, they could have an adverse effect on its business. The increased costs will decrease Tvardi's net income or increase Tvardi's net loss and may require Tvardi to reduce costs in other areas of its business or increase the prices of its products or services. For example, Tvardi expects these rules and regulations to make it more difficult and more expensive for Tvardi to obtain director and officer liability insurance and Tvardi may be required to incur substantial costs to maintain the same or similar coverage. Tvardi cannot predict or estimate the amount or timing of additional costs Tvardi may incur to respond to these requirements. The impact of these requirements could also make it more difficult for Tvardi to attract and retain qualified persons to serve on its board of directors, its board committees or as executive officers.

Tvardi is subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security. Tvardi's actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of its business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, Tvardi collects, receives, stores, processes, generates, uses, transfers, discloses, makes accessible, protects, secures, disposes of, transmits, and shares (collectively, process or processing) certain sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data it collects about clinical trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). The global data protection landscape is rapidly evolving and Tvardi is or may become subject to numerous data privacy and security obligations, such as various state, federal and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations governing the collection use, disclosure, retention, and security of personal information or otherwise relating to data privacy and security, including as relates to information that Tvardi may collect in connection with clinical trials in the United States and abroad.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and Tvardi cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on its business. This evolution may create uncertainty in Tvardi's business, affect its ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in its contracts, result in liability or impose additional costs on Tvardi. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by Tvardi to comply with federal, state or foreign laws or regulations, its internal policies and procedures or its contracts governing the processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to Tvardi's reputation, any of which could have a material adverse effect on its business, results of operation, and financial condition.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, data privacy laws, and other similar laws. For example, HIPAA, as amended by HITECH (collectively, HIPAA), imposes among other things, certain requirements relating to the privacy, security, transmission, and breach of individually identifiable health information. Tvardi may obtain health information from third parties (including research institutions from which it obtains clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, Tvardi could be subject to significant penalties if it violates HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for Tvardi and its future customers and strategic partners. For example, the California Consumer Privacy Act (CCPA), went into effect on January 1, 2020 and applies to the personal information of California consumers, business representatives, and employees, and increases the privacy and security obligations of entities handling certain personal information, including among other things, requiring businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties of up to \$7,500 per violation as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing the likelihood of, and risks associated with, data breach litigation. Although the law includes limited exceptions, including for certain information collected as part of clinical trials, the CCPA may impact Tvardi's processing of personal information and increases its compliance costs. Additionally, the California Privacy Rights Act of 2020 (CPRA) generally went into effect on January 1, 2023, and significantly expands the CCPA, such as granting additional rights to California residents, including the right to correct personal information and additional opt-out rights for certain uses and sensitive data, and imposes additional data protection obligations on covered businesses, including additional limitations on data uses and new audit requirements for higher risk data. The CPRA also established a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Other states, such as Virginia, Indiana, Oregon, Texas, Tennessee, Montana, Iowa, Delaware, Connecticut, Utah and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these state privacy laws, like the CCPA, also exempt some data processed in the context of clinical trials, these laws could have potentially conflicting requirements that further complicate compliance efforts, and increase legal risk and compliance costs for Tvardi and the third parties upon whom it relies. In the event that Tvardi is subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect its financial condition. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on Tvardi. In addition to data privacy and security laws, Tvardi is also bound by other contractual obligations related to data privacy and security, and its efforts to comply with such obligations may not be successful

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to Tvardi's business, or restrict its collection, use, storage or processing of personal information, which may increase its compliance expenses and make its business more costly or less efficient to conduct. In addition, any such changes could compromise Tvardi's ability to develop an adequate marketing strategy and pursue its growth strategy effectively or even prevent Tvardi from providing certain products in jurisdictions in which it currently operates and in which Tvardi may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect its business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by Tvardi, one of its CROs, CMOs, partners or another third party, could adversely affect its business, financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding Tyardi's privacy and security practices; requirements that it provides notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against Tvardi's licenses to do business; reputational damage; and injunctive relief. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase its costs of doing business. In this regard, Tvardi expects that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EEA and other jurisdictions, and it cannot determine the impact such future laws, regulations and standards may have on its business.

Any actual or perceived failure by Tvardi or its third-party service providers to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or

codes of conduct, regulatory guidance, orders to which Tvardi may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect Tvardi's reputation, brand and business. Tvardi may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that Tvardi stores or handles as part of operating its business. Any of these events could adversely affect Tvardi's reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in its business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize its products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to its business model or operations.

Tvardi cannot assure you that its CROs, CMOs or other third-party service providers with access to its or its suppliers', manufacturers', clinical trial participants' and employees' sensitive information in relation to which Tvardi is responsible will not breach contractual obligations imposed by Tvardi, or that they will not experience data security incidents, which could have a corresponding effect on its business, including putting Tvardi in breach of its obligations under privacy laws and regulations and/or which could in turn adversely affect its business, financial condition, results of operations and prospects. Tvardi cannot assure you that its contractual measures and its own privacy and security-related safeguards will protect Tvardi from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect its business, financial condition, results of operations and prospects.

Tvardi also publicly posts its privacy policies and practices concerning its collection, use, disclosure and other processing of the personal information provided to Tvardi. Although it endeavors to comply with its public statements and documentation, Tvardi may at times fail to do so or be perceived to have failed to do so. Tvardi's publication of its privacy policies and other statements it publishes that provide promises and assurances about privacy and security can subject Tvardi to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of its actual practices. Any actual or perceived failure by Tvardi to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause its customers to lose trust in Tvardi, any of which could adversely affect its business, financial condition, results of operations and prospects.

The successful assertion of one or more large claims against Tvardi that exceeds its available insurance coverage, or results in changes to its insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on its business. In addition, Tvardi cannot be sure that its existing insurance coverage will continue to be available on acceptable terms or that its insurers will not deny coverage as to any future claim.

Changes in U.S. tax law could adversely affect Tvardi's financial condition and results of operations.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect Tvardi or holders of its common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on its business, cash flow, financial condition or results of operations. Tvardi urges investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in its common stock.

Tvardi's information systems, or those of its collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of its product development programs.

Tvardi's information systems and those of its current and any future collaborators, other contractors or consultants and third-party suppliers (i.e., its supply chain) are vulnerable to damage from computer viruses,

unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Tvardi exercises little or no direct control over how these third parties operate their networks, which increases its vulnerability to problems with their systems. While Tvardi has not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in its information systems or those of Tvardi's collaborators, vendors, contractors or consultants, it could result in a disruption of its development programs and its business operations, whether due to a loss of Tvardi's trade secrets or other proprietary information or other similar disruptions, as well as reputational harm and adverse legal and regulatory consequences. For example, the loss of clinical trial data from future clinical trials could result in delays in Tvardi's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, Tvardi's data or applications, or inappropriate disclosure of confidential or proprietary information, it could incur liability, its competitive position could be harmed and the further development and commercialization of its product candidates could be delayed.

Tvardi is also subject to cybersecurity risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release, exposure or loss of information maintained in the information systems and networks of Tvardi's company and its vendors, including personal information of Tvardi's employees and clinical trial subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate Tvardi's systems or those of its vendors or fraudulently induce its personnel or the personnel of its vendors to disclose sensitive information in order to gain access to Tvardi's data and/or systems. Tvardi may experience threats to its data and systems, including malicious code and viruses, supply chain attacks, phishing and other cyberattacks. The number and complexity of these threats continue to increase over time. While Tvardi has not experienced, to date, a cybersecurity threat, including as a result of any previous cybersecurity incidents, that has materially affected or is reasonably likely to materially affect Tvardi, including its business strategy, results of operations or financial condition, it cannot guarantee that it will not experience such a threat or incident in the future. If a material breach of, or accidental or intentional loss of data from, Tvardi's information technology systems or those of its vendors occurs, the market perception of the effectiveness of its security measures could be harmed and Tvardi's reputation and credibility could be damaged, and Tvardi could be subject to adverse legal and regulatory consequences. Tvardi could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

In addition, Tvardi could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although Tvardi develops and maintains systems and controls designed to prevent these events from occurring, and Tvardi has a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite Tvardi's efforts, the possibility of these events occurring cannot be eliminated entirely. As Tvardi outsources more of its information systems to vendors, engage in more electronic transactions with payors and patients and rely more on cloud-based information systems, the related security risks will increase, and Tvardi will need to expend additional resources to protect its technology and information systems.

In addition, there can be no assurance that Tvardi's internal information technology systems or those of its third-party contractors, or its consultants' efforts to implement adequate security and control measures, will be sufficient to protect Tvardi against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks, which could result in financial, legal, business or reputational harm.

In addition, while Tvardi maintains insurance policies that may cover certain liabilities in connection with a cybersecurity incident, it cannot be certain that the insurance coverage will be adequate for liabilities actually incurred, that insurance will continue to be available to Tvardi on commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims that exceed available insurance coverage, or the occurrence of changes in insurance

policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on its business, including its financial condition, results of operations and reputation.

Unfavorable global economic conditions could adversely affect Tvardi's business, financial condition or results of operations.

Tvardi's results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of Tvardi's future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials costlier to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, due to factors including the effects of health epidemics and pandemics, such as COVID-19, geopolitical events, such as the Russian invasion of Ukraine, the Israel-Hamas conflict and related global escalation of geopolitical tensions, and inflationary pressures could result in a variety of risks to Tvardi's business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain its suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of the foregoing could harm its business and Tvardi cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect Tvardi's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems.

Since March 2023, several financial institutions have experienced failures and have been placed into receivership. In addition, if any of Tvardi's customers, suppliers or other parties with whom it conducts business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to Tvardi or to enter into new commercial arrangements requiring additional payments to Tvardi could be adversely affected. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, Federal Deposit Insurance Corporation (FDIC), and Federal Reserve Board have announced a program to provide up to \$25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although Tvardi assesses its banking and customer relationships as it believes necessary or appropriate, its access to funding sources and other credit arrangements in amounts adequate to finance or capitalize its current and projected future business operations could be significantly impaired by factors that affect Tvardi, the financial institutions with whom Tvardi has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which Tvardi has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on Tvardi's current and projected business operations and its financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- delayed or lost access to working capital sources and/or delays, inability or reductions in its ability to
 enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require Tvardi to maintain letters of credit or other credit support arrangements;
- · potential or actual breach of financial covenants in any credit agreements or credit arrangements; or
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for Tvardi to acquire financing on acceptable terms or at all.

Any decline in available funding or access to its cash and liquidity resources could, among other risks, adversely impact Tvardi's ability to meet its operating expenses, financial obligations or fulfill its other obligations, result in breaches of its financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on Tvardi's liquidity and its current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by Tvardi's customers or suppliers, which in turn, could have a material adverse effect on i current and/or projected business operations and results of operations and financial condition. For example, a supplier may determine that it will no longer deal with Tvardi as a customer. In addition, a supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on Tvardi, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any supplier bankruptcy or insolvency, or any breach or default by a supplier, or the loss of any significant supplier relationships, could result in material losses to Tvardi and may have a material adverse impact on its business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about Tvardi's clinical development programs and the diseases its therapeutics are being developed to treat, and Tvardi intends to utilize appropriate social media in connection with its commercialization efforts following approval of its product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to its business, resulting in potential regulatory actions against Tvardi, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that clinical trial enrollment may be adversely impacted, that Tvardi may fail to monitor and comply with applicable adverse event reporting obligations or that Tvardi may not be able to defend its business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what Tvardi may say about its product candidates. There is also a risk of inappropriate

disclosure of sensitive information or negative or inaccurate posts or comments about Tvardi on any social networking website. If any of these events were to occur or Tvardi otherwise fails to comply with applicable regulations, Tvardi could incur liability, face regulatory actions or incur other harm to its business.

Risks Related to the Combined Company

In determining whether you should approve the proposals contained in this proxy statement/prospectus, you should carefully read the following risk factors in addition to the risks described above.

The combined company will need to raise additional financing in the future to fund its operations, which may not be available to it on favorable terms or at all.

The combined company will require substantial additional funds to conduct the costly and timeconsuming clinical efficacy trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of TTI-101 and future product candidates. The combined company's future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; proceeds from collaboration agreements or other strategic transactions; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit the combined company's ability to achieve its business objectives. If the combined company raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely the rights of its common stockholders. Further, to the extent that the combined company raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, its stockholder's ownership interest in the combined company will be diluted. In addition, any debt financing may subject the combined company to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the combined company raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, the combined company may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. Even if the combined company were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to the combined company or its stockholders.

The market price of the combined company's common stock is expected to be volatile, and the market price of the common stock may drop following the Merger.

The market price of the combined company's common stock following the Merger could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the combined company's common stock to fluctuate include:

- the ability of the combined company to obtain regulatory approvals for its product candidates, and delays or failures to obtain such approvals;
- failure of any of the combined company's product candidates, if approved, to achieve commercial success;
- failure by the combined company to maintain its existing third-party license and supply agreements;
- failure by the combined company or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to the combined company's product candidates;
- any inability to obtain adequate supply of the combined company's product candidates or the inability to do so at acceptable prices;



- · adverse regulatory authority decisions;
- introduction of new products, services or technologies by the combined company's competitors;
- failure to meet or exceed financial and development projections the combined company may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by the combined company or its competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and the combined company's ability to obtain patent protection for its technologies;
- · additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the combined company's business, or if they issue an adverse or misleading opinion regarding its business and stock;
- · changes in the market valuations of similar companies;
- · general market or macroeconomic conditions;
- sales of its common stock by the combined company or its stockholders in the future;
- trading volume of the combined company's common stock;
- failure to maintain compliance with the listing requirements of The Nasdaq Capital Market;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of the combined company;
- · changes in the structure of health care payment systems; and
- period-to-period fluctuations in the combined company's financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company's profitability and reputation.

Additionally, a decrease in the stock price of the combined company may cause the combined company's common stock to no longer satisfy the continued listing standards of Nasdaq. If the combined company is not able to maintain the requirements for listing on Nasdaq, it could be delisted, which could have a materially adverse effect on its ability to raise additional funds as well as the price and liquidity of its common stock.

The combined company will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies.

The combined company will incur significant legal, accounting and other expenses that Tvardi did not incur as a private company, including costs associated with public company reporting requirements.

The combined company will also incur costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC as well as the Nasdaq rules. These laws, rules and regulations are expected to increase the combined company's legal and financial compliance costs and to make some activities more time consuming and costly. For example, the combined company's management team will include executive officers of Tvardi prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These laws, rules and regulations also may make it difficult and expensive for the combined company to obtain directors' and officers' liability insurance. As a result, it may be more difficult for the combined company to attract and retain qualified individuals to serve on the Combined Company Board or as executive officers of the combined company, which may adversely affect investor confidence in the combined company and could cause the combined company's business or stock price to suffer.

Anti-takeover provisions in the combined company's charter documents and under Delaware law could make an acquisition of the combined company more difficult and may prevent attempts by the combined company stockholders to replace or remove the combined company management.

Provisions in the combined company's certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because the combined company will be incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding combined company voting stock from merging or combining with the combined company. Although Cara and Tvardi believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with the combined company's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the combined company's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

The amended and restated certificate of incorporation of the combined company will provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between the combined company and its stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with the combined company or its directors, officers or other employees, and could make it more costly for stockholders to bring a claim against the combined company.

The amended and restated certificate of incorporation and amended and restated bylaws of the combined company will be the amended and restated certificate of incorporation and amended and restated bylaws of Cara, which provide, among other things, that that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) generally will be the exclusive forum for any derivative action or proceeding brought on the combined company's behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against the combined company arising pursuant to the DGCL, the combined company's amended and restated bylaws, or any action asserting a claim against the combined company that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, the amended and restated certificate of incorporation and the amended and restated bylaws of the combined company will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. However, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims, and investors cannot waive compliance with

the federal laws and rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, the combined company would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of its amended and restated certificate of incorporation and amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there is uncertainty that the provision would be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in the combined company's amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, the combined company may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm its business, financial condition, results of operations, and prospects. This exclusive forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the combined company or its directors, officers or other employees or stockholders, which may discourage such lawsuits against the combined company and its directors, officers and other employees and stockholders. Alternatively, if a court were to find the choice of forum provision contained in the combined company's amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, the combined company may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect its business, financial condition and results of operations.

Cara and Tvardi do not anticipate that the combined company will pay any cash dividends in the foreseeable future.

The current expectation is that the combined company will retain its future earnings, if any, to fund the development and growth of the combined company's business. As a result, capital appreciation, if any, of the common stock of the combined company will be its stockholders' sole source of gain, if any, for the foreseeable future.

An active trading market for the combined company's common stock may not develop and its stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for Tvardi's common stock. An active trading market for the combined company's shares of common stock may never develop or be sustained. If an active market for its common stock does not develop or is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause the combined company's stock price to decline.

If existing stockholders of Cara and Tvardi sell, or indicate an intention to sell, substantial amounts of the combined company's common stock in the public market after legal restrictions on resale discussed in this proxy statement/prospectus lapse, the trading price of the common stock of the combined company could decline. Neither Cara nor Tvardi is able to predict the effect that sales may have on the prevailing market price of the combined company's common stock.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the combined company, its business or its market, its stock price and trading volume could decline.

The trading market for the combined company's common stock will be influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect not to provide research coverage of the combined company's common stock after the completion of the Merger, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, the combined company will not have any control over the analysts, or the content and opinions included in their reports. The price of the combined company's

common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of the combined company or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

The unaudited pro forma condensed combined financial statements included in this proxy statement/prospectus are presented for illustrative purposes only and may not be an indication of the combined company's financial condition or results of operations following the completion of the Merger.

The unaudited pro forma condensed combined financial statements contained in this proxy statement/ prospectus are presented for illustrative purposes only and may not be an indication of the combined company's financial condition or results of operations following the Merger for several reasons. The unaudited pro forma condensed combined financial statements have been derived from the historical audited financial statements of Cara and Tvardi for the year ended December 31, 2023 and the unaudited interim financial statements of Cara and Tvardi for the nine months ended September 30, 2024 and certain adjustments and assumptions have been made regarding the combined company after giving effect to the Merger. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with accuracy. Moreover, the unaudited pro forma condensed combined financial statements do not reflect all costs that are expected to be incurred by the combined company in connection with the Merger. For example, the impact of any incremental costs incurred in integrating the two companies is not reflected in the unaudited pro forma condensed combined financial statements. As a result, the actual financial condition of the combined company following the Merger may not be consistent with, or evident from, these unaudited pro forma condensed combined financial statements. The assumptions used in preparing the unaudited pro forma condensed combined financial statements may not prove to be accurate, and other factors may affect the combined company's financial condition following the Merger. For more information, please see the section titled "Unaudited Pro Forma Condensed Combined Financial Statements" in this proxy statement/prospectus.

If the combined company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

The combined company will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that the combined company maintain effective disclosure controls and procedures and internal control over financial reporting. The combined company must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, Tvardi has never been required to test its internal controls within a specified period. This will require that the combined company incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. The combined company may experience difficulty in meeting these reporting requirements in a timely manner.

The combined company may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its financial statements. The combined company's internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If the combined company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, the combined company may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

If the combined company fails to attract and retain management and other key personnel, it may be unable to continue to successfully develop or commercialize its product candidates or otherwise implement its business plan.

The combined company's ability to compete in the highly competitive pharmaceuticals industry depends on its ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. The combined company will be highly dependent on its management and scientific personnel. The loss of the services of any of these individuals could impede, delay, or prevent the successful development of the combined company's product pipeline, completion of its planned clinical trials, commercialization of its product candidates or in-licensing or acquisition of new assets and could impact negatively its ability to implement successfully its business plan. If the combined company loses the services of any of these individuals, it might not be able to find suitable replacements on a timely basis or at all, and its business could be harmed as a result. The combined company might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

The combined company is expected to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in its common stock being less attractive to investors.

Following the Merger, the combined company is expected to have a public float of less than \$250 million and therefore will qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, the combined company will be able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in its SEC filings. Decreased disclosures in the combined company's SEC filings due to its status as a smaller reporting company may make it harder for investors to analyze its results of operations and financial prospects. Cara and Tvardi cannot predict if investors will find the combined company's common stock less attractive if it relies on these exemptions. If some investors find its common stock less attractive as a result, there may be a less active trading market for its common stock and its stock price may be more volatile. The combined company may take advantage of the reporting exemptions applicable to a smaller reporting company until it is no longer a smaller reporting company, which status would end once it has a public float greater than \$250 million. In that event, the combined company could still be a smaller reporting company if its annual revenues were below \$100 million and it has a public float of less than \$700 million.

Changes in tax laws may materially adversely affect the combined company's business, prospects, financial condition and operating results.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect the combined company's business, prospects, financial condition and operating results. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to the combined company. For example, the Tax Act, the CARES Act, and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect the combined company, and certain aspects of such legislation could be repealed or modified in future legislation. Such tax law changes could have a material adverse impact on the combined company. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. While it is too early to assess the overall impact of these changes, as these and other tax laws and related regulations are revised, enacted, and implemented, the combined company's financial condition, results of operations, and cash flows could be materially adversely impacted.

The combined company's ability to use net operating loss carryforwards and other tax attributes may be limited, including as a result of the Merger.

Each of Cara and Tvardi has incurred losses during its history, and the combined company does not expect to become profitable in the near future and may never achieve profitability. To the extent that the combined company continues to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. As of December 31, 2023, Cara had U.S. federal net operating loss (NOL) carryforwards and state NOL carryforwards of \$467.0 million and \$473.3

million, respectively, and Tvardi had U.S. federal NOL carryforwards of approximately \$34.5 million. Under current law, U.S. federal NOL carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Code, federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The combined company's ability to utilize its NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with the Merger or other transactions. Similar rules may apply under state tax laws. If the combined company earns taxable income, such limitations could result in increased future income tax liability to the combined company, and the combined company's future cash flows could be adversely affected.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This proxy statement/prospectus and the documents incorporated by reference into this proxy statement/prospectus contain forward-looking statements. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events and neither Cara nor Tvardi can assure you that the events or circumstances reflected in these statements will be achieved or will occur. You can identify forward-looking statements by the use of forward-looking terminology including "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "pro forma," "should," "would" or the negative of these words and phrases or other variations of these words and phrases or comparable terminology. For example, forward-looking statements include, but are not limited to statements about:

- the strategies, prospects, plans, expectations and objectives of management of Cara or Tvardi for future operations of the combined company following the closing of the Merger;
- the progress, scope or duration of the development of product candidates or programs;
- the benefits that may be derived from the advancement of potential product candidates into clinical development and, the commercial or market opportunity of the potential product candidates of Cara, Tvardi and the combined company;
- the ability of Cara, Tvardi and the combined company to protect their intellectual property rights;
- the ability of Cara and the combined company to maintain compliance with Nasdaq listing standards;
- the anticipated operations, financial position, losses, costs or expenses of Cara, Tvardi or the combined company following the closing of the Merger;
- statements regarding future economic conditions or performance;
- · statements concerning current or proposed programs or product candidates;
- the approval and closing of the Merger, including the timing of the Merger, the ability of Cara to obtain a sufficient number of proxies to approve the Merger, other conditions to the completion of the Merger and relative ownership levels as of the closing of the Merger;
- the expected benefits of and potential value created by the Merger for the stockholders of Cara and the combined company; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

For a discussion of the factors that may cause Cara, Tvardi or the combined company's actual results, performance or achievements following closing of the proposed Merger to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, and for a discussion of risk associated with the ability of Cara and Tvardi to complete the Merger and the effect of the Merger on the business of Cara, Tvardi and the combined company following the completion of the Merger, see "*Risk Factors*" beginning on page 25 of this proxy statement/prospectus. Additional factors that could cause actual results to differ materially from those expressed in the forward-looking statements are discussed in reports filed with the SEC by Cara which are incorporated by reference into this proxy statement/prospectus. See "*Where You Can Find More Information*" beginning on page 284 of this proxy statement/prospectus. There can be no assurance that the Merger will be completed, or if it is completed, that it will close within the anticipated time period or that the expected benefits of the Merger will be realized.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of the combined company following completion of the Merger could differ materially from the forward-looking statements. All forward-looking statements in this proxy statement/prospectus are current only as of the date on which the statements were made. Cara and Tvardi do not undertake any obligation (and expressly disclaim any such obligation) to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events, except as required by applicable law.

In addition, statements that "Cara believes" or "Tvardi believes" and similar statements reflect Cara's or Tvardi's beliefs and opinions on the relevant subject. These statements are based upon information available to Cara or Tvardi, as the case may be, as of the date of this proxy statement/prospectus, and while Cara or Tvardi, as the case may be, believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and such statements should not be read to indicate that such party has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

THE SPECIAL MEETING OF CARA'S STOCKHOLDERS

Date, Time and Place

The Cara special meeting will be held exclusively online via live audio-only webcast on , 2025 at Eastern Time. The Cara special meeting can be accessed by visiting , where you will be able to vote your shares and submit questions during the Cara special meeting webcast by logging in to the website listed above using the 16-digit control number included in your proxy card. Online check-in will begin at , and Cara encourages you to allow ample time for the online check-in procedures. Cara intends to mail this proxy statement/prospectus and the enclosed form of proxy to its stockholders entitled to vote at the Cara special meeting on or about , 2025. This proxy statement/prospectus provides Cara stockholders with information they need to know to be able to vote or instruct their vote to be cast at the Cara special meeting.

Purpose of the Cara Special Meeting

The purpose of the Cara special meeting is:

- 1. **Proposal 1** *(Stock Issuance Proposal)* To consider and vote upon a proposal to approve (i) the issuance of shares of Cara common stock pursuant to the Merger, which will represent more than 20% of the shares of Cara common stock outstanding immediately prior to the Merger and (ii) the change of control of Cara resulting from the Merger, pursuant to Rules 5635(a) and 5635(b) of Nasdaq, respectively;
- 2. **Proposal 2** (*Equity Plan Proposal*) To consider and vote upon a proposal to approve the Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan;
- 3. **Proposal 3** *(ESPP Proposal)* To consider and vote upon a proposal to approve the Tvardi Therapeutics, Inc. 2025 Employee Stock Purchase Plan;
- 4. Proposal 4 (*Reverse Stock Split Proposal*) To consider and vote upon the proposed amendment to the amended and restated certificate of incorporation of Cara to effect a reverse stock split of Cara common stock at a ratio within the range between -for-1 to -for-1 (with such ratio to be mutually agreed upon by the Cara Board and the Tvardi Board prior to the effectiveness of the Merger or, if the Stock Issuance Proposal is not approved by Cara stockholders, determined solely by the Cara Board);
- 5. **Proposal 5** (*Authorized Share Proposal*) To consider and vote upon the proposed amendment to the amended and restated certificate of incorporation of Cara to increase the number of authorized shares of Cara common stock from shares to shares; and
- 6. **Proposal 6** (*Adjournment Proposal*) To consider and vote upon the postponement or adjournment of the Cara special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal.

Cara expects to transact no business other than the Cara Proposals at the Cara special meeting except such business as may properly be brought before the Cara special meeting or any adjournment or postponement thereof.

Recommendation of the Cara Board

- The Cara Board has determined and believes that the issuance of shares of Cara common stock pursuant to the Merger Agreement is fair to, advisable, and in the best interests of, Cara and its stockholders and has approved such proposal. The Cara Board unanimously recommends that Cara stockholders vote "FOR" the Stock Issuance Proposal as described in this proxy statement/ prospectus.
- The Cara Board has determined and believes that it is fair to, advisable, and in the best interests of, Cara and its stockholders to approve the Equity Plan Proposal. The Cara Board unanimously

recommends that Cara stockholders vote "FOR" the Equity Plan Proposal as described in this proxy statement/prospectus.

- The Cara Board has determined and believes that it is fair to, advisable, and in the best interests of, Cara and its stockholders to approve the ESPP Proposal. The Cara Board unanimously recommends that Cara stockholders vote "FOR" the ESPP Proposal as described in this proxy statement/ prospectus.
- The Cara Board has determined and believes that it is fair to, advisable, and in the best interests of, Cara and its stockholders to approve the amendment to the certificate of incorporation of Cara effecting a reverse stock split at a ratio in the range from -for-1 to -for-1, with such specific ratio to be mutually agreed upon by the Cara Board and the Tvardi Board or, if the Stock Issuance Proposal is not approved by Cara stockholders, determined solely by the Cara Board following the Cara special meeting as described in this proxy statement/prospectus. The Cara Board unanimously recommends that Cara stockholders vote "FOR" the Reverse Stock Split Proposal as described in this proxy statement/prospectus.
- The Cara Board has determined and believes that it is fair to, advisable, and in the best interests of, Cara and its stockholders to approve the amendment to the amended and restated certificate of incorporation of Cara to increase the number of authorized shares of Cara common stock from shares to shares. The Cara Board unanimously recommends that Cara stockholders vote "FOR" the Authorized Share Proposal as described in this proxy statement/prospectus.
- The Cara Board has determined and believes that adjourning the Cara special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal is fair to, advisable, and in the best interests of, Cara and its stockholders and has approved and adopted the proposal. The Cara Board Unanimously (as defined in the Merger Agreement) recommends that Cara stockholders vote "FOR" the Adjournment Proposal to adjourn the Cara special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal.

Record Date and Voting Power

Only holders of record of Cara common stock at the close of business on the record date, , are entitled to notice of, and to vote at, the Cara special meeting. There were approximately holders of record of Cara common stock at the close of business on the record date. At the close of business on the record date, shares of Cara common stock were issued and outstanding. Each share of Cara common stock entitles the holder thereof to one vote on each matter submitted for stockholder approval. See the section titled "*Principal Stockholders of Cara*" beginning on page <u>278</u> of this proxy statement/prospectus for information regarding persons known to Cara's management to be the beneficial owners of more than 5% of the outstanding shares of Cara common stock.

Voting and Revocation of Proxies

The proxy accompanying this proxy statement/prospectus is solicited on behalf of the Cara Board for use at the Cara special meeting.

If you are a stockholder of record of Cara as of the record date referred to above, you may vote in person at the Cara special meeting or vote by proxy on the Internet, by telephone, or using the enclosed proxy card. Whether or not you plan to attend the Cara special meeting, Cara urges you to vote by proxy to ensure your vote is counted. You may still attend the Cara special meeting and vote in person if you have already voted by proxy. As a stockholder of record, you are entitled:

- to vote (virtually) in person, log onto the Cara special meeting and submit your ballot following the instructions online;
- to vote using the proxy card, simply mark, sign and date your proxy card and return it promptly in the postage-paid envelope provided. If you return your signed proxy card to Cara before the Cara special meeting, Cara will vote your shares as you direct;



- to vote on the Internet, go to the website on the proxy card or voting instruction form to complete an electronic proxy card. You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by
 Eastern Time on
 to be counted; or
- to vote by telephone, go to the website on the proxy card or voting instruction form to complete an electronic proxy card, or call the toll-free number on the proxy card or voting instruction form to vote.

You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by Eastern Time on to be counted.

If your Cara shares are held by your broker as your nominee, that is, in "street name," the enclosed voting instruction card is sent by the institution that holds your shares. Please follow the instructions included on that proxy card regarding how to instruct your broker to vote your Cara shares.

If you do not give instructions to your broker, the question of whether your broker or nominee will still be able to vote your shares depends on whether the New York Stock Exchange (NYSE) deems the particular proposal to be a "routine" matter and how your broker or nominee exercises any discretion they may have in the voting of the shares that you beneficially own. Brokers and nominees can use their discretion to vote "uninstructed" shares with respect to matters that are considered to be "routine," but not with respect to "non-routine" matters. Under the rules and interpretations of the NYSE, "non-routine" matters are matters that may substantially affect the rights or privileges of stockholder, such as mergers, stockholder proposals, elections of directors (even if not contested), executive compensation (including any advisory stockholder votes on executive compensation and on the frequency of stockholder votes on executive compensation), and certain corporate governance proposals, even if management-supported.

For any Cara Proposal that is considered a "routine" matter, your broker or nominee may vote your shares in its discretion either for or against the proposal even in the absence of your instruction. For any Cara Proposal that is considered a "non-routine" matter for which you do not give your broker instructions, the Cara shares will be treated as broker non-votes. Broker non-votes occur when a beneficial owner of shares held in street name does not give instructions to the broker or nominee holding the shares as to how to vote on matters deemed "non-routine." Cara believes each of the Cara Proposals will be considered "non-routine" matters. Therefore, if you are a beneficial owner and want to ensure that shares you beneficially own are voted in favor or against any or all of the Cara Proposals, the only way you can do so is to give your broker or nominee specific instructions as to how the shares are to be voted.

All properly executed proxies that are not revoked will be voted at the Cara special meeting and at any adjournments or postponements of the Cara special meeting in accordance with the instructions contained in the proxy. If a holder of Cara common stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted:

- "FOR" the Stock Issuance Proposal to approve the issuance of shares of Cara common stock pursuant to the Merger Agreement;
- **"FOR**" the Equity Plan Proposal to approve the Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan;
- **"FOR**" the ESPP Proposal to approve the Tvardi Therapeutics, Inc. 2025 Employee Stock Purchase Plan;
- **"FOR**" the Reverse Stock Split Proposal to approve the amendment to the amended and restated certificate of incorporation of Cara to effect a reverse stock split of Cara common stock at a ratio within the range between -for-1 to -for-1 (with such ratio to be mutually agreed upon by the Cara Board and the Tvardi Board prior to the effectiveness of the Merger or, if the Stock Issuance Proposal is not approved by Cara stockholders, determined solely by the Cara Board);
- **"FOR"** the Authorized Share Proposal to approve the amendment to the amended and restated certificate of incorporation of Cara to increase the number of authorized shares of Cara common stock from shares to shares; and

• **"FOR"** the Adjournment Proposal to adjourn the Cara special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal in accordance with the recommendation of the Cara Board.

Cara stockholders of record, other than those Cara stockholders who have executed the Support Agreements, may change their vote at any time before their proxy is voted at the Cara special meeting in one of three ways. You can revoke your proxy at any time before it is exercised by delivering a properly executed, later-dated proxy (including a proxy submitted by Internet or telephone), by delivering a written revocation before the Cara special meeting or by voting at the Cara special meeting. Executing your proxy in advance will not limit your right to vote at the Cara special meeting if you decide to attend the Cara special meeting. However, if your shares are held in the name of a broker, bank or other holder of record, you cannot vote at the Cara special meeting unless you have a legal proxy, executed in your favor, from the holder of record. If a Cara stockholder of record or a stockholder who owns Cara shares in "street name" has instructed a broker to vote its shares of Cara common stock, the stockholder must follow directions received from its broker to change those instructions.

A complete list of Cara stockholders entitled to vote at the Cara special meeting will be available for examination by any Cara stockholder in the Corporate Secretary's Office at 400 Atlantic Street, Suite 500, Stamford, CT 06901, for purposes pertaining to the Cara special meeting, during ordinary business hours for a period of 10 days before the Cara special meeting, and at the Cara special meeting. A complete list of Cara stockholders entitled to vote at the Cara special meeting will also be available for inspection during the Cara special meeting at by logging in using unique link and password.

Required Vote

The presence, in person, by remote communication, if applicable, or by proxy duly authorized, of the holders of one-third of the outstanding shares of stock entitled to vote shall constitute a quorum for the transaction of business. Abstentions and broker non-votes will be counted towards a quorum. Assuming a quorum is present, the required vote for each of the Cara Proposals is as follows:

Proposal Number	Proposal Description	Vote Required for Approval	Effect of Abstentions	Effect of Broker Non-Votes
1	Stock Issuance Proposal	FOR votes from a majority of the votes cast by the holders of shares present at the meeting (by virtual attendance) or represented by proxy and voting on the matter	None	None
2	Equity Plan Proposal	FOR votes from a majority of the votes cast by the holders of shares present at the meeting (by virtual attendance) or represented by proxy and voting on the matter	None	None
3	ESPP Proposal	FOR votes from a majority of the votes cast by the holders of shares present at the meeting (by virtual attendance) or represented by proxy and voting on the matter	None	None
4	Reverse Stock Split Proposal	FOR votes from a majority of the votes cast by the holders of shares present at the meeting (by virtual attendance) or represented by proxy and voting on the matter	None	None
5	Authorized Share Proposal	FOR votes from a majority of the votes cast by the holders of shares present at the meeting (by virtual attendance) or represented by proxy and voting on the matter	None	None

Proposal	Proposal	Vote Required for Approval	Effect of	Broker
Number	Description		Abstentions	Non-Votes
6	Adjournment Proposal	FOR votes from a majority of shares present in person (by virtual attendance) or represented by proxy at the meeting and entitled to vote on the matter	Against	None

Effect of

The information in the preceding table with respect to the effect of broker non-votes may be incorrect or change before the special meeting. Therefore, if you are a beneficial owner and want to ensure that shares you beneficially own are voted in favor or against any or all of the Cara Proposals, the only way you can do so is to give your broker or nominee specific instructions as to how the shares are to be voted.

If on the date of the Cara special meeting, or a date preceding the date on which the Cara special meeting is scheduled, Cara reasonably believes that (i) it will not receive proxies sufficient to obtain the required vote to approve the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal, whether or not a quorum would be present or (ii) it will not have sufficient shares of Cara common stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Cara special meeting, Cara may postpone or adjourn, or make one or more successive postponements or adjournments of, the Cara special meeting as long as the date of the Cara special meeting is not postponed or adjourned more than an aggregate of 30 calendar days in connection with any postponements or adjournments.

No Cara Proposal is contingent upon any other Cara Proposal. However, each of the Stock Issuance Proposal, the Reverse Stock Split Proposal and the Authorized Share Proposal is a condition to the consummation of the Merger. Therefore, the Merger cannot be consummated without the approval of the Stock Issuance Proposal, the Reverse Stock Split Proposal and the Authorized Share Proposal. The Equity Plan Proposal and the ESPP Proposal are conditioned upon the consummation of the Merger.

As of December 1, 2024, the directors and executive officers of Cara owned approximately 4.2% of the outstanding shares of Cara common stock entitled to vote at the Cara special meeting. The directors and executive officers of Cara owning these shares are subject to Support Agreements to vote all shares of Cara common stock owned by them as of the record date in favor of the issuance of shares of Cara common stock in the Merger pursuant to the Merger Agreement. As of December 1, 2024, Cara is not aware of any affiliate of Tvardi owning any shares of Cara common stock entitled to vote at the Cara special meeting.

Attendance at the Cara Special Meeting and Voting at the Cara Special Meeting

You or your authorized proxy may attend the Cara special meeting virtually if you were a registered or beneficial stockholder of Cara common stock as of the record date.

To participate in the Cara special meeting, pre-register at

If Cara experiences technical difficulties during the Cara special meeting (e.g., a temporary or prolonged power outage), it will determine whether the Cara special meeting can be promptly reconvened (if the technical difficulty is temporary) or whether the Cara special meeting will need to be reconvened on a later day (if the technical difficulty is more prolonged). In any situation, Cara will promptly notify stockholders of the decision via . Cara will have technicians ready to assist you with any technical difficulties you may have accessing the virtual meeting website. If you encounter any difficulties accessing the virtual meeting time, please call the technical support number that will be posted on the virtual meeting website log-in page at

Please Note That You Will Not Be Able To Attend The Cara Special Meeting In Person.

The Cara special meeting will be held virtually conducted via live audio webcast. You will be able to attend the Cara special meeting by visiting as further explained in this proxy statement/ prospectus. Cara recommends that you log in at least 15 minutes before the Cara special meeting to ensure you are logged in when the meeting starts.

If you own shares in street name through an account with a bank, broker or other nominee, please send proof of your Cara share ownership as of the Cara record date (for example, a brokerage firm account statement or a "legal proxy" from your intermediary) along with your registration request. If you are not sure what proof to send, check with your intermediary.

If your shares are registered in your name with Cara's stock registrar and transfer agent, Equiniti Trust Company, LLC, no proof of ownership is necessary because Cara can verify your ownership.

Solicitation of Proxies; Expenses of Solicitation

The Cara Board is soliciting proxies for the Cara special meeting from its stockholders. Cara will bear a portion of the cost of the solicitation of proxies, including preparation, assembly and delivery, as applicable, of this proxy statement/prospectus, the Cara proxy card and any additional materials furnished to Cara stockholders. Proxies may be solicited by directors, officers and a small number of Cara's regular employees by mail, email, in person and by telephone, but such persons will not receive any additional compensation for these activities. Cara has retained, a proxy solicitation firm, to assist in the solicitation of proxies for a fee of approximately \$50,000 plus reasonable out-of-pocket costs and expenses. Cara and Tvardi have agreed to split the costs associated with the printing and filing with the SEC of this proxy statement/prospectus and any amendments and supplements thereto and paid to a financial printer or to the SEC and the costs of Cara's proxy solicitation firm.

Tabulation of Votes

Cara expects to appoint Broadridge Investor Communication Solutions, Inc. (Broadridge) to serve as the Inspector of Election for the Cara special meeting. Broadridge will independently tabulate affirmative and negative votes and abstentions.

Adjournments

Subject to certain restrictions contained in the Merger Agreement, the Cara special meeting may be adjourned to allow additional time for obtaining additional proxies. No notice of an adjourned meeting need be given if the time and place thereof are announced at the Cara special meeting at which the adjournment was taken unless: the adjournment is for more than 30 days, in which case a notice of the adjourned meeting will be given to each Cara stockholder of record entitled to vote at the Cara special meeting; or if, after the adjournment, a new record date for determination of Cara stockholders entitled to vote is fixed for the adjourned meeting, in which case the Cara Board will fix as the record date for determining Cara stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of Cara stockholders entitled to vote at the adjourned meeting, and will give notice of the adjourned meeting to each Cara stockholder of record as of such record date.

At any adjourned meeting, all proxies will be voted in the same manner as they would have been voted at the original convening of the Cara special meeting, except for any proxies that have been effectively revoked or withdrawn prior to the adjourned meeting.

Other Matters

As of the date of this proxy statement/prospectus, the Cara Board does not know of any business to be presented at the Cara special meeting other than as set forth in the notice accompanying this proxy statement/prospectus. If any other matters should properly come before the Cara special meeting, it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the persons voting the proxies.

Assistance and Additional Information

If you need assistance with submitting a proxy to vote your shares via the Internet, by telephone or by completing your Cara proxy card, or have questions regarding the Cara special meeting, please contact Alliance Advisors, LLC, the proxy solicitor for Cara, at 844-876-6183 (toll-free) or by email at CARA@allianceadvisors.com.

Your vote is very important regardless of the number of shares of Cara common stock that you own, and the matters to be considered at the Cara special meeting are of great importance to the stockholders of Cara. Accordingly, you are urged to read and carefully consider the information contained in or incorporated by reference into this proxy statement/prospectus and promptly submit your proxy via the Internet or by telephone or complete, date, sign and promptly return the enclosed Cara proxy card or voting instruction form in the enclosed postage-paid envelope. If you submit your proxy via the Internet or by telephone, you do not need to return the enclosed Cara proxy card.

Please vote your shares via the Internet or by telephone, or sign, date and return a Cara proxy card or voting instruction form promptly to ensure that your shares can be represented, even if you otherwise plan to attend the Cara special meeting.

THE MERGER

Background of the Merger

Prior to Cara's June 14, 2024 announcement of its intention to explore strategic options for enhancing and preserving stockholder value, Cara was a biopharmaceutical company focused on leading a new treatment paradigm to improve the lives of patients suffering from chronic pruritus. Since 2004, Cara has been focused on organizing and staffing itself, developing its lead product and product candidates, including conducting preclinical studies and clinical trials of difelikefalin-based product candidates, and raising capital. As part of the ongoing consideration and evaluation of its long-term prospects and strategies, the Cara Board frequently reviews, with Cara's management and outside advisors, strategic and financial alternatives, considering developments in Cara's business, the sectors in which it competes, the economy generally and financial markets, all with the goal of enhancing value for its stockholders. As part of this process, from time to time, members of Cara's management and its advisors have engaged in business development and strategic discussions with industry participants, including strategic out-licensing and collaboration arrangements.

On May 7, 2024, the Cara Board held a teleconference meeting with representatives of management and representatives of Cara's regular outside legal counsel at Cooley LLP also attending. At this meeting, the Cara Board discussed what strategic options Cara would have in the event of negative data from the KOURAGE-1 Part A clinical trial, including prospects for remaining as a standalone company, financing options, dissolution or insolvency and a sale of Cara. The Cara Board discussed its fiduciary duties in connection with each of the discussed options available to Cara in that scenario.

On June 10, 2024, the Cara Board, representatives of Cara management and representatives of Cara's regular outside legal counsel held separate videoconference meetings with two prospective financial advisors, including Piper Sandler. The representatives of each prospective financial advisor separately presented to the Cara Board regarding the M&A industry landscape and M&A possibilities for Cara, as well as their capabilities with respect to such potential strategic alternatives.

On June 11, 2024, the Cara Board held a videoconference meeting with representatives of Cara management and representatives of Cara's regular outside legal counsel also attending. The Cara Board reviewed the outcome from the dose-finding Part A of the KOURAGE-1 study evaluating the efficacy and safety of oral difelikefalin for moderate-to-severe pruritus in adult patients with notalgia paresthetica (NP) in which oral difelikefalin did not demonstrate a meaningful clinical benefit at any dose compared to placebo. At this same meeting, the Cara Board discussed again the go-forward strategic options for Cara in light of the topline data. The Cara Board also discussed steps to preserve and extend Cara's cash runway. The Cara Board determined to discontinue Cara's clinical program for NP at such meeting.

On June 12, 2024, Cara announced that it was discontinuing its clinical program for NP.

On June 14, 2024, the Cara Board held a videoconference meeting with representatives of Cara management and representatives of Cara's regular outside legal counsel also attending. The Cara Board considered the strategic options for Cara, including, among other things, prospects for remaining as a standalone company, dissolving Cara and distributing remaining cash to stockholders, a possible financing, insolvency and an acquisition of Cara, including through a reverse merger, sale to another company or sale to a private investor. The Cara Board discussed its fiduciary duties in connection with the evaluation of the strategic options available to Cara. The Cara Board considered the benefits and risks of the various strategic alternatives, including the likelihood of finding a counterparty for a transaction, and the timeline and costs associated with such strategic options.

At this same meeting, the Cara Board discussed again whether to engage a financial advisor to assist the Cara Board in evaluating strategic alternatives. The Cara Board reviewed the qualifications of the two potential financial advisors that it met with separately on June 10, 2024, including their respective expertise in mergers and acquisitions in the biotechnology industry. In determining to engage Piper Sandler, the Cara Board took into consideration that Piper Sandler is an internationally recognized investment banking, financial advisory and securities firm with expertise in the biopharmaceutical sector that is regularly engaged in the valuation and financial assessment of businesses and securities in connection with mergers and acquisitions, including reverse merger transactions. The Cara Board then authorized Cara's management to

negotiate the terms of engagement of Piper Sandler as Cara's financial advisor, which engagement letter was subsequently executed on July 10, 2024.

At this same meeting, the Cara Board established a committee of the Cara Board comprised solely of independent directors for the purposes of reviewing and evaluating possible strategic transactions and alternatives that may be available to Cara (Transaction Committee). Martin Vogelbaum and Jeffrey Ives, each of whom the Cara Board determined is an independent director, were designated as members of the Transaction Committee. Following this meeting of the Cara Board, members of the Transaction Committee met from time to time with representatives of Cara management and representatives of Piper Sandler to provide direction regarding the strategic review process.

On June 18, 2024, Cara announced that the Cara Board had approved a streamlined operating plan exploring strategic alternatives after Cara announced its decision to discontinue the clinical program in NP, including a reduction in Cara's workforce by approximately 70%, which reduction Cara expected to be substantially complete by June 30, 2024. Cara also reported it had approximately \$70 million in cash, cash equivalents, and marketable securities as of March 31, 2024.

On July 11, 2024, Cara announced in a press release that it was exploring and reviewing strategic alternatives and that it had engaged Piper Sandler to act as its financial advisor in connection with the process.

From July 15, 2024 through August 22, 2024, at the direction of the Transaction Committee, representatives of Piper Sandler contacted a total of 66 parties to solicit interest in a potential transaction with Cara. Starting on July 22, 2024, Piper Sandler sent out initial process letters, which requested submission of a preliminary indication of interest by August 16, 2024 from such parties and confidentiality agreements that would provide such parties access to a virtual data room that included Cara's then-current cash runway. On July 27, 2024, Cara's virtual data room was opened to potential counterparties in a strategic transaction. During the course of this process, Cara management also initiated workstreams at the direction of the Cara Board in order to minimize its cash spend and preserve its cash runway, such as reducing its employee base, subletting Cara's headquarters and pursuing a sale of Cara's legacy assets and unwinding its associated liabilities.

During July and August 2024, Cara executed confidentiality agreements with 33 companies, each of which contains a customary standstill provision that allows for confidential proposals to the Cara Board and which terminates if Cara enters into a merger transaction.

Additionally, from July through October 11, 2024, at the direction of the Transaction Committee, Cara management negotiated a term sheet with CSL Vifor regarding a potential asset disposition and the treatment of the HCR obligations.

On August 7, 2024, the Cara Board held a videoconference meeting with representatives of Cara management and representatives of Cara's regular outside legal counsel also attending. At this meeting, the Cara Board discussed the status of outreach to potential parties, including the two preliminary indications of interest received at that stage.

On August 14, 2024, Cara reported cash and cash equivalents totaling \$49.239 million as of June 30, 2024.

On August 16, 2024, Cara received an indication of interest from Tvardi.

By August 19, 2024, Cara had received 24 preliminary indications of interest from potential counterparties. The proposals were comprised of 23 proposals for a reverse merger with Cara, including Tvardi's, and one proposal for an all cash acquisition of Cara at an aggregate price representing a discount to Cara's anticipated cash balance at closing plus a contingent value right equal to a percentage of the net proceeds payable from any license or disposition of Cara's existing assets. The cash tender offer was also predicated upon a closing cash amount of Cara that was below the amount anticipated to be held at a potential consummation of the transaction.

On August 27, 2024, the Transaction Committee held a videoconference meeting with representatives of Cara management, representatives of Piper Sandler and representatives of Cara's regular outside legal

counsel also attending. At this meeting, the Transaction Committee evaluated the 24 preliminary indications of interest from potential counterparties, including Tvardi. Representatives of Cara management and representatives of Piper Sandler reviewed their perspectives and recommendations with respect to the various proposals, including, among other things, the proposals' preliminary valuation of such counterparty and Cara, the strength of each counterparty's existing investor base, the availability of audited financials for each such counterparty and the strength of each such counterparty's product candidates (including therapeutic areas, number of drug candidates, stages of development and need for cash runway for upcoming preclinical or clinical inflection points), among other factors.

The Transaction Committee then approved proceeding with eight potential counterparties, including Tvardi, to a second-round process, which would include management presentations by each of the counterparties. At this meeting, the Transaction Committee also approved putting seven other candidates "on hold" pending discussion with the eight potential counterparties identified as most promising. The eight proposals that advanced to the second-round process were selected based on the Transaction Committee's evaluation of certain characteristics, including the strength of such counterparty's product candidate programs and intellectual property from clinical, regulatory and commercial perspectives as well as financial terms of the counterparty's proposal relative to the risks and potential benefits of such counterparty. In evaluating the strength of each counterparty's product candidate programs and intellectual property, the Transaction Committee considered factors (to the extent such information was then-available to the Transaction Committee) such as the stage of each counterparty's product candidate development programs, the strength of the pre-clinical and clinical data, the number of programs as well as the potential for success and level of program risk. In evaluating the financial terms of each counterparty's proposal, the Transaction Committee considered factors such as the rationale for the counterparty's valuation, the need for additional financing to achieve clinical milestones, the quality of the counterparty's existing investors, the ability of the counterparty to meet the reporting requirements of a public company, the timeline for value creation for Cara's stockholders as well as the experience of the counterparty's management. The Transaction Committee also determined at that meeting that, despite a potentially quicker pathway to closing, the proposal for a cash tender offer for Cara would not be expected to represent an attractive outcome to Cara's stockholders compared to the potential reverse merger candidates, including Tvardi, due to the aggregate valuation being meaningfully below Cara's then-anticipated cash balance at consummation and the proposal not providing for any ability to share in future increases in value.

Between September 4, 2024 and September 12, 2024, the Transaction Committee, together with representatives of Cara management and representatives of Piper Sandler, met with six of the eight second round counterparties, including with representatives of Tvardi on September 11, 2024, during which each counterparty presented information regarding such counterparty's product candidates and business plan, valuation, anticipated funding needs, access to potential new biotech-focused investors and preparedness to transact with Cara in a timely manner. One of the eight counterparties was not responsive to further email and telephone requests to schedule a management presentation. The last of the eight counterparties asked to be removed from consideration by Cara due to recent leadership and clinical strategy changes.

On September 16, 2024, the Transaction Committee held a videoconference meeting with representatives of Cara management, Piper Sandler and Cara's regular outside legal counsel also attending. At such meeting, the Transaction Committee evaluated the six remaining potential counterparties, including Tvardi, and discussed with Cara management and Piper Sandler their recommendations with respect to the various counterparties. The Transaction Committee also considered if any of the counterparties that were "on hold" regarding a second-round process should be contacted given that two of the second round counterparties had passed on the opportunity or been unresponsive. The Transaction Committee determined that four of the six existing potential counterparties were more compelling as potential reverse merger partners than the other two, and more compelling than any of the seven "on hold" candidates, due to a combination of factors such as product candidate viability, economics of the transaction, interested investors and quick pathways to consummating a transaction. The Transaction Committee determined to proceed with conducting continued due diligence with the four (of six) second-round counterparties that it considered most compelling, including Tvardi.

Between September 16, 2024 and October 14, 2024, the Transaction Committee, together with representatives of Piper Sandler, met with the four remaining counterparties, including Tvardi, during

which time clarifying due diligence was conducted based on the information that each counterparty had presented in its initial meetings between September 4, 2024 and September 12, 2024. This clarifying due diligence was conducted over at least one meeting for each remaining counterparty and included both written and verbal questions to ascertain greater detail on each counterparty's product candidates and business plan, valuation, anticipated funding needs, access to potential new biotech-focused investors and preparedness to transact with Cara in a timely manner.

Subsequent to their follow-up due diligence meetings held between September 16, 2024 and October 14, 2024, two of the four remaining counterparties asked to be removed from consideration by Cara due to factors including their preparedness to transact with Cara in a timely manner and changes in their valuation.

On September 25, 2024, Cara assigned the lease for its Stamford, Connecticut headquarters, thereby reducing its cash burn by \$1.3 million per year.

On September 26, 2024, Cara engaged Syneos Health, Inc., a third-party consultant in the biopharmaceutical space (Syneos Health), to perform scientific due diligence on Tvardi's development programs including Tvardi's approach, its preclinical and clinical data and the markets it intends to serve. Syneos Health conducted its due diligence with the use of external key opinion leaders, its own internal subject matter experts, meetings with the Tvardi and Cara management teams, review of the Tvardi virtual data room and review of published scientific literature. Cara management did not need to engage a third-party consultant to perform scientific due diligence with respect to the other remaining counterparty due to the nature of the business model that focuses on the manufacturing, distribution and marketing of a portfolio of commercial products.

During this same timeframe, following agreement on the term sheet for the Asset Disposition with CSL Vifor on October 11, 2024, Cara and CSL Vifor negotiated the APA (as defined below) concurrently with the negotiation of the Merger Agreement, with the transactions to be announced largely contemporaneously. CSL Vifor, Cara and HCR also concurrently negotiated the letter agreement and the amended and restated purchase agreement to replace the Original HCR Agreement in connection with the Asset Disposition.

On October 17, 2024, Syneos Health delivered its final report to the Cara Board summarizing its due diligence review of Tvardi.

On October 17, 2024, following review of Syneos Health's final report by the Cara Board and the Transaction Committee, the Cara Board decided to negotiate a non-binding term sheet with Tvardi rather than the other finalist counterparty. Tvardi was chosen over the other finalist because, in the Cara Board's assessment based on the due diligence performed on both finalist counterparties, Tvardi had greater prospects for creating future value for Cara stockholders due to the nature of its business model as a research-driven, clinical stage biopharmaceutical company with an innovative product pipeline and based on Cara's assessment that, with respect to Tvardi's product pipeline and the potential market opportunity for Tvardi's product candidates, Tvardi's product candidates have the potential to create meaningful value for the stockholders of the combined company and the opportunity for Cara's stockholder to participate in the potential growth of the combined company. The other finalist counterparty remained under consideration while the Cara Board undertook negotiations with Tvardi but was subsequently informed, on a no-names basis, of the Cara Board's decision to pursue another target.

On October 21, 2024, in consultation with members of the Transaction Committee, Cara determined to engage Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (Mintz) as its outside legal counsel in connection with the Merger because different attorneys at Cooley LLP, Cara's regular outside legal counsel, represent Tvardi. Cara selected Mintz based on, among other things, Mintz's reputation as a law firm with extensive expertise in public company representation and M&A and strategic transactions in the biopharmaceutical space.

On October 21, 2024, after discussions between Cara's management team and Tvardi's management team, Cara sent Tvardi a form of non-binding term sheet proposing, among other things, an economic split of the combined company that contemplated that Cara equityholders would hold 19.8% and Tvardi equityholders would hold 80.2% of the combined company on a treasury-stock method basis, not accounting for any future financing, and based on a Tvardi valuation of \$210.0 million and a Cara valuation of \$52 million (October 21 Term Sheet). The October 21 Term Sheet also contemplated a financing with a

targeted subscription amount of \$25.0 million, including a closing condition, for Cara's benefit, of at least \$25 million of financing having been raised and funded at Closing. The October 21 Term Sheet also contemplated an exclusivity period.

On October 25, 2024, Tvardi sent Cara a revised term sheet reflecting, among other things, (i) an economic split of the combined company that contemplated that Cara equityholders would hold 17% and Tvardi equityholders would hold 83% of the combined company on a treasury stock method basis, not accounting for any future financing, and based on a Tvardi valuation of \$210.0 million and a Cara valuation of \$43.0 million, (ii) the insertion of a "force the vote" provision and (iii) the insertion of a closing condition for Tvardi's benefit, that Cara shall have a Cara net cash balance of at least \$20 million at the closing of the Merger (October 25 Term Sheet). The October 25 Term Sheet also contemplated that the parties would share in the dilution associated with any future financings.

On October 28, 2024, representatives of Cara and Tvardi management and representatives of Piper Sandler reviewed Cara's cash model.

On October 29, 2024, the Transaction Committee held a videoconference meeting with representatives of Cara management, Piper Sandler and Mintz also attending. At such meeting, the Transaction Committee discussed updates with respect to the negotiation of the term sheet with Tvardi, including a discussion of the valuations proposed.

On October 30, 2024, Cara sent Tvardi a revised term sheet reflecting, among other things, (i) an economic split of the combined company that contemplated that Cara equityholders would hold 17.6% and Tvardi equityholders would hold 82.4% of the combined company on a treasury stock method basis, not accounting for any future financing, and based on a Tvardi valuation of \$210.0 million and a Cara valuation of \$45.0 million, (ii) the removal of the "force the vote" provision and (iii) modifying the Cara net cash closing condition to \$18 million.

On October 31, 2024, Tvardi sent Cara a revised term sheet reflecting, among other things, (i) an economic split of the combined company that contemplated that Cara equityholders would hold 17% and Tvardi equityholders would hold 83% of the combined company, not accounting for any future financing, and based on a Tvardi valuation of \$210.0 million and a Cara valuation of \$43.0 million, (ii) the reinsertion of the "force the vote" provision, (iii) modifying the Cara net cash closing condition to \$20 million and (iv) and insertion of a closing condition, for Cara's benefit, that the financing at closing shall not be less than \$20 million (October 31 Term Sheet). The October 31 Term Sheet also contemplated that the parties would share in the dilution associated with any future financings but proposed that any discount associated with the conversion of any bridge notes would only dilute Tvardi's stockholders.

Also on October 31, 2024, the Transaction Committee held a videoconference meeting with representatives of Cara management, Piper Sandler and Mintz also attending. At such meeting, the Transaction Committee discussed updates with respect to the negotiation of the term sheet with Tvardi, including a discussion of the valuations proposed.

On November 1, 2024, Cara sent Tvardi a revised term sheet reflecting, among other things, (i) an economic split of the combined company that contemplated that Cara equityholders would hold 17% and Tvardi equityholders would hold 83% of the combined company on a treasury stock method basis, not accounting for any future financing, and based on a Tvardi valuation of \$210.0 million and a Cara valuation of \$43.0 million, (ii) modifying the Cara net cash closing condition to \$18 million, (iii) modifying the financing closing condition for the benefit of Cara to \$25 million and (iv) agreeing that the parties would share in the dilution associated with any future financings but that any discount associated with the conversion of any bridge notes would only dilute Tvardi's stockholders.

Later on November 1, 2024, Tvardi sent Cara a revised term sheet, among other things, (i) modifying the Cara net cash closing condition to \$20 million and (ii) modifying the financing closing condition to \$20 million.

On November 2, 2024, Tvardi sent Cara a further revised term sheet, among other things, modifying the Cara net cash closing condition to \$18 million.



On November 3, 2024, Cara send Tvardi a revised term sheet finalizing the agreed upon economic splits of the combined company following the anticipated financing (November 3 Term Sheet).

On November 4, 2024, the Transaction Committee held a videoconference meeting with representatives of Cara management, representatives of Piper Sandler and Mintz also attending. At such meeting, the Transaction Committee was presented with, and discussed with such representatives, the final agreed-upon terms of the term sheet with Tvardi. The Transaction Committee approved the entry into the November 3 Term Sheet.

On November 4, 2024, the parties agreed upon the terms set forth in the November 3 Term Sheet. The executed November 3 Term Sheet contained an exclusivity period through December 4, 2024.

On November 6, 2024, Mintz sent an initial draft of the Merger Agreement to Tvardi and attorneys at Cooley LLP acting as Tvardi's counsel in connection with the merger (Cooley).

On November 8, 2024, the audit committee of the Cara Board and the Cara Board held their regularly scheduled quarterly meeting to review Cara's financial update for the most recently ended quarter, with representatives of Cara management and Cara's regular outside legal counsel attending. Cara management reviewed Cara's financial position as of the end of third quarter of 2024, including an update on Korsuva net sales, as well as the assignment of the lease of Cara's corporate headquarters, and Cara's expected cash position and cash management plan going forward. Representatives of Piper Sandler joined a portion of the meeting during which representatives of Cara management and Piper Sandler provided the Cara Board with an update with respect to the strategic transaction process, including the counterparties considered by the Transaction Committee, the expected timeline of the process, the status of the discussions with CSL Vifor on the Asset Disposition, the diligence conducted on the potential counterparties and the November 3 Term Sheet, including Tvardi's pre-clinical and clinical programs and its current financial position. Cara management updated the Cara Board with respect to the scientific diligence efforts conducted to date on Tvardi, as well as the positive feedback received with respect to Tvardi's programs from independent consultants as well as independent key opinion leaders.

On November 12, 2024, Mintz sent drafts of the forms of lock-up agreement, Cara support agreement and Tvardi support agreement, and the agreements were subsequently negotiated and finalized.

On November 19, 2024, Cooley sent Mintz a revised draft of the Merger Agreement, which, among other things, included revisions to the representations and warranties, interim operating covenants, the non-solicitation provisions, the deal protection provisions, the closing conditions, the termination provisions, including limiting the circumstances under which Cara can terminate the Merger Agreement and the definitions of Exchange Ratio, Cara Change in Circumstance, Cara Net Cash, Cara Triggering Event and Superior Offer.

On November 21, 2024, Piper Sandler delivered to Cara management a written disclosure statement with respect to Piper Sandler's pre-existing relationships with Cara, Tvardi and their respective affiliates. The disclosure statement noted, among other things, that, as of November 19, 2024 and based on its customary conflicts-related clearance procedures, since January 1, 2022, Piper Sandler had no material relationships (other than with respect to a proposed financing which was abandoned after November 21, 2024) with, and had not received any fees for investment banking services from, any of Cara, Tvardi, or their respective affiliates. Cara management then provided the written disclosure statement to the Cara Board.

On November 25, 2024, Mintz sent Cooley a revised draft of the Merger Agreement, which, among other things, included revisions to the representations and warranties, interim operating covenants, the deal protection provisions, the closing conditions, the termination fee provisions, including reducing the size of the termination fee that would be payable by Cara in certain circumstances and the definition of Cara Net Cash.

On December 3, 2024, Cooley sent Mintz a revised draft of the Merger Agreement which, among other things, included revisions to the representations and warranties, interim operating covenants, the deal protection provisions, the closing conditions, the termination fee provisions, including increasing the size of the termination fee that would be payable by Cara in certain circumstances and the definitions of Exchange Ratio and Cara Net Cash.

On December 3, 2024 and December 6, 2024, representatives of Mintz and Cooley held a telephonic meeting to discuss the open issues in the merger agreement, including, among other things, with respect to the interim operating covenants, the deal protection provisions, the closing conditions, the termination fee that would by payable by Cara to Tvardi and the definition of Cara Net Cash.

On December 4, 2024, the parties executed an extension of exclusivity, agreeing to extend the end of the exclusivity period from December 4, 2024 to December 11, 2024.

On December 5, 2024, Mintz sent Cooley a revised draft the Merger Agreement which, among other things, included revisions to the interim operating covenants, the closing conditions, the deal protection provisions, the termination fee provisions, including reducing the size of the termination fee that would be payable by Cara in certain circumstances and the definition of Cara Net Cash. The parties continued to negotiate and exchange drafts of the Merger Agreement until it was finalized and subsequently executed on December 17, 2024.

On December 9, 2024, the Cara Board held a videoconference meeting, with Cara's management and representatives of Piper Sandler and representatives of Mintz present, to review the terms of the Merger Agreement and related ancillary agreements. Representatives of Mintz reviewed the material terms of the draft Merger Agreement and related ancillary agreements and reviewed with the Cara Board its fiduciary duties applicable in connection with the strategic transaction process. Representatives of Piper Sandler reviewed with the Cara Board the approach taken by Piper Sandler in preparing its financial analyses of the Exchange Ratio and highlighted for the Cara Board the presentation that Piper Sandler would be giving to the Cara Board at a meeting to be held later in the week to formally approve the contemplated transactions, including the proposed Merger. The Cara Board then discussed the potential transaction with representatives of Cara management, Piper Sandler and Mintz. Following this discussion, representatives of Cara's management provided an update to the Cara Board on the status of the asset disposition to CSL Vifor.

On December 11, 2024, the parties executed an extension of exclusivity, agreeing to extend the end of the exclusivity period from December 11, 2024 to December 20, 2024.

On December 11, 2024, the Cara Board held a videoconference meeting, with Cara's management and representatives of Piper Sandler and representatives of Mintz present. Representatives of Piper Sandler reviewed with the Cara Board Piper Sandler's financial analyses of the Exchange Ratio (without giving effect to the Reverse Stock Split). The Cara Board then discussed the timeline for the proposed Merger with Cara's management and representatives from Mintz providing updates.

On December 17, 2024, the Cara Board held a videoconference meeting, with Cara's management and representatives of Piper Sandler and representatives of Mintz present. Representatives of Piper Sandler indicated that there were no material changes to Piper Sandler's financial analyses of the Exchange Ratio (without giving effect to the Reverse Stock Split) as presented to the Cara Board on December 11, 2024. Representatives of Piper Sandler then delivered to the Cara Board the oral opinion of Piper Sandler, which was subsequently confirmed in writing via a written opinion dated December 17, 2024, to the effect that, as of that date and based on and subject to various assumptions made, procedures followed, matters considered, and qualifications and limitations on the scope of review undertaken by Piper Sandler as set forth in its written opinion, the Exchange Ratio (without giving effect to the Reverse Stock split) was fair, from a financial point of view, to Cara, as more fully described below in the section titled "- Opinion of Cara's Financial Advisor." Representatives of Mintz then reviewed the limited updates to the Merger Agreement from the previous discussion on December 9, 2024 and noted that there were no material changes to the Merger Agreement since that date. Representatives of Cara management then reviewed with the Cara Board the terms of the Asset Disposition. Following these presentations, the Cara Board then discussed the potential transaction with members of Cara management Piper Sandler and Mintz, and, after considering the matters discussed during the meeting and prior meetings of the Cara Board and the Transaction Committee (for more information, see the section titled "- Cara Reasons for the Merger"), the Cara Board unanimously (i) determined that entry into the Merger Agreement and the Contemplated Transactions, were advisable and fair to, and in the best interests of, Cara and its stockholders; (ii) authorized, approved and declared advisable the Merger Agreement and the Contemplated Transactions, the change of control of Cara, and other actions contemplated by the Merger Agreement, (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that the stockholders of

Cara vote to approve the Cara Stockholder Matters; (iv) approved the Cara Stockholder Support Agreements, the Tvardi Stockholder Support Agreements, the Cara Lock-Up Agreements and the transactions contemplated thereby and (v) approved the Asset Disposition and the entry into the APA and a letter agreement with CSL Vifor and HCR providing for the entry into an amended and restated purchase agreement to amend and replace the Original HCR Agreement.

On December 17, 2024, representatives of Cara and Tvardi (together with Merger Sub) executed the definitive Merger Agreement. Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of Cara and Tvardi delivered the Cara Stockholder Support Agreements, Cara Lock-Up Agreements, Tvardi Stockholder Support Agreements and Tvardi Lock-Up Agreements, as applicable. On the same day, representatives of Cara (together with Royalty Sub) and CSL Vifor entered into the APA and representatives of Cara, CSL Vifor and HCR entered into a letter agreement with CSL Vifor and HCR providing for the entry into an amended and restated purchase agreement to amend and replace the Original HCR Agreement.

On December 18, 2024, the execution of the Merger Agreement and the entry into the APA was publicly announced before the Nasdaq Stock Market opened for the day.

Cara Reasons for the Merger

At a meeting held on December 17, 2024, the Cara Board unanimously (i) determined that the Merger and the other transactions and actions contemplated by the Merger Agreement (collectively, the Contemplated Transactions) are fair to, advisable and in the best interests of Cara and its stockholders; (ii) authorized, approved and declared advisable the Merger Agreement and the Contemplated Transactions, including the issuance of shares of Cara common stock to the stockholders of Tvardi pursuant to the terms of the Merger Agreement, the change of control of Cara, and other actions contemplated by the Merger Agreement; (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that the stockholders of Cara vote to approve the Cara Stockholder Matters (as defined in the section titled "*Special Meeting of Cara Stockholders*"); and (iv) approved the Cara Stockholder Support Agreements and the transactions contemplated thereby.

The Cara Board considered the following reasons in reaching its conclusion to approve the Merger Agreement, the Merger and the other Contemplated Transactions and to recommend that the stockholders of Cara vote to approve the Cara Stockholder Matters, all of which the Cara Board viewed as supporting its decision to approve the Merger with Tvardi:

- the financial condition and prospects of Cara and the risks associated with continuing to operate Cara on a stand-alone basis, particularly in light of Cara's June 2024 decision to suspend its clinical program in notalgia paresthetica and July 2024 decision to streamline its operating plan and focus on cost-containment and cash conservation;
- the Cara Board, with the assistance of its advisors, undertook a comprehensive and thorough process of reviewing and analyzing potential strategic options, including to remain a standalone company pursuing a focused pipeline, a liquidation to distribute available cash, and strategic transactions, including through a reverse merger or sale to a third party, to identify the opportunity that would, in the Cara Board's opinion, create the most value for Cara's stockholders;
- the Cara Board believes that, as a result of arm's length negotiations with Tvardi, Cara and its
 representatives negotiated the most favorable Exchange Ratio for Cara's stockholders to which
 Tvardi was willing to agree, and that the terms of the Merger Agreement include the most favorable
 terms to Cara in the aggregate to which Tvardi was willing to agree;
- the Cara Board's belief, after a thorough review of strategic alternatives and discussions with Cara senior management, representatives of its financial advisor and legal counsel, that the Merger is more favorable to Cara's stockholders than the potential value that might have resulted from other strategic transactions available to Cara;
- the fact that the estimated return to stockholders of Cara in a potential liquidation of Cara would result in a payment of approximately \$0.53 per share of Cara Common Stock, representing approximately \$0.24 less per share than the implied value of the Exchange Ratio on a per share basis;

- the Cara Board's belief, based in part on clinical and scientific diligence and an analysis process
 conducted over several weeks by Cara's management and reviewed with the Cara Board (which
 included numerous clinical and scientific diligence calls by Cara's diligence team composed of
 internal and external subject matter experts, specializing in pre-clinical science, clinical
 development, clinical operations, regulatory, manufacturing, intellectual property, and
 commercialization, which diligence team had access to and comprehensively reviewed Tvardi's
 virtual data room, with Tvardi's management on Tvardi's programs, including its lead clinical
 development program TTI-101, and with feedback from such diligence calls from consultants and
 key opinion leaders), that with respect to Tvardi's product pipeline and the potential market
 opportunity for Tvardi's product candidates, Tvardi's product candidates have the potential to create
 meaningful value for the stockholders of the combined company and an opportunity for Cara's
 stockholders to participate in the potential growth of the combined company;
- the Cara Board also reviewed with the management of Cara and the management of Tvardi the current plans of Tvardi for developing TTI-101 and Tvardi's other product candidates to confirm the likelihood that the combined company would possess sufficient financial resources to allow the combined company's management team to focus on the continued development and anticipated commercialization of those development candidates;
- the Cara Board's belief that the combined company would be able to raise additional funds in the future based on the combination of Cara's public company structure with Tvardi's business;
- the ability of Tvardi to operate as a public company;
- the fact that the combined company will be led by an experienced industry chief executive officer and management team, many members of which have extensive drug development, research and development, business and regulatory expertise, and a board of directors with representation from the current Cara Board and Tvardi Board; and
- the oral opinion of Piper Sandler, (which was subsequently confirmed in writing by delivery of Piper Sandler's written opinion), to the Cara Board (in its capacity as such), to the effect that, as of December 17, 2024, and based upon and subject to the various assumptions made, procedures followed, matters considered and qualifications and limitations on the review undertaken by Piper Sandler in preparing its opinion set forth in its written opinion, the Exchange Ratio (without giving effect to the Reverse Stock Split) was fair, from a financial point of view, to Cara, as more fully described below under the section captioned "*The Merger Opinion of Cara's Financial Advisor*."

The Cara Board also reviewed various reasons impacting the financial condition, results of operations and prospects of Cara, including:

- the strategic alternatives to the Merger, including potential transactions that could have resulted from discussions that Cara's management conducted with other potential merger partners;
- the current and historical market prices of Cara's stock, including the market performance of the shares relative to general market indices and the general downturn among stock prices among biopharmaceutical companies as well as the current state of the U.S. and global economies, including the downward trend in the biopharmaceutical financial markets;
- the risks associated with Cara remaining a standalone company pursuing a limited pipeline including liquidity needs and cash-burn related to, among other things, funding Cara's development pipeline;
- the risks associated with the expected length of the program timelines of Cara's current assets, including KOURAGE program timelines, and business development opportunities and the financing sources available to Cara based on such timelines;
- the risks associated with Cara's ability to attract and retain talent;
- the risks associated with the need to obtain substantial amounts of financing to continue its operations and to continue the development of its current programs if Cara were to remain an independent company and the unlikelihood that such financing would be able to be obtained; and
- the risks and delays associated with, and uncertain value and costs to Cara's stockholders of, liquidating Cara, including, without limitation, the uncertainties of continuing cash burn while

contingent liabilities are resolved and uncertainty of timing of release of cash until contingent liabilities are resolved.

The Cara Board also reviewed the terms and conditions of the Merger Agreement and the Contemplated Transactions, as well as the safeguards and protective provisions included therein intended to mitigate risks, including:

- the initial estimated Exchange Ratio used to establish the number of shares of Cara common stock to
 be issued to Tvardi's stockholders in the Merger was determined based on the relative valuations of
 Cara and Tvardi and an implied combined company valuation, and thus the relative percentage
 ownership of Cara's stockholders, Tvardi's stockholders and the Convertible Note holders
 immediately following the completion of the Merger is subject to change, including based on the
 amount of Cara Net Cash at Closing to the extent it is greater than \$23.125 million or less than
 \$22.875 million, subject to certain exceptions as more fully described below under the caption "The
 Merger Exchange Ratio";
- a dollar-for-dollar adjustment to Cara Net Cash for amounts Cara will receive for the sale of its legacy assets, if successful, on or about the anticipated Closing Date (the Anticipated Closing Date);
- the limited number and nature of the conditions to Tvardi's obligation to consummate the Merger and the limited risk of non-satisfaction of such conditions as well as the likelihood that the Merger will be consummated on a timely basis;
- the ability of Cara to consider certain unsolicited Acquisition Proposals under certain circumstances should Cara receive a Superior Offer;
- the reasonableness of the potential termination fee of \$2.25 million and related reimbursement of certain transaction expenses capped at \$750,000, which could become payable by Cara to Tvardi if the Merger Agreement is terminated in certain circumstances;
- the Support Agreements, pursuant to which certain directors, officers and stockholders of Cara and Tvardi have agreed, solely in their capacity as stockholders of Cara and Tvardi, respectively, to vote all of their shares of Cara common stock or Tvardi capital stock in favor of the approval or adoption, respectively, of the Merger Agreement and the Contemplated Transactions;
- the agreement of Tvardi to provide the written consent of Tvardi's stockholders necessary to adopt and approve the Merger Agreement and the Contemplated Transactions within seven business days of the Registration Statement becoming effective and the fact that stockholders holding the necessary votes have entered into Support Agreements; and
- the belief that the terms of the Merger Agreement, including the parties' representations, warranties and covenants, and the conditions to their respective obligations, are reasonable under the circumstances.

In the course of its deliberations, the Cara Board also considered a variety of risks and other countervailing factors related to entering into the Merger, including:

- the effect of the non-solicitation provisions of the Merger Agreement that restrict Cara's ability to solicit or, subject to certain exceptions, engage in discussions or negotiations with third parties regarding an Acquisition Proposal, and the fact that, upon termination of the Merger Agreement under certain specified circumstances, Cara will be required to pay a termination fee of \$2.25 million, which could discourage certain other potential acquirers from proposing an alternative transaction that may be more advantageous to Cara's stockholders;
- the substantial expenses to be incurred in connection with the Merger, including the costs associated with the Registration Statement and any related litigation;
- the possibility of disruptive stockholder litigation following announcement of the Merger;
- the possible volatility, at least in the short term, of the trading price of Cara common stock resulting from the announcement of the Merger;



- the risk that the Merger might not be consummated in a timely manner or at all and the potential adverse effect of the public announcement of the Merger or delay or failure to complete the Merger on the reputation of Cara;
- the likely detrimental effect on Cara's cash position, stock price and ability to initiate another process and to successfully complete an alternative transaction should the Merger not be completed;
- the risk to Cara's business, operations and financial results in the event that the Merger is not consummated, including the diminution of Cara's cash and the significant challenges associated with the need to raise additional capital through the public or private sale of equity securities;
- the early stage of development of Tvardi's product candidates, which, in the future, may not generate acceptable clinical data or be successfully developed into products that are marketed and sold;
- the strategic direction of the combined company following the completion of the Merger, which will be determined by a board of directors initially comprised of six directors designated by Tvardi and one director designated by Cara;
- the restrictions in the Merger Agreement on the conduct of Cara's business prior to the consummation of the Merger, which may delay or prevent Cara from undertaking business opportunities that may arise prior to the consummation of the Merger; and
- various other risks associated with the combined company and the Merger, including those described in the section titled "Risk Factors" beginning on page <u>25</u> of this proxy statement/prospectus.

The foregoing information and reasons considered by the Cara Board are the material factors considered by the Cara Board. In view of the wide variety of reasons considered in connection with its evaluation of the Merger and the complexity of these matters, the Cara Board did not find it useful to attempt, and did not attempt, to quantify, rank or otherwise assign relative weights to these reasons. In considering the reasons described above, individual members of the Cara Board may have given different weight to different reasons. The Cara Board conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, Cara's management team and the legal and financial advisors of Cara, and considered the reasons overall to be favorable to, and to support, its determination. In arriving at their respective recommendations, the members of the Cara Board considered the interests of Cara's executive officers and directors as described under the caption "*The Merger* — *Interests of the Cara Directors and Executive Officers in the Merger*".

Opinion of Cara's Financial Advisor

Piper Sandler was retained by the Cara Board to act as its financial advisor on July 10, 2024, in connection with Cara's subsequent announcement of its exploration of a range of strategic alternatives.

On December 17, 2024, Piper Sandler rendered its oral opinion to the Cara Board (which was subsequently confirmed in writing by delivery of Piper Sandler's written opinion dated December 17, 2024) to the effect that, as of such date and based upon and subject to the various assumptions made, procedures followed, matters considered, and qualifications and limitations upon the review undertaken by Piper Sandler in preparing its opinion, the Exchange Ratio (without giving effect to the Reverse Stock Split) was fair, from a financial point of view, to Cara (the Piper Sandler Opinion).

The full text of the written opinion is attached to this proxy statement/prospectus as Annex B and is incorporated into this proxy statement/prospectus by reference. The description of the Piper Sandler Opinion set forth in this proxy statement/prospectus is qualified in its entirety by reference to the full text of the written opinion. Cara stockholders are urged to read the written opinion carefully and in its entirety for a discussion of the assumptions made, procedures followed, matters considered, and qualifications and limitations upon the review undertaken by Piper Sandler in preparing the Piper Sandler Opinion. The Piper Sandler Opinion was prepared at the request of, and furnished solely to, the Cara Board (in the Cara Board members' individual capacities as directors and not in any other capacity) for its information and assistance in connection with its consideration of the financial terms of the Merger, and was only one of many factors considered by the Cara Board in its evaluation of the Merger. Further, the Piper Sandler Opinion only addresses the fairness, from a financial point of view as of the date thereof, to Cara of the Exchange Ratio (without giving effect to the



Reverse Stock Split). The Piper Sandler Opinion did not address, among other things, (i) any other terms or agreements relating to the Merger or any other terms of the Merger Agreement, (ii) the relative merits of the Merger as compared to other transactions or strategies that might be available to Cara, or (iii) the underlying business decision of Cara to proceed with the Merger. The Piper Sandler Opinion was not intended to, and does not, constitute a recommendation to the Cara Board, Cara, any security holder of Cara, or any other party as to how to vote or otherwise act with respect to the Merger or any other matter relating thereto.

In connection with Piper Sandler's review of the Merger, and in arriving at the Piper Sandler Opinion, Piper Sandler:

- reviewed and analyzed the financial terms of a draft of the Merger Agreement dated December 15, 2024;
- reviewed certain financial and other data with respect to Cara which was publicly available;
- reviewed and analyzed certain information regarding Cara furnished to Piper Sandler by management
 of Cara, including financial forecasts relating to the estimated cash expenditures and receipts of Cara
 from October 31, 2024 through March 31, 2025, estimated balance sheet data with respect to the cash
 and debt positions of Cara as of November 30, 2024, and a liquidation analysis of Cara prepared by
 management of Cara, dated as of December 6, 2024 (the Management Liquidation Analysis);
- reviewed and analyzed certain information regarding Tvardi furnished to Piper Sandler by management of Cara, including balance sheet data with respect to the cash and debt positions of Tvardi as of November 30, 2024 and quarterly financial forecasts relating to the business, earnings, cash flows, and prospects of Tvardi from December 31, 2024 through December 31, 2026;
- conducted discussions with members of senior management and representatives of each of Cara and Tvardi concerning the matters described in the second, third, and fourth bullets above, as well as Cara's business and prospects before and after giving effect to the Merger;
- reviewed the current and historical reported prices and trading activity of Cara common stock;
- compared the business profile of Tvardi to the business profile of certain other companies, the securities of which are publicly traded, that were deemed by Piper Sandler to be comparable to Tvardi for purposes of the Piper Sandler Opinion; and
- reviewed the valuations of certain companies implied by the pricing of such companies' initial public offerings which companies were deemed by Piper Sandler to be comparable to Tvardi for purposes of the Piper Sandler Opinion.

In addition, Piper Sandler conducted such other analyses, examinations and inquiries and considered such other financial, economic and market criteria as Piper Sandler deemed necessary in arriving at the Piper Sandler Opinion.

Piper Sandler relied upon and assumed, without assuming liability or responsibility for independent verification, the accuracy and completeness of all information that was publicly available or was furnished, or otherwise made available, to Piper Sandler or discussed with or reviewed by Piper Sandler. Piper Sandler further relied upon the assurances of management of Cara that the financial information provided was prepared on a reasonable basis in accordance with industry practice, and that management of Cara was not aware of any information or facts that would make any information provided to Piper Sandler Opinion, Piper Sandler assumed, with respect to financial forecasts, estimates (including with respect to the estimated cash expenditures) and other forward-looking information, that such financial forecasts, estimates and forward-looking information were reasonably prepared based on assumptions reflecting the best currently available estimates and judgments of the managements of Cara and Tvardi, as applicable. Further, Piper Sandler expressed no opinion as to any such financial forecasts, estimates or forward-looking information or the assumptions on which they were based.

In addition, the Piper Sandler Opinion and the underlying analyses relating thereto were, with the Cara Board's knowledge and approval, based upon the following additional key assumptions: (i) the estimated

amount of Cara Net Cash at Closing, as provided to Piper Sandler by management of Cara, would not result in an adjustment to the Exchange Ratio; (ii) the Reverse Stock Split would not be completed as of the Effective Time; (iii) the Management Liquidation Analysis was reasonably prepared in good faith based on assumptions reflecting the best currently available estimates and judgments of management of Cara as to (a) the expected realizable value for Cara's assets, assuming an orderly liquidation of such assts, and (b) the remaining amounts estimated to be available upon completion of such liquidation for distribution to Cara's equity holders; (iv) immediately prior to the Effective Time, the fully diluted outstanding shares of Cara common stock (calculated using the treasury stock method and taking into account outstanding in the money options and restricted stock units) would be approximately 56.076 million and the fully diluted outstanding shares of Tvardi common stock would be approximately 54.204 million, as provided to Piper Sandler by management of Cara; and (v) the pro forma ownership of Cara, immediately following the Effective Time, assuming completion of (Y) the Preferred Stock Conversion and the Bridge Note Conversion and (Z) the conversion of all other instruments convertible into Tvardi common stock, but without giving effect to the Reverse Stock Split, would be 15.25% held by the holders of Cara common stock immediately prior to the Effective Time and 84.75% by the holders of Tvardi common stock (including, for this purpose, the holders of Bridge Notes) immediately prior to the Effective Time as provided to Piper Sandler by management of Cara.

Piper Sandler expressed no view or opinion with respect to the Management Liquidation Analysis or the assumptions on which it is based. With the Cara Board's knowledge and approval, Piper Sandler did not analyze, or otherwise consider the effect of the Reverse Stock Split on the Exchange Ratio as of the Effective Time.

Piper Sandler further assumed that the Merger would have the tax consequences described in the Merger Agreement. Piper Sandler relied, with the Cara Board's knowledge and approval, on the conclusions of the outside counsel and the independent accountants to Cara, and on the assumptions of management of Cara as to all accounting, legal, tax and financial reporting matters with respect to the Cara, Tvardi, and the Merger Agreement.

In arriving at the Piper Sandler Opinion, Piper Sandler assumed that the executed Merger Agreement would be, in all material respects, identical to the last draft reviewed by Piper Sandler. Piper Sandler relied upon and assumed, without independent verification, that (i) the representations and warranties of all parties to the Merger Agreement and all other related documents and instruments that are referred to therein were true and correct; (ii) each party to such agreements would fully and timely perform all of the covenants and agreements required to be performed by such party; (iii) the Merger would be consummated pursuant to the terms of the Merger Agreement without amendments thereto; and (iv) all conditions to the consummation of the Merger would be satisfied without waiver by any party of any conditions or obligations thereunder. Additionally, Piper Sandler assumed that all the necessary regulatory approvals and consents required for the Merger would be obtained in a manner that would not adversely affect Cara, Tvardi, or the contemplated benefits of the Merger.

In arriving at the Piper Sandler Opinion, (i) Piper Sandler did not perform a discounted cash flow analysis of Cara or Tvardi because managements of Cara and Tvardi advised Piper Sandler that neither Cara nor Tvardi had, or could reasonably be expected to prepare, current and reliable financial forecasts regarding Cara's or Tvardi's future financial performance, in each case, for a sufficient period of time that would allow Piper Sandler to perform a discounted cash flow analysis, (ii) Piper Sandler did not perform an analysis of precedent merger transactions with publicly available financial terms, because Piper Sandler did not identify a sufficient number of transactions that Piper Sandler deemed to be comparable to the Merger, and (iii) with respect to Cara, Piper Sandler did not perform an analysis of companies with publicly traded equity securities that Piper Sandler deemed comparable to Cara, because Piper Sandler did not identify a sufficient number of publicly traded companies that Piper Sandler deemed to be sufficiently comparable to Cara.

In addition, in arriving at the Piper Sandler Opinion, Piper Sandler did not perform any appraisals or valuations of any specific assets or liabilities (fixed, contingent or other) of Cara or Tvardi, and Piper Sandler was not furnished or provided with any such appraisals or valuations, nor did Piper Sandler evaluate the solvency of Cara or Tvardi under any state or federal law relating to bankruptcy, insolvency or similar matters. The analyses performed by Piper Sandler with respect to Tvardi in connection with the Piper Sandler

Opinion were going concern analyses. Piper Sandler expressed no view or opinion regarding the liquidation value of Cara, Tvardi, or any other entity. Without limiting the generality of the foregoing, Piper Sandler undertook no independent analysis of any pending or threatened litigation, regulatory action, possible unasserted claims or other contingent liabilities to which Cara, Tvardi, or any of their respective affiliates was a party or may have been subject, and the Piper Sandler Opinion made no assumption concerning, and therefore did not consider, the possible assertion of claims, outcomes or damages arising out of any such matters. Piper Sandler also assumed, based on information furnished to Piper Sandler by management of Cara and management of Tvardi, that neither Cara nor Tvardi was party to any material pending transaction, including without limitation any financing, recapitalization, acquisition or merger, or divestiture or spin-off, other than the Merger, the Bridge Notes financing, the Asset Disposition, and the Reverse Stock Split.

No company or transaction used in any analysis for purposes of comparison is identical to Cara, Tvardi, or the Merger. Accordingly, an analysis of the results of the comparisons is not mathematical; rather, it involves complex considerations and judgments about differences in the companies and transactions to which Cara, Tvardi, and the Merger were compared and other factors that could affect the public trading value or transaction value of the companies.

The Piper Sandler Opinion was necessarily based upon the information available to Piper Sandler and facts and circumstances as they existed and were subject to evaluation on the date thereof; events occurring after the date thereof could materially affect the assumptions used in preparing the Piper Sandler Opinion. Piper Sandler did not express any opinion in the Piper Sandler Opinion as to the price at which shares of Cara common stock may trade following announcement of the Merger or at any future time. Piper Sandler has not undertaken to reaffirm or revise the Piper Sandler Opinion or otherwise comment upon any events occurring after the date of the Piper Sandler Opinion, and does not have any obligation to update, revise or reaffirm the Piper Sandler Opinion.

The Piper Sandler Opinion was provided solely to the Cara Board (in the Board members' individual capacities as directors and not in any other capacity) in connection with, and solely for purposes of, the Cara Board's consideration of the Merger and was not intended to, and does not, constitute a recommendation to the Cara Board, Cara, any security holder of Cara, or any other party as to how to act or vote with respect to the Merger or any matter relating thereto. The Piper Sandler Opinion may not be disclosed, referred to, published or otherwise used (in whole or in part), and no public references to Piper Sandler may be made without the prior written consent of Piper Sandler, which consent was obtained for the purpose of the inclusion of the Piper Sandler Opinion and the summary thereof in this proxy statement/prospectus. The Piper Sandler Opinion was approved for issuance by the Piper Sandler Opinion Committee.

The Piper Sandler Opinion addresses solely the fairness, from a financial point of view, to Cara of the Exchange Ratio (without giving effect to the Reverse Stock Split) and did not address any other terms or agreement relating to the Merger or any other terms of the Merger Agreement. Piper Sandler was not requested to opine as to, and the Piper Sandler Opinion did not address: (i) the basic business decision to proceed with or effect the Merger; (ii) the merits of the Merger relative to any alternative transaction or business strategy that may have been or may be available to Cara; (iii) the fairness of any portion or aspect of the Merger (or of the Bridge Notes financing or the Reverse Stock Split) to any one class or group of Cara's or Tvardi's or any other party's security holders or other constituents vis-à-vis any other class or group of Cara's, Tvardi's or such other party's security holders or other constituents (including, without limitation, the allocation of any consideration amongst or within such classes or groups of security holders or other constituents), (iv) any other terms contemplated by the Merger Agreement (or the agreements entered into in connection with the Bridge Notes financing or the Reverse Stock Split) or the fairness of the Merger to any creditor or other constituency of Cara; (v) whether or not Cara, Tvardi, their respective security holders or any other party is receiving or paying reasonably equivalent value in the Merger (or with respect to the Bridge Notes financing or the Reverse Stock Split); or (vi) the solvency or financial viability of Cara or Tvardi at the date of the Piper Sandler Opinion, upon consummation of the Merger, or at any future time. Furthermore, Piper Sandler expressed no opinion with respect to the amount or nature of compensation to any officer, director or employee of any party to the Merger, or any class of such persons, relative to the Merger Consideration to be paid by Cara in the Merger or with respect to the fairness of any such compensation, including whether such payments were reasonable in the context of the Merger.

Summary of Piper Sandler's Financial Analysis

The following is a summary of the material financial analyses prepared by Piper Sandler and reviewed with the Cara Board in connection with the Piper Sandler Opinion. The summary set forth below does not purport to be a complete description of the financial analyses performed by or factors considered by Piper Sandler, or underlying the Piper Sandler Opinion, nor does the order of the financial analyses described represent the relative importance or weight given to those financial analyses by Piper Sandler. Piper Sandler may have deemed various assumptions more or less probable than other assumptions, so the reference ranges resulting from any particular portion of the analyses summarized below should not be understood as Piper Sandler's view of the actual value, whether enterprise, equity, or otherwise, of Cara or Tvardi. Some of the summaries of the financial analyses set forth below include information presented in tabular format. In order to fully understand the financial analyses, the tables must be read together with the text of each summary, as the tables alone do not constitute a complete description of the financial analyses or factors or the full narrative description of such analyses or factors, including the methodologies and assumptions underlying such analyses or factors, could create a misleading or incomplete view of the processes underlying Piper Sandler's financial analyses and the Piper Sandler Opinion.

In performing its analyses, Piper Sandler made numerous assumptions with respect to industry performance, general business and economic conditions and other matters, many of which are beyond the control of Cara, Tvardi, or any other party to the Merger. None of Cara, Tvardi, or Piper Sandler or any other person assumes responsibility if future results are materially different from those discussed. Any estimates contained in these analyses are not necessarily indicative of actual values or predictive of future results or values, which may be significantly more or less favorable than the results as set forth below. In addition, analyses relating to the value of Cara and Tvardi do not purport to be appraisals or reflect the prices at which Cara or Tvardi may actually be sold. Accordingly, the assumptions and estimates used in, and the results derived or calculated from, the financial analyses are inherently subject to substantial uncertainty. Except as otherwise noted, the following quantitative information, to the extent that it is based on market data, is based on market data as it existed on or before December 16, 2024 (the last business day immediately preceding the day on which Piper Sandler delivered its oral opinion) and is not necessarily indicative of current market conditions.

Cara Intrinsic Valuation

Piper Sandler reviewed, among other things, the current (as of December 16, 2024) market capitalization, enterprise valuations, cash balances, and projected closing cash balances of Cara.

The review indicated, among other things, that, as of December 16, 2024, (i) the closing price per share of Cara common stock was \$0.26 (the Cara Nasdaq Closing Price Per Share) and (ii) Cara had (a) approximately 55.8 million shares of Cara common stock outstanding (using the treasury stock method and taking into account outstanding in the money options and restricted stock units), (b) \$39.5 million of estimated cash and cash equivalents as of November 30, 2024, (c) a current implied enterprise value of approximately \$(25.1) million, and (d) estimated net cash and cash equivalents as of the consummation of the Merger of approximately \$23.2 million (such estimated net cash and cash equivalents hereinafter referred to as, the Cara Intrinsic Value).

References below to the Cara Intrinsic Value Per Share refers to \$0.42, equal to the Cara Intrinsic Value divided by approximately 55.8 million shares of Cara common stock outstanding (using the treasury stock method and taking into account outstanding in the money options and restricted stock units).

Management Liquidation Analysis

Piper Sandler reviewed and considered the Management Liquidation Analysis, as prepared by management of Cara, as of December 6, 2024. Piper Sandler noted that the estimates of the future cash distributions to Cara's stockholders, after applying discount rates selected by management of Cara based on the expected hypothetical distribution dates and using the interest rates of U.S. Treasury bills and notes having similar durations, resulted in an implied equity value of \$29.6 million for Cara, implying a value of \$0.53 per share of Cara common stock (the Cara Liquidation Value Per Share).

For additional information on the Management Liquidation Analysis, see the section titled "*The Merger* — *Management Liquidation Analysis*" on page <u>125</u> of this proxy statement/prospectus.

Exchange Ratio & Assumptions; Cara Post-Merger Ownership

At the direction of management of Cara, Piper Sandler assumed, for purposes of its financial analyses and the Piper Sandler Opinion, that the Exchange Ratio would be equal to 4.8997 shares of Cara common stock for each share of Tvardi common stock, as determined pursuant to the terms of the Merger Agreement. This assumption was based, in part, on the following assumptions: (i) the Bridge Note Conversion and the Preferred Stock Conversion would occur prior to, or simultaneously with, the Closing, (ii) the Reverse Stock Split would not occur prior to the Closing, (iii) the Cara Net Cash at Closing would be within a range which would not result in an adjustment to the Exchange Ratio, (iv) Cara had a valuation of \$43.0 million (implying Cara common stock had a value per share of approximately \$0.77) (the Cara Deal Value Per Share), and (v) Tvardi had a valuation of \$210.0 million.

Based on the Exchange Ratio as calculated above, immediately following the consummation of the Merger, (a) holders of Cara common stock as of immediately prior to the Merger would own approximately 15.25% of the fully-diluted shares of Cara common stock (such ownership percentage, the Cara Post-Merger Ownership Percentage), and (b) holders of Tvardi common stock as of immediately prior to the Merger (including, for this purpose, the holders of Bridge Notes on an as-converted basis) would own approximately 84.75% of the fully-diluted shares of Cara common stock, in each case, subject to adjustment of the Exchange Ratio (other than with respect to the Reverse Stock Split) as set forth in the Merger Agreement.

Financial Analyses

Selected Public Companies Analysis

Piper Sandler reviewed certain financial and other data for selected companies with publicly traded securities which Piper Sandler deemed to be comparable to Tvardi for purposes of this analysis (each, a Tvardi Public Company Comparable). The Tvardi Public Company Comparables were selected, among other reasons, because such companies (i) had (a) a lead asset focused on idiopathic pulmonary fibrosis (IPF), (b) a single clinical-stage asset in Phase 2 (ready or ongoing) for inflammation & immunology indication(s), or (c) a single clinical-stage asset in Phase 2 (ready or ongoing) for solid tumor indication(s) without a technology platform that could generate multiple assets and excluding cell therapies, (ii) had an asset in development for no more than three indications, and (iii) were U.S.-based or U.S.-exchange-listed companies. None of the Tvardi Public Company Comparables reviewed is identical to Tvardi, and certain of the Tvardi Public Company Comparables have financial and operating characteristics that are materially different from those of Tvardi.

The analyses necessarily involve complex considerations and judgments concerning differences in financial and operational characteristics of the Tvardi Public Company Comparables as well as other factors that could affect the Tvardi Public Company Comparables differently from how they would affect Tvardi.

Set forth below are the Tvardi Public Company Comparables, as well as such companies' targeted lead treatment indications and stages of development:

Tvardi Public Company Comparable	Lead Treatment Indication	Stage of Development
Selected Idiopathic Pulmonary Fibrosis (IPF) Companies		
Pliant Therapeutics, Inc.	IPF	Phase 2b
Contineum Therapeutics, Inc.	IPF	Phase 1b
Trevi Therapeutics, Inc.	IPF	Phase 2b
Aileron Therapeutics, Inc.	IPF	Phase 1b
Vicore Pharma Holding ⁽¹⁾	IPF	Phase 2b

Tvardi Public Company Comparable	Lead Treatment Indication	Stage of Development
Selected Inflammation and Immunology (I&I) Compa	inies	
Upstream Bio, Inc.	Severe Asthma	Phase 2
Dianthus Therapeutics, Inc. ⁽²⁾	Generalized Myasthenia Gravis	Phase 2
Tourmaline Bio, Inc.	Thyroid Eye Disease	Phase 2b
Selected Oncology (Solid Tumors) Companies		
Black Diamond Therapeutics, Inc.	2L/3L Non-Small Cell Lung Cancer	Phase 2
Leap Therapeutics, Inc. ⁽³⁾	Gastric Cancer	Phase 2
Protara Therapeutics, Inc. ⁽⁴⁾	Non-Muscle Invasive Bladder Cancer	Phase 2
PMV Pharmaceuticals, Inc	Advanced Solid Tumors	Phase 2

⁽¹⁾ Vicore Pharma Holding is listed on the Stockholm Stock Exchange, but was included in the analysis based on Piper Sandler's industry knowledge and judgment.

- (2) Dianthus Therapeutics, Inc. is in Phase 2 for its lead program, as per its November 2024 corporate presentation, despite also having a Phase 3-ready program.
- (3) Leap Therapeutics, Inc. has two clinical-stage assets, but was included in the analysis based on Piper Sandler's industry knowledge and judgment.
- (4) Protara Therapeutics, Inc. is in Phase 2 for its lead program, as per its website, despite also having a Phase 3-ready program.

For each Tvardi Public Company Comparable, Piper Sandler reviewed its current (i) diluted market capitalization, calculated as the aggregate value of such Tvardi Public Company Comparable's outstanding equity securities (determined using the treasury stock method and taking into account any outstanding inthe-money options, in-the-money warrants, restricted stock units and other potentially dilutive securities), based on the closing stock price of its common stock as of December 16, 2024, and (ii) implied enterprise value. The implied enterprise values were calculated as diluted market capitalization, as described in the immediately preceding sentence, plus such Tvardi Public Company Comparable's net debt (equal to the book value of such company's debt less its cash and cash equivalents), plus its preferred stock and minority interests, and less its short-term and long-term investments, in each case, as of such company's most recent reported quarter-end.

The analyses indicated the following maximum, 75th percentile, mean, median, 25th percentile and minimum diluted market capitalization and implied enterprise values of the Tvardi Public Company Comparables:

(\$ in millions)	Diluted Market Capitalization of the Tvardi Public Company Comparables	Implied Enterprise Value of the Tvardi Public Company Comparables
Maximum	\$1,106.3	\$616.9
75th Percentile	\$ 661.6	\$437.2
Mean	\$ 428.2	\$217.0
Median	\$ 292.6	\$108.4
25th Percentile	\$ 143.3	\$ 49.6
Minimum	\$ 71.9	(\$115.8)

For the Selected Public Companies Analysis, Piper Sandler calculated a range of implied equity values for Tvardi based on the range of implied enterprise values for the Tvardi Public Company Comparables and then adjusted for Tvardi's net cash and cash equivalents (as of November 30, 2024).

(§ in millions)Implied Equity
Value of TvardiMaximum\$622.975th Percentile\$443.2Mean\$223.0Median\$114.425th Percentile\$ 55.6Minimum(\$109.8)

The resulting range of implied equity values for Tvardi is shown in the table below.

Selected Public Companies Analysis — Exchange Ratio Analysis

Piper Sandler then calculated a range of implied exchange ratios by applying the calculations described in the definition of "Exchange Ratio" set forth in the Merger Agreement, based on (i) the implied equity values of Tvardi and (ii) the Cara Intrinsic Value.

The range of implied exchange ratios, and the corresponding implied ownership percentage that holders of Cara common stock prior to the Merger would have in the implied post-merger company are set forth in the table below.

	25th			75th		
	Minimum	Percentile	Median	Mean	Percentile	Maximum
Implied Exchange Ratio	NM	2.2486x	4.8245x	9.6242x	19.3855x	27.3633x
Implied Ownership Percentage of Cara stockholders in the Post-Merger						
Company	NM	21.5%	13.9%	8.4%	4.7%	3.4%

Piper Sandler then compared the range of the implied exchange ratios and the range of implied ownership percentages that holders of Cara common stock immediately prior to the Merger would have in the implied post-merger company, each set forth in the table above, to the Exchange Ratio (4.8997x) and the Cara Post-Merger Ownership Percentage (15.25%), respectively.

Selected Public Companies Analysis — Implied Price per Share

Piper Sandler then calculated, (i) in each case, after giving effect to the Bridge Note Conversion, (A) a range of implied aggregate valuations of Tvardi, assuming the range of implied equity values of Tvardi set forth in the table above and (B) a corresponding range of the implied shares of Tvardi common stock outstanding immediately prior to the Merger and (ii) a range of implied values per share of Tvardi common stock (equal to the preceding (i)(A) divided by the preceding (i)(B)).

Piper Sandler then divided the resulting range of implied values per share of Tvardi common stock by the Exchange Ratio, resulting in a range of implied values per share of Cara common stock.

The range of implied values per share of Tvardi common stock and the range of implied values per share of Cara common stock are set forth in the table below.

	Minimum	25th Percentile	Median	Mean	75th Percentile	Maximum
Implied Values Per Share of Tvardi Common						
Stock	NM	\$0.93	\$2.00	\$4.00	\$8.05	\$11.37
Implied Values Per Share of Cara Common						
Stock	NM	\$0.19	\$0.41	\$0.82	\$1.64	\$ 2.32

Piper Sandler then compared the range of implied values per share of Cara common stock set forth in the table above to the Cara Deal Value Per Share (\$0.77), the Cara Liquidation Value Per Share (\$0.53), the Cara Intrinsic Value Per Share (\$0.42), and the Cara Nasdaq Closing Price Per Share (\$0.26).

Selected IPO Analysis

Piper Sandler reviewed certain financial data of U.S.-listed companies that completed an initial public offering (referred to as an IPO) of common stock since January 1, 2020 (each, a Tvardi IPO Comparable Company), which Piper Sandler judged to be comparable to Tvardi for purposes of this analysis. The Tvardi IPO Comparable Companies were selected, among other reasons, because, at the time of the IPO, such companies (i) had a single clinical-stage (non-oncology) asset with an ongoing Phase 2 trial or a completed Phase 1 trial or (B) were development stage companies (regardless of phase of development) with the lead asset targeting IPF. None of the Tvardi IPO Comparable Companies reviewed is identical to Tvardi, and certain of the Tvardi IPO Comparable Companies have financial and operating characteristics that are materially different from those of Tvardi.

The analyses necessarily involve complex considerations and judgments concerning differences in financial and operational characteristics of the Tvardi IPO Comparable Companies, as well as other factors that could affect the Tvardi IPO Comparable Companies differently from how they would affect Tvardi.

Set forth below are the Tvardi IPO Comparable Companies, as well as such companies' targeted lead treatment indications, stage of development, and IPO pricing dates:

Tvardi IPO Comparable Company	Lead Treatment Indication	Stage of Development	IPO Pricing Date
Single Clinical-Stage (Non-Oncology) Asse			
Upstream Bio, Inc.	Severe asthma	Phase 2	10/10/2024
HilleVax, Inc.	Norovirus vaccine	Phase 2b	04/28/2022
CinCor Pharma, Inc.	Hypertension	Phase 2	01/06/2022
Vera Therapeutics, Inc.	Immunoglobulin A nephropathy	Phase 2b	05/13/2021
Reneo Pharmaceuticals, Inc.	Primary mitochondrial myopathies	Phase 2b	04/08/2021
Spruce Biosciences, Inc.	Classic congenital adrenal hyperplasia	Phase 2b	10/08/2020
Graybug Vision, Inc.	Wet AMD	Phase 2b	09/24/2020
COMPASS Pathways plc	Treatment-resistant depression	Phase 2b	09/17/2020
Athira Pharma, Inc.	Alzheimer's disease	Phase 2/3	09/17/2020
Lyra Therapeutics, Inc.	Chronic rhinosinusitis	Phase 2	04/30/2020
IMARA Inc.	Sickle cell disease	Phase 2a	03/11/2020
Lead Asset Targeting Idiopathic Pulmona			
Contineum Therapeutics, Inc.	IPF	Phase 1b	04/04/2024
Galecto, Inc.	IPF	Phase 2b	10/28/2020
Pliant Therapeutics, Inc.	IPF	Phase 2a	06/02/2020

For each Tvardi IPO Comparable Company, Piper Sandler reviewed (i) its implied diluted pre-money equity value, based on the offering price of such Tvardi IPO Comparable Company's shares in its IPO and the number of such Tvardi IPO Comparable Company's diluted shares outstanding prior to its IPO, excluding any shares being issued in such Tvardi IPO Comparable Company's IPO (using the treasury stock method) (referred to herein as the Diluted Pre-Money Equity Value), and (ii) its implied diluted pre-money enterprise value, calculated as the Diluted Pre-Money Equity Value, plus net debt (calculated as the book value of such company's debt less its cash and cash equivalents), plus any preferred stock and minority interests, and less any short-term and long-term investments, as reported in the effective registration statement of the IPO of each Tvardi IPO Comparable Company (referred to herein as the Diluted Pre-Money Enterprise Value).

The analysis indicated the following maximum, 75th percentile, mean, median, 25th percentile and minimum Diluted Pre-Money Equity Values and Diluted Pre-Money Enterprise Values for the Tvardi IPO Comparable Companies:

(\$ in millions)	Diluted Pre-Money Equity Value	Diluted Pre-Money Enterprise Value
Maximum	\$693.0	\$471.9
75th Percentile	\$421.7	\$271.3
Mean	\$348.9	\$256.3
Median	\$314.6	\$248.2
25th Percentile	\$266.8	\$195.4
Minimum	\$150.8	\$115.5

For the Selected IPO analysis, Piper Sandler calculated a range of implied equity values for Tvardi based on the range of the Diluted Pre-Money Enterprise Values for the Tvardi IPO Comparable Companies and then adjusted for Tvardi's net cash and cash equivalents (as of November 30, 2024).

The resulting range of implied equity values for Tvardi is shown in the table below.

(\$ in millions)	Implied Equity Value of Tvardi
Maximum	\$477.9
75th Percentile	\$277.3
Mean	\$262.3
Median	\$254.2
25th Percentile	\$201.4
Minimum	\$121.5

Selected IPO Analysis — Exchange Ratio Analysis

Piper Sandler then calculated a range of implied exchange ratios by applying the calculations described in the definition of "Exchange Ratio" set forth in the Merger Agreement, based on (i) the implied equity values of Tvardi and (ii) the Cara Intrinsic Value.

The range of implied exchange ratios, and the corresponding implied ownership percentage that holders of Cara common stock prior to the Merger would have in the implied post-merger company are set forth in the table below.

	Minimum	25th Percentile	Median	Mean	75th Percentile	Maximum
Implied Exchange Ratio	5.1384x	8.6676x	11.0046x	11.3636x	12.0294x	20.9255x
Ownership Percentage of Cara stockholders in the Implied Post-						
Merger Company	13.3%	9.1%	7.6%	7.4%	7.0%	4.4%

Piper Sandler then compared the range of the implied exchange ratios and the range of implied ownership percentages that holders of Cara common stock immediately prior to the Merger would have in the implied post-merger company, each set forth in the table above, to the Exchange Ratio (4.8997x) and the Cara Post-Merger Ownership Percentage (15.25%), respectively.

Selected IPO Analysis — Implied Price per Share

Piper Sandler then calculated, (i) in each case, after giving effect to the Bridge Note Conversion, (A) an implied aggregate valuation of Tvardi assuming the range of implied equity values of Tvardi and (B) an

implied number of shares of Tvardi common stock outstanding immediately prior to the Merger and (ii) an implied value per share of Tvardi common stock (equal to the preceding (i)(A) divided by the preceding (i) (B).

Piper Sandler then divided the resulting range of implied values per share of Tvardi common stock by the Exchange Ratio, resulting in a range of implied value per share of Cara common stock.

The range of implied value per share of Tvardi common stock and the range of implied value per share of Cara common stock are set forth in the table below.

	Minimum	25th Percentile	Median	Mean	75th Percentile	Maximum
Implied Value Per Share of Tvardi Common Stock	\$2.13	\$3.60	\$4.57	\$4.72	\$5.00	\$8.69
Implied Value Per Share of Cara Common Stock	\$0.44	\$0.73	\$0.93	\$0.96	\$1.02	\$1.77

Piper Sandler then compared the range of implied values per share of Cara common stock set forth in the table above to the Cara Deal Value Per Share (\$0.77), the Cara Liquidation Value Per Share (\$0.53), the Cara Intrinsic Value Per Share (\$0.42), and the Cara Nasdaq Closing Price Per Share (\$0.26).

Other Information

Piper Sandler also noted for the Cara Board the following additional information that was not relied upon by Piper Sandler in rendering the Piper Sandler Opinion, but which was provided to the Cara Board for informational purposes.

- *Historical Trading Analysis.* Piper Sandler provided the historical closing prices for the shares of Cara common stock over the one-year period ended December 16, 2024, which reflected low and high closing prices during such period, ranging from \$0.24 to \$1.23 per share of Cara common stock, respectively.
- Selected Precedent M&A Transactions. Piper Sandler considered certain financial terms of certain M&A transactions entered into since January 1, 2020 involving target companies that Piper Sandler deemed relevant. The illustrative M&A transactions were selected because they involved target companies that were, based on Piper Sandler's experience and judgment, deemed by Piper Sandler to be comparable to Tvardi in one or more respects, and included U.S.-based biopharmaceutical companies with a single clinical-stage asset in Phase 2 (ready or ongoing), excluding platform companies and only including transactions where the financial terms were fully disclosed. No specific numeric or other similar criteria were used to select the selected precedent M&A transactions, and all criteria were evaluated in their entirety without application of definitive qualifications or limitations to individual criteria. The financial data reviewed included overall transaction value, the value of upfront consideration payable on closing of the transactions were calculated using the enterprise value for public targets and the publicly disclosed transaction value for private targets. Piper Sandler then compared such transaction values of the selected precedent M&A transactions to the Tvardi attributed valuation.
- Selected Precedent Reverse Merger Transactions. Piper Sandler considered certain financial terms, to the extent the information was publicly available, of biopharmaceutical reverse merger transactions since January 2019. Piper calculated the range of values delivered for the public company from the selected precedent reverse merger transactions in excess of such public company's net cash, and compared such range to the value delivered for Cara in excess of Cara's net cash.

General

The preparation of a financial opinion is a complex analytical process involving various determinations as to the most appropriate and relevant methods of financial analysis and the application of those methods to the particular circumstances. Therefore, a financial opinion is not readily susceptible to summary description. In arriving at the Piper Sandler Opinion, Piper Sandler did not draw, in isolation, conclusions

from, or with regard to, any factor or analysis that it considered. Rather, Piper Sandler made its determination as to fairness on the basis of its experience and professional judgment, after considering the results of all of the analyses.

Piper Sandler's financial analyses and the Piper Sandler Opinion were only one of many factors taken into consideration by the Cara Board in its evaluation of the Merger. Consequently, the analyses described above should not be viewed as determinative of the views of the Cara Board or management of Cara with respect to the Exchange Ratio or as to whether the Cara Board would have been willing to determine that a different exchange ratio was fair. The Exchange Ratio was determined through arm's-length negotiations between the Cara Board and Tvardi and was approved by the Cara Board.

The Cara Board selected Piper Sandler as its financial advisor in connection with the Merger based on, among other factors, its qualifications, professional reputation, and industry expertise. Piper Sandler is an internationally recognized investment banking firm that has substantial experience in transactions similar to the Merger.

In connection with Piper Sandler's services as the financial advisor to the Cara Board, Cara agreed to pay Piper Sandler a fee of \$2,500,000, which is contingent upon consummation of the Merger (the Success Fee) and a fee of \$500,000 (the Opinion Fee), which was earned by Piper Sandler upon delivery of the Piper Sandler Opinion. The payment of the Opinion Fee was not contingent upon consummation of the Merger or the conclusions reached in the Piper Sandler Opinion and is fully creditable against the Success Fee. Cara also agreed to indemnify Piper Sandler against certain liabilities and reimburse Piper Sandler for certain expenses in connection with Piper Sandler's services. In addition, based on Piper Sandler's customary conflicts-related clearance procedures, Piper Sandler informed Cara management on November 21, 2024 that, since January 1, 2022, Piper Sandler had no material relationships (other than with respect to a proposed financing which was later abandoned) with, and had not received any fees for investment banking services from, any of Cara, Tvardi, or their respective affiliates.

Piper Sandler is a securities firm engaged in securities trading and brokerage activities and providing investment banking and financial advisory services. Piper Sandler may, in the future, provide investment banking and financial advisory services to Cara (and any of its affiliates) for which Piper Sandler would expect to receive compensation. In addition, in the ordinary course of its business, Piper Sandler and its affiliates may actively trade securities of Cara for its own account or the account of its customers and, accordingly, may at any time hold a long or short position in such securities.

Consistent with applicable legal and regulatory requirements, Piper Sandler has adopted policies and procedures to establish and maintain the independence of Piper Sandler's research department and personnel. As a result, Piper Sandler's research analysts may hold opinions, make statements or investment recommendations and/or publish research reports with respect to the Merger and other participants in the Merger that differ from the opinions of Piper Sandler's investment banking personnel.

Management Liquidation Analysis

Cara generally does not prepare liquidation analyses as it has operated as a going concern. However, in connection with the Cara Board's evaluation of strategic alternatives, including the Merger, Cara's management prepared a non-public, internal unaudited financial analysis of a hypothetical liquidation of Cara (the Management Liquidation Analysis), which was shared with the Cara Board. The Management Liquidation Analysis of the value that may be realized in a hypothetical liquidation of Cara as an alternative to pursuing the Merger. This analysis does not, therefore, give effect to the Merger.

Cara has included below a summary of the Management Liquidation Analysis. In preparing this analysis, Cara's management considered a number of factors. Cara's management also provided the liquidation analysis to Piper Sandler and approved the liquidation analysis for Piper Sandler's use in connection with their financial analysis and fairness opinion. The summary of this analysis is not being included in this proxy statement/prospectus to influence a Cara stockholder's decision whether to vote for or against the proposal to approve the Merger Agreement, but is being included because the analysis was provided to the Cara Board and Piper Sandler.

The Management Liquidation Analysis included in this proxy statement/prospectus has been prepared by, and is the responsibility of, Cara's management. This analysis was not prepared with a view toward public disclosure or toward complying with GAAP, any published guidelines of the SEC regarding prospective financial information or guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information. Ernst & Young LLP, Cara's independent registered public accounting firm, has not examined, compiled or performed any procedures with respect to the Management Liquidation Analysis and, accordingly, does not express an opinion or any other form of assurance with respect thereto.

The Management Liquidation Analysis was based on numerous variables and assumptions that are inherently uncertain and many of which are beyond the control of Cara's management. As a result, the assumptions upon which this analysis was based necessarily involve judgments with respect to, among other things, actual expenses incurred during the liquidation including, without limitation: (i) the actual amount of liquidation costs, (ii) the actual amount that would be required to settle Cara's remaining obligations under current contracts, (iii) the actual amount that would be necessary to retain key employees to facilitate the liquidation, (iv) the actual amounts necessary to retain the services of external advisors necessary to assist Cara with the liquidation and (v) the actual amounts necessary to enable Cara to satisfy its remaining obligations (including obligations to comply with its SEC filing obligations during the liquidation process). In addition, Cara management cannot predict the actual amounts of funds that Cara would need to retain for unknown or contingent liabilities, any of which could be material and the total amount of which cannot currently be estimated. There can be no assurance that any fees, expenses, contingencies, or other obligations that Cara may incur will be within the range of estimated amounts provided in the Management Liquidation Analysis, that the Management Liquidation Analysis accounts for all possible such fees, expenses, contingencies, or other obligations of Cara or that the estimated Distributions set forth in the table below would be realized in the estimated amounts, or at the estimated dates, if at all.

Cara management made the following key assumptions in connection with preparing the Management Liquidation Analysis:

- the Cara Board would have approved a liquidation of Cara in December 2024, with an initial distribution (the Initial Distribution) of net residual value to Cara stockholders being made on March 31, 2025, and a second, final distribution of net residual value to Cara stockholders being made on March 31, 2028 (the Final Distribution and together with the Initial Distribution, the Distributions).
- based on non-public, unaudited, internal data, management of Cara estimated that Cara's ending cash balance as of March 31, 2025, in a liquidation scenario, would be \$30.4 million, which included Cara management's estimate of Cara's cash expenditures and receipts for the period covering October 31, 2024 through March 31, 2025.
- \$0.8 million of the estimated March 31, 2025 cash balance would be held back from the Initial Distribution to cover the estimated expense of a liquidation administrator and other potential expenses or charges between March 31, 2025 and March 31, 2028 (the Hold Back Amount). Management further assumed that \$0.5 million of the Hold Back Amount would be distributed to Cara stockholders on March 31, 2028, constituting the Final Distribution.

As set forth in the table below, with the foregoing assumptions, the Management Liquidation Analysis results in an Initial Distribution of \$29.6 million on March 31, 2025, and a Final Distribution of \$0.5 million on March 31, 2028. Cara management further calculated the present value, as of November 30, 2024, of the Initial Distribution and the Final Distribution utilizing discount rates based on the yields of U.S. Treasury bills and notes of durations similar to the respective distribution periods.

In light of the foregoing factors and the uncertainties inherent in the Management Liquidation Analysis, Cara stockholders are cautioned not to place undue, if any, reliance on this analysis.

The following table and other information below is a summary of the Management Liquidation Analysis.

Management Liquidation Analysis (\$ and figures in millions; except per share data)	
Ending Cash (as of 3/31/2025)	\$30.4
Less: Operating Expenses during Liquidation Period	\$ (0.3)
3/31/25 Ending Cash, Net Future Operating Costs	\$30.1
Less: Expected Final Distribution	\$ (0.5)
Initial Distribution (3/31/2025)	\$29.6
Diluted Shares Outstanding (Using treasury stock method)	55.8
Undiscounted Initial Distribution Per Share (3/31/25)	\$0.53
Discounted Initial Distribution (Aggregate)	\$29.1
Discounted Initial Distribution (Per Share)	\$0.52
3/31/25 Ending Cash, Net Initial Distribution	\$ 0.8
Less: Operating Expenses during Liquidation Period	\$ (0.3)
Cash Available to Distribute (3/31/2028)	\$ 0.5
Diluted Shares Outstanding (Using Treasury Stock Method)	55.8
Undiscounted Final Distribution Per Share (3/31/2028)	\$0.01
Discounted Final Distribution (Aggregate)	\$ 0.4
Discounted Final Distribution (Per Share)	\$0.01
Total Present Value of Distributions (Aggregate)	\$29.6
Total Present Value of Distribution (Per Share)	\$0.53

The above analysis results in an implied aggregate equity value of Cara of \$29.6 million, or \$0.53 per share of Cara common stock.

The Management Liquidation Analysis does not take into account any circumstances or events occurring after the date it was prepared. Cara can give no assurance that, had Management Liquidation Analysis been prepared as of the date of this proxy statement/prospectus, similar estimates and assumptions would be used. Cara does not intend to, and disclaims any obligation to, make publicly available any update or other revision to the Management Liquidation Analysis to reflect circumstances existing since its preparation or to reflect the occurrence of unanticipated events, even in the event that any or all of the assumptions underlying the Management Liquidation Analysis is shown to be in error, or to reflect changes in general economic or industry conditions. The Management Liquidation Analysis does not take into account the possible financial and other effects on Cara of the Merger and does not attempt to predict or suggest future results of the post-Merger company. The Management Liquidation Analysis does not give effect to the Merger, including the impact of negotiating or executing the Merger Agreement, the expenses that may be incurred in connection with consummating the Merger, or the effect of any other business or strategic decisions or actions which would likely have been taken if the Merger Agreement had not been executed, but which were instead altered, accelerated, postponed or not taken in anticipation of the Merger. None of Cara, Piper Sandler or their respective affiliates, officers, directors, advisors or other representatives has made, makes or is authorized in the future to make any representation to any Cara stockholder or any other person regarding Cara's actual performance in the event of an actual liquidation of Cara, as compared to the information contained in the Management Liquidation Analysis or regarding whether the forecasted Distributions would actually be achieved.

In light of the foregoing, and considering that the Special Meeting will be held after the Management Liquidation Analysis was prepared, as well as the uncertainties inherent in any forecasted information, Cara stockholders are cautioned not to place unwarranted reliance on such information, and Cara urges all Cara stockholders to review Cara's most recent SEC filings for a description of Cara's reported financial results. See "Where You Can Find More Information."

Interests of the Cara Directors and Executive Officers in the Merger

In considering the recommendation of the Cara Board with respect to the approval of the Merger Agreement, the Merger and the issuance of shares of Cara common stock as contemplated by the Merger Agreement, and the Cara Stockholder Matters, Cara's stockholders should be aware that certain members of the Cara Board and current and former executive officers of Cara have interests in the Merger that may be different from, or in addition to, the interests of Cara's stockholders.

As more fully described below, these interests relate to or arise from, among other things:

- severance benefits to which each of Cara's executive officers may become entitled in the event of his termination of employment following consummation of the Merger;
- action the Cara Board has taken in accordance with the Merger Agreement to accelerate the vesting in full of all Cara options and RSUs upon the consummation of the Merger, including Cara options and RSUs held by Cara's directors and executive officers;
- the accelerated vesting of all options to purchase shares of Cara common stock and RSUs held by Cara's executive officers in the event of specified terminations or resignations of employment within 12 months following consummation of the Merger; and
- the agreement that one of Cara's directors will serve on the Combined Company Board following the consummation of the Merger.

The Cara Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching their respective decisions to approve the Merger Agreement and the Merger, and to recommend, as applicable, that Cara's stockholders approve the proposals to be presented to Cara's stockholders for consideration at the Cara special meeting as contemplated by this proxy statement/ prospectus.

Ownership Interests

As of December 1, 2024, Cara's executive officers and directors and such directors affiliated funds beneficially owned, in the aggregate, approximately 4.2% of the shares of Cara common stock. See the section titled "*Principal Stockholders of Cara*" beginning on page <u>278</u> of this proxy statement/prospectus for additional information. Certain Cara officers and directors, and their affiliates, have also entered into the Support Agreements in connection with the Merger. For a more detailed discussion of the Support Agreements, please see the section titled "*Agreements Related to the Merger*" beginning on page <u>163</u> of this proxy statement/prospectus.

Executive Severance Arrangements

Christopher Posner

Cara is party to an executive employment agreement with Mr. Posner that was entered into in October 2021 (Posner Employment Agreement). The Posner Employment Agreement provides for an initial annual base salary and target bonus. Mr. Posner does not currently participate in the Severance Plan (defined below) and instead is eligible for severance benefits under the Posner Employment Agreement. Under the terms of the Posner Employment Agreement, upon execution and effectiveness of a general release of claims, Mr. Posner will be entitled to severance payments if Cara terminates his employment without Cause (as defined in the Posner Employment Agreement) (and not including death or disability), or if he resigns his employment with Cara for Good Reason (as defined in the Posner Employment Agreement).

If such termination occurs other than during the 12-month period following a Change in Control (as defined in the Posner Employment Agreement and including consummation of the Merger), Mr. Posner will be eligible to receive the following enhanced severance benefits:

- (a) an amount equal to 12 months of continued base salary, payable on regular payroll dates;
- (b) payment of applicable COBRA premiums for up to 12 months following termination;

(c) a lump-sum payment equal to his target bonus, pro-rated for the portion of the year he was employed; and

(d) 12 additional months of equity vesting for time-based vesting equity awards.

If such termination occurs during the 12-month period following a Change in Control, including consummation of the Merger, Mr. Posner will be eligible to receive the following enhanced severance benefits:

- (a) an amount equal to 18 months of continued base salary, payable on regular payroll dates;
- (b) payment of applicable COBRA premiums for up to 18 months following termination;
- (c) a lump-sum payment equal to 1.5 times his target bonus; and

(d) to the extent Mr. Posner's equity awards have been continued, assumed, or substituted by the surviving entity in the Change in Control, then all outstanding equity awards will accelerate and vest in full effective as of his termination or resignation.

Ryan Maynard and Scott Terrillion

Cara has entered into participation agreements with each of Mr. Maynard and Mr. Terrillion with respect to the Severance Plan that the Cara Board approved in October 2021 upon the recommendation of the Compensation Committee (Severance Plan).

The Severance Plan provides for certain severance benefits for each employee of Cara who (i) is the Chief Executive Officer or has been designated by the Cara Board or Cara's compensation committee to participate in the Severance Plan, (ii) has executed Cara's standard confidential information and inventions assignment agreement, and (iii) has timely and properly executed and delivered a participation agreement to Cara (Covered Employee) in the event the Covered Employee's employment is terminated by Cara without Cause (and not including death or disability) or the Covered Employee resigns for Good Reason (each such term as defined in the Severance Plan), so long as, in either case, such termination is not due to the Covered Employee's death or disability (Covered Termination). Mr. Maynard and Mr. Terrillion are both Covered Employees under the Severance Plan. In the event of a Covered Termination outside of the Change in Control Period (as defined below), each such individual will be eligible to receive:

(a) cash severance in an amount equal to the Covered Employee's base salary for nine months paid in installments;

(b) a prorated portion of the Covered Employee's target annual bonus (if any), for the year in which the Covered Termination occurs paid in installments; and

(c) payment of the applicable premiums for the Covered Employee and the Covered Employee's eligible dependents to continue coverage under COBRA following the date of the Covered Termination for up to nine months.

If a Covered Termination occurs within the period beginning on the effective date of the Change in Control (including consummation of the Merger) and ending on the first anniversary of such effective date (the Change in Control Period), then each such individual will be eligible to receive the following enhanced severance benefits:

(a) the base salary and COBRA severance described in clauses (a) and (c) above, except the amount of the base salary severance and duration of the COBRA severance will be calculated based on a 12-month period;

(b) a cash amount equal to the Covered Employee's target annual bonus for the year of the Covered Termination paid in installments; and

(c) each of the Covered Employee's then-outstanding equity awards subject to time-based vesting will accelerate and vest as to all unvested shares subject to the equity award. The Covered Employee must timely execute, deliver to us and allow to become effective a general release of claims,

to be eligible for any of the severance benefits described above. The Severance Plan contains certain covenants regarding confidential information and non-disparagement.

The base salary and target annual bonus severance amount for Mr. Terrillion would presently aggregate to \$834,000. His equity award holdings are described below.

Golden Parachute Compensation

The following table and related footnotes present information about the compensation payable to Cara's named executive officers in connection with the Merger. The compensation shown in the table below is intended to comply with Item 402(t) of Regulation S-K, which requires disclosure of information about compensation for each named executive officer that is based on or otherwise relates to the Merger. This compensation is referred to as "golden parachute" compensation by the applicable SEC disclosure rules. Cara's named executive officers who are no longer employed by Cara have been excluded from the table below and will not receive any "golden parachute" compensation in connection with the Merger. The Cara named executive officers will not receive pension, tax reimbursement or other benefits in connection with the Merger.

The values in the table below are based on the following assumptions:

- the relevant price per share of Cara common stock is approximately \$, which, in accordance with SEC requirements, is equal to the average closing price of a share of Cara common stock over the first five business days following the first public announcement of the Merger on ;
- each of Cara's named executive officers who is currently employed by Cara will remain employed through the closing of the Merger, and their employment is terminated without "cause" (and not including death or disability) or by the executive officer for "good reason" as of immediately following the assumed effective time of the Merger on December 1, 2024 (in each case, referred to as a "qualifying termination");
- each of Cara's named executive officers holds the outstanding equity awards that were held by such named executive officer as of December 1, 2024, the latest practicable date before the filing of this proxy statement; and
- the base salary, target annual incentive compensation, and health and welfare benefit elections of each Cara named executive officer remains the same as of December 1, 2024.

The following table and footnotes describe payments and benefits that will be paid solely based on the closing of the Merger ("single-trigger payments"), and payments and benefits that will be paid based on the closing of the Merger and a qualifying termination of employment following the Merger ("double-trigger payments") (in thousands):

		Perquisites/		
Name	Cash (\$) ⁽¹⁾	Equity (\$) ⁽²⁾	Benefits (\$) ⁽³⁾	Total (\$)
Chris Posner	2,184		183	2,367
Ryan Maynard	860	—	105	965

⁽¹⁾ For Mr. Posner, amount represents installment payments equal to 150% of the sum of Mr. Posner's current base salary plus a lump sum payment of his target bonus for that year, which amounts are double trigger payments. For Mr. Maynard, amount represents installment payments equal to 100% of the sum of Mr. Maynard's current base salary plus target bonus for that year, which amounts are double trigger payments.

⁽²⁾ Pursuant to the Merger Agreement, the vesting of each equity award of the Cara named executive officers will fully accelerate on the Closing Date and thus constitute a single-trigger benefit. The total values in the table below for options represent the product of (i) the difference between \$ and the applicable exercise price of any unvested option multiplied by (ii) the number of shares of Cara common stock subject to the option and for RSUs represent \$ multiplied by the number of shares of Cara common stock subject to the RSU:

	Per Share Value of				
	Number of Cara	Executive Equity			
	Shares Subject to	Award	Total		
Name	Equity Award (#)	(\$)	(\$)		
Chris Posner					

Ryan Maynard

These amounts are single-trigger payments.

(3) Amount represents the payment for accrued vacation and reimbursement of COBRA premiums for health benefit coverage in an amount equal to the monthly employer contribution that Cara would have made to provide health insurance to Mr. Posner and Mr. Maynard had the executive remained employed with Cara until 12 months following the date of termination, based on the costs of coverage and benefit elections in effect as of December 1, 2024. This amount represents 18 months and 12 months, respectively, of benefits allowance for Mr. Posner and Mr. Maynard, respectively. Such amounts are double-trigger payments.

Cara Options

As of December 1, 2024, Cara's executive officers and directors collectively held unvested stock options to purchase 1,863,589 shares of Cara common stock and vested stock options to purchase 1,823,318 shares of Cara common stock, for a total of options to purchase 3,686,907 shares of Cara common stock. The Cara Board has taken action to accelerate in full, effective upon consummation of the Merger, the vesting of all Cara options then outstanding. All outstanding and unexercised options to purchase shares of Cara common stock will remain effective and outstanding.

Any Cara options granted after consummation of the Merger that are not yet vested will be subject to "double-trigger" accelerated vesting upon a termination by Cara without "cause" (and not including death or disability) or resignation for "good reason," in either case, on or within 12 months following the occurrence of a "change in control" (which will occur upon consummation of the Merger), in accordance with the terms of the Posner Employment Agreement and the Severance Plan, as described above. The definitions of "cause" and "good reason" applicable to each executive officer are contained in the Posner Employment Agreement and the Severance Plan, as applicable, and have not been modified in connection with the Merger or the transactions contemplated thereby.

The following table presents certain information concerning the outstanding Cara stock options held by each of Cara's executive officers and directors as of December 1, 2024 and describes the vesting of the awards determined without regard to the accelerated vesting that will occur upon consummation of the Merger:

	Option Awards				
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date
Christopher Posner	8/2/2018 ⁽¹⁾	35,000	0	17.94	8/2/2028
	$6/4/2019^{(2)}$	9,000	0	20.47	6/4/2029
	$6/4/2020^{(2)}$	10,800	0	15.62	6/4/2030
	6/3/2021 ⁽²⁾	10,800	0	13.06	6/3/2031
	$10/29/2021^{(3)}$	17,823	5,941	16.83	10/29/2031
	$10/29/2021^{(3)}$	406,677	135,559	16.83	10/29/2031
	2/25/2022 ⁽⁴⁾	2	5,044	10.46	2/25/2032
	2/25/2022 ⁽⁴⁾	83,185	32,769	10.46	2/25/2032
	3/1/2023 ⁽⁴⁾	0	14,637	10.06	3/1/2033
	3/1/2023 ⁽⁴⁾	109,375	125,988	10.06	3/1/2033

	Option Awards				
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date
Ryan Maynard	9/12/2022 ⁽⁵⁾	17,828	37,208	10.75	9/12/2032
	9/12/2022 ⁽⁵⁾	104,047	83,745	10.75	9/12/2032
	3/1/2023(4)	0	5,063	10.06	3/1/2033
	3/1/2023(4)	35,437	40,500	10.06	3/1/2033
Scott Terrillion	11/28/2016 ⁽⁵⁾	43,380	0	9.22	11/28/2026
	11/28/2016 ⁽⁵⁾	91,620	0	9.22	11/28/2026
	3/9/2018 ⁽⁴⁾	9,856	0	14.39	3/9/2028
	3/9/2018 ⁽⁴⁾	36,644	0	14.39	3/9/2028
	3/6/2019 ⁽⁴⁾	8,300	0	16.10	3/6/2029
	3/6/2019 ⁽⁴⁾	66,700	0	16.10	3/6/2029
	$2/24/2020^{(4)}$	2,832	0	16.36	2/24/2030
	$2/24/2020^{(4)}$	29,168	0	16.36	2/24/2030
	3/30/2021 ⁽⁴⁾	3,479	2,317	20.59	3/30/2031
	3/30/2021 ⁽⁴⁾	25,854	350	20.59	3/30/2031
	2/25/2022(4)	2	7,291	10.46	2/25/2032
	2/25/2022(4)	27,498	5,209	10.46	2/25/2032
	3/1/2023 ⁽⁴⁾	35,437	32,293	10.06	3/1/2033
	3/1/2023 ⁽⁴⁾	0	13,270	10.06	3/1/2033
Martin Vogelbaum	6/8/2015 ⁽²⁾	13,500	0	9.94	6/8/2025
	6/15/2016 ⁽²⁾	15,000	0	5.32	6/15/2026
	$6/21/2017^{(2)}$	15,000	0	19.50	6/21/2027
	6/6/2018 ⁽²⁾	18,000	0	16.07	6/6/2028
	6/4/2019 ⁽²⁾	9,000	0	20.47	6/4/2029
	6/4/2020 ⁽²⁾	21,600	0	15.62	6/4/2030
	6/3/2021 ⁽²⁾	21,600	0	13.06	6/3/2031
	6/2/2022 ⁽²⁾	33,993	0	8.42	6/3/2032
	6/1/2023 ⁽²⁾	89,923	0	3.09	6/1/2033
	6/4/2024 ⁽⁶⁾	0	390,000	0.66	6/4/2034
Jeffrey L. Ives, Ph.D.	$6/8/2015^{(2)}$	13,500	0	9.94	6/8/2025
	$6/15/2016^{(2)}$	15,000	0	5.32	6/15/2026
	$6/21/2017^{(2)}$	15,000	0	19.50	6/21/2027
	$6/6/2018^{(2)}$	18,000	0	16.07	6/6/2028
	$6/4/2019^{(2)}$	9,000	0	20.47	6/4/2029
	$6/4/2020^{(2)}$	10,800	0	15.62	6/4/2030
	6/3/2021 ⁽²⁾	10,800	0	13.06	6/3/2031
	6/2/2022 ⁽²⁾	16,996	0	8.42	6/3/2032
	$6/1/2023^{(2)}$	44,961	0	3.09	6/1/2033
	6/4/2024 ⁽⁶⁾	0	195,000	0.66	6/4/2034

		Option Awards				
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date	
Susan Shiff, Ph.D.	6/26/2020 ⁽⁷⁾	38,000	0	17.03	6/4/2030	
	6/3/2021 ⁽²⁾	10,800	0	13.06	6/3/2031	
	6/2/2022 ⁽²⁾	16,996	0	8.42	6/3/2032	
	6/1/2023 ⁽²⁾	44,961	0	3.09	6/1/2033	
	6/4/2024 ⁽⁶⁾	0	195,000	0.66	6/4/2034	
Lisa von Moltke, M.D.	1/2/2023 ⁽⁷⁾	30,560	15,281	10.74	1/2/2033	
	6/1/2023 ⁽²⁾	44,961	0	3.09	6/1/2033	
	$6/4/2024^{(6)}$	0	195,000	0.66	6/4/2034	
Helen M. Boudreau	8/2/2023 ⁽⁷⁾	64,894	90,853	3.09	8/2/2033	
	6/4/2024 ⁽⁶⁾	0	195,000	0.66	6/4/2034	

(1) The stock option award vests in three equal annual installments beginning on the one year anniversary of the grant date. This award is fully vested.

(2) The stock option award vests annually over a one-year period. This award is fully vested.

(3) The stock option award vests as to 25% of the shares on the first anniversary of the vesting commencement date and vest as to the remaining 75% of the shares in 12 substantially equal quarterly installments thereafter, such that all awards will be vested on the anniversary of the vesting commencement date, subject to the executive officer's continued service to Cara through such vesting date.

(4) The stock option award vests in 48 substantially equal monthly installments thereafter, such that all awards will be vested on the anniversary of the vesting commencement date, subject to the executive officer's continued service to Cara through such vesting date.

(5) The stock option award vests as to 25% of the shares on the first anniversary of the vesting commencement date and vest as to the remaining 75% of the shares in 36 substantially equal monthly installments thereafter, such that all awards will be vested on the fourth anniversary of the vesting commencement date.

(6) The stock option award vests on the earlier of (i) June 4, 2025 and (ii) immediately prior to Cara's next annual meeting of stockholders following the grant date, in each case, subject to the director's continued service as a director through such date.

(7) The stock option award vests in 12 substantially equal quarterly installments, such that all awards will be vested on the anniversary of the vesting commencement date, subject to the director's continued service to Cara through such vesting date.

Cara RSUs

As of December 1, 2024, Cara's executive officers and directors collectively held 959,052 unvested RSUs. The Cara Board has taken action to accelerate in full, effective upon consummation of the Merger, the vesting of all Cara RSUs then outstanding.

Any Cara RSUs granted after consummation of the Merger that are not yet vested will be subject to "double-trigger" accelerated vesting upon a termination by Cara without "cause" (and not including death or disability) or resignation for "good reason," in either case, on or within 12 months following the occurrence of a "change in control" (which will occur upon the closing of the Merger), in accordance with the terms of the Posner Employment Agreement and the Severance Plan, as described above. The definitions of "cause" and "good reason" applicable to each executive officer are contained in the Posner Employment Agreement

and the Severance Plan, as applicable, and have not been modified in connection with the Merger and the transactions contemplated thereby.

The following table presents certain information concerning the outstanding Cara RSUs held by each of Cara's executive officers and directors as of December 1, 2024:

Vesting Commencement Date	Number of Shares of Cara Common Stock Underlying Unvested RSUs that will Vest upon the Consummation of the Merger (#)
10/29/2021	35,500
2/25/2022	13,000
2/25/2022	6,666
6/4/2024	301,295
6/4/2024	150,647
6/4/2024	150,647
6/4/2024	150,647
6/4/2024	150,647
	Commencement Date 10/29/2021 2/25/2022 2/25/2022 6/4/2024 6/4/2024 6/4/2024 6/4/2024

Accelerated Vesting of Cara Options and Cara RSUs

The Severance Plan provides that, in the event that, within the 12-month period immediately following a change in control (which includes consummation of the Merger), a holder of outstanding awards experiences a termination by Cara without "cause" (and not including death or disability) or by the holder for "good reason," then the vesting and, if applicable, exercisability of then-outstanding equity awards subject to time-based vesting held by such holder will accelerate in full upon the date of such termination of service. Messrs. Maynard and Terrillion are participants in the Severance Plan.

Mr. Posner's employment agreement provides that, in the event that, within the 12-month period immediately following a change in control (which includes consummation of the Merger), Mr. Posner experiences a termination of service by Cara other than for "cause" or Mr. Posner terminates his employment for "good reason," then the vesting and, if applicable, exercisability of outstanding awards held by Mr. Posner will accelerate in full upon the date of such termination of service.

The Cara Board has taken action to accelerate the vesting in full of all options and RSUs outstanding upon the consummation of the Merger.

Indemnification and Insurance

For a discussion of the indemnification and insurance provisions related to the Cara directors and officers under the Merger Agreement, please see the section titled, see the section titled "*The Merger Agreement* — *Other Agreements* — *Director Indemnification and Insurance*."

Ownership Interests of Tvardi Directors and Executive Officers

As of December 1, 2024, Tvardi's executive officers and directors and such directors affiliated funds beneficially owned, in the aggregate, approximately 26.38% of the shares of Tvardi common stock. See the section titled "*Principal Stockholders of Tvardi*" beginning on page <u>280</u> of this proxy statement/prospectus for additional information. Certain Tvardi officers and directors, and their affiliates, have also entered into the Support Agreements in connection with the Merger. For a more detailed discussion of the Support Agreements, please see the section titled "*Agreements Related to the Merger*" beginning on page <u>163</u> of this proxy statement/prospectus.

Executive Officers of the Combined Company Following the Merger

Immediately following the Merger, the executive management team of the combined company is expected to comprise of the following individuals with such additional officers as may be added by Tvardi or the combined company:

Name	Position with the Combined Company	Current Position at Tvardi
Imran Alibhai, Ph.D.	Chief Executive Officer and Director	Chief Executive Officer and Director
Dan Conn, J.D., M.B.A.	Chief Financial Officer	Chief Financial Officer
John Kauh, M.D.	Chief Medical Officer	Chief Medical Officer
Jeffrey Larson, Ph.D., DABT	Senior Vice President, Research & Development	Senior Vice President, Research & Development
Yixin "Joseph" Chen, Ph.D.	Vice President, Chemistry, Manufacturing and Controls	Vice President, Chemistry, Manufacturing and Controls

Directors of the Combined Company Following the Merger

At the Effective Time, the combined company is expected to initially have a seven-member board of directors, comprising (a) Sujal Shah, Michael Wyzga, Wallace Hall, Shaheen Wirk and Imran Alibhai, each as an Tvardi designee and (b) one member to be designated by Cara prior to Closing, with one vacancy, to be designated by Tvardi if prior to the closing of the Merger or by the combined company if following the consummation of the Merger, each until their respective successors are duly elected or appointed and qualified or their earlier death, resignation or removal.

The aforementioned board of directors will have an audit committee, a compensation committee and a nominating and corporate governance committee, in accordance with the Nasdaq rules. All of Cara's current directors, other than the member to be designated by Cara prior to Closing are expected to resign from their positions as directors of Cara, effective as of the Effective Time.

Merger Consideration

For a discussion of merger consideration and the Exchange Ratio, please see the section titled "*The Merger Agreement* — *Merger Consideration and Exchange Ratio*" beginning on page <u>140</u>.

Treatment of Cara Stock Options and RSUs

All outstanding and unexercised options to purchase shares of Cara common stock will be accelerated in full and remain effective and outstanding in accordance with their terms, except that the post-termination exercise period shall not exceed 90 days and the number of shares underlying such options will be adjusted based on the Reverse Stock Split. As of December 1, 2024, there were outstanding options to purchase up to an aggregate of 4,086,079 shares of Cara common stock and 959,052 shares of Cara common stock underlying RSUs. As of December 1, 2024, Cara's current executive officers and directors held outstanding options to purchase an aggregate of 3,686,907 shares of Cara common stock and 959,052 shares of Cara common stock underlying RSUs. The Cara Board has taken action to accelerate the vesting in full of all Cara stock options and RSUs upon the consummation of the Merger.

Treatment of Tvardi Stock Options

Under the terms of the Merger Agreement, each option to purchase shares of Tvardi common stock that is outstanding and unexercised immediately prior to the Effective Time, whether or not vested, will be converted into and become an option to purchase shares of Cara common stock. Cara will assume the Tvardi Plan and all such Tvardi stock options in accordance with the terms of the Tvardi Plan and the terms of the stock option agreement by which such option is evidenced. Neither the vesting nor exercisability of the options will be affected by consummation of the transactions contemplated by the Merger Agreement.

Accordingly, from and after the Effective Time: (i) each outstanding Tvardi stock option assumed by Cara may be exercised solely for shares of Cara common stock; (ii) the number of shares of Cara common stock subject to each outstanding Tvardi stock option assumed by Cara will be determined by multiplying (A) the number of shares of Tvardi common stock that were subject to such Tvardi stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Cara common stock; (iii) the per share exercise price for the Cara common stock issuable upon exercise of each Tvardi stock option assumed by Cara will be determined by dividing (A) the per share exercise price of Cara common stock subject to such Tvardi stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any Tvardi stock option assumed by Cara will continue in full force and effect and the term, exercisability, vesting schedule, accelerated vesting provisions, and any other provisions of such Tvardi stock option will otherwise remain unchanged; provided, however, that the Cara Board or a committee thereof will succeed to the authority and responsibility of the Tvardi Board or any committee thereof with respect to each Tvardi stock option assumed by Cara.

Merger Expenses

Except as otherwise expressly provided in the Merger Agreement, all costs and expenses incurred in connection with the Merger Agreement and the transactions contemplated therein, including the Merger, will be paid by the party incurring such expense, whether or not the Merger is consummated provided that Cara and Tvardi shall each pay 50% of all fees and expenses incurred in relation to (i) the printing and filing with the SEC of this proxy statement/prospectus and any amendments and supplements thereto and paid to a financial printer or to the SEC and (ii) the proxy solicitation firm engaged in connection with the Cara special meeting.

Effective Time of the Merger

The Merger will be completed as promptly as practicable (but no later than the second business day) after all of the conditions to the closing of the Merger are satisfied or waived, including the approval of the stockholders of Cara and Tvardi, unless earlier terminated in accordance with the terms of the Merger Agreement. For more information on termination rights, see the section titled "*The Merger Agreement* — *Termination and Termination Fees*" on page <u>158</u>. The Merger is anticipated to occur after the Cara special meeting, which is further described on page <u>97</u>. Cara and Tvardi cannot predict the exact timing of the closing of the Merger because it is subject to various conditions.

Regulatory Approvals

In the United States, Cara must comply with applicable federal and state securities laws and the rules and regulations of Nasdaq in connection with (i) the issuance of shares of Cara common stock to Tvardi's stockholders in connection with the transactions contemplated by the Merger Agreement and the change of control resulting from the Merger and (ii) the filing of this proxy statement/prospectus with the SEC. Cara does not intend to seek any regulatory approval from antitrust authorities to consummate the transactions.

Material U.S. Federal Income Tax Consequences of the Merger

Cara stockholders will not sell, exchange or dispose of any shares of Cara common stock as a result of the Merger. Thus, there will be no material U.S. federal income tax consequences to Cara stockholders as a result of the Merger.

Nasdaq Listing

Cara common stock currently is listed on The Nasdaq Capital Market under the symbol "CARA." Cara has agreed to use commercially reasonable efforts (i) to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Cara common stock to be issued in connection with the Contemplated Transactions, and to cause such shares to be approved for listing (subject to official notice of issuance), (ii) to effect the Reverse Stock Split and (iii) to

the extent required by Nasdaq Marketplace Rule 5110, to file an initial Nasdaq Listing Application for the Cara common stock on Nasdaq and to cause such listing application to be conditionally approved prior to the Effective Time.

In addition, under the Merger Agreement, each of Tvardi's and Cara's obligation to complete the Merger is subject to the satisfaction or waiver by each of the parties, at or prior to the Merger, of various conditions, including that the shares of Cara common stock to be issued in the Merger have been approved for listing on Nasdaq as of the closing of the Merger. The terms of the Merger Agreement permit that this condition may be waived by agreement among Tvardi, Cara and Merger Sub, without recirculation or resolicitation of this proxy statement/prospectus.

If the Nasdaq Listing Application is accepted, Cara anticipates that the common stock of the combined company will be listed on the Nasdaq Capital Market following the closing of the Merger under the trading symbol "TVRD."

Anticipated Accounting Treatment

The Merger will be treated by Cara as a reverse recapitalization under GAAP. For accounting purposes, Tvardi is considered to be the accounting acquirer in this transaction.

Appraisal Rights

Cara

Under the DGCL, Cara stockholders are not entitled to appraisal rights in connection with the Merger.

Tvardi

Tvardi stockholders are entitled to appraisal rights in connection with the Merger under Section 262 of the DGCL.

The discussion below is not a complete summary regarding Tvardi stockholders' appraisal rights under Delaware law and is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached as *Annex C*. Stockholders intending to exercise appraisal rights should carefully review *Annex C*. Failure to follow precisely any of the statutory procedures set forth in *Annex C* may result in a termination or waiver of these rights. This summary does not constitute legal or other advice, nor does it constitute a recommendation that Tvardi stockholders exercise their appraisal rights under Delaware law.

Under Section 262, where a merger is adopted by stockholders by written consent in lieu of a meeting of stockholders pursuant to Section 228 of the DGCL, either the constituent corporation before the effective date of such merger or the surviving corporation, within 10 days after the effective date of such merger, must notify each stockholder of the constituent corporation entitled to appraisal rights of the approval of such merger, the effective date of such merger and that appraisal rights are available.

If the Merger is completed, within 10 days after the effective date of the Merger, Tvardi will notify its stockholders that the Merger has been approved, the effective date of the Merger and that appraisal rights are available to any stockholder who has not approved the Merger. Holders of shares of Tvardi capital stock who desire to exercise their appraisal rights must deliver a written demand for appraisal to Tvardi within 20 days after the date of the giving of that notice, and that stockholder must not have delivered a written consent approving the Merger. A demand for appraisal must reasonably inform Tvardi of the identity of the stockholder and that such stockholder intends thereby to demand appraisal of the shares of Tvardi capital stock held by such stockholder. Failure to deliver a written consent approving the Merger will not in and of itself constitute a written demand for appraisal satisfying the requirements of Section 262. All demands for appraisal should be addressed to Tvardi, 2533 S Coast Hwy 101, Suite #210, Cardiff, CA 92007, Attention: Michael Mueller, Email: mmueller@Tvardi.com, and should be executed by, or on behalf of, the record holder of shares of Tvardi capital stock. ALL DEMANDS MUST BE RECEIVED BY TVARDI WITHIN 20 DAYS AFTER THE DATE TVARDI GIVES A NOTICE TO ITS STOCKHOLDERS NOTIFYING



THEM THAT THE MERGER HAS BEEN APPROVED, THE EFFECTIVE DATE OF THE MERGER AND THAT APPRAISAL RIGHTS ARE AVAILABLE TO ANY STOCKHOLDER WHO HAS NOT APPROVED THE MERGER.

If you fail to deliver a written demand for appraisal within the time period specified above, you will be entitled to receive the merger consideration for your shares of Tyardi capital stock as provided for in the Merger Agreement, but you will have no appraisal rights with respect to your shares of Tvardi capital stock. To be effective, a demand for appraisal by a holder of shares of Tvardi capital stock must be made by, or in the name of, the registered stockholder, fully and correctly, as the stockholder's name appears on the stockholder's stock certificate(s). Beneficial owners who do not also hold the shares of record may not directly make appraisal demands to Tvardi. The beneficial owner must, in these cases, have the registered owner, such as a broker, bank or other custodian, submit the required demand in respect of those shares. If shares are owned of record in a fiduciary capacity, such as by a trustee, guardian or custodian, execution of a demand for appraisal should be made by or for the fiduciary; and if the shares are owned of record by more than one person, as in a joint tenancy or tenancy in common, the demand should be executed by or for all joint owners. An authorized agent, including an authorized agent for two or more joint owners, may execute the demand for appraisal for a stockholder of record; however, the agent must identify the record owner or owners and expressly disclose the fact that, in executing the demand, he or she is acting as agent for the record owner. A record owner, such as a broker, who holds shares as a custodian for others, may exercise the record owner's right of appraisal with respect to the shares held for one or more beneficial owners, while not exercising this right for other beneficial owners. In that case, the written demand should state the number of shares as to which appraisal is sought. Where no number of shares is expressly mentioned, the demand will be presumed to cover all shares held in the name of the record owner. In addition, the stockholder must continuously hold the shares of record from the date of making the demand through the Effective Time.

If you hold your shares of Tvardi capital stock in a brokerage account or in other custodian form and you wish to exercise appraisal rights, you should consult with your bank, broker or other custodian to determine the appropriate procedures for the making of a demand for appraisal by the custodian.

At any time within 60 days after the Effective Time, any stockholder who has demanded an appraisal, but has neither commenced an appraisal proceeding or joined an appraisal proceeding as a named party, has the right to withdraw such stockholder's demand and accept the terms of the Merger by delivering a written withdrawal to Tvardi. If, following a demand for appraisal, you have withdrawn your demand for appraisal in accordance with Section 262, you will have the right to receive the merger consideration for your shares of Tvardi capital stock.

Within 120 days after the effective date of the Merger, any stockholder who has delivered a demand for appraisal in accordance with Section 262 will, upon written request to the surviving corporation, be entitled to receive a written statement setting forth the aggregate number of shares not voted in favor of the Merger Agreement and with respect to which demands for appraisal rights have been received and the aggregate number of holders of these shares. This written statement will be given to the requesting stockholder within 10 days after the stockholder's written request is received by the surviving corporation or within 10 days after expiration of the period for delivery of demands for appraisal, whichever is later. Within 120 days after the effective date of the merger, either the surviving corporation or any stockholder who has delivered a demand for appraisal in accordance with Section 262 may file a petition in the Delaware Court of Chancery demanding a determination of the fair value of the shares held by all such stockholders. Upon the filing of the petition by a stockholder, service of a copy of the petition must be made upon the surviving corporation. The surviving corporation has no obligation to file a petition in the Delaware Court of Chancery in the event there are dissenting stockholders, and Tvardi, which is expected to be the surviving corporation, has no present intent to file a petition in the Delaware Court of Chancery. Accordingly, the failure of a stockholder to file a petition within the period specified could nullify the stockholder's previously written demand for appraisal.

If a petition for appraisal is duly filed by a stockholder and a copy of the petition is delivered to the surviving corporation, the surviving corporation will then be obligated, within 20 days after receiving service of a copy of the petition, to provide the Delaware Court of Chancery with a duly verified list containing the names and addresses of all stockholders who have demanded an appraisal of their shares and with whom agreements as to the value of their shares have not been reached by the surviving corporation.

After notice to dissenting stockholders who demanded appraisal of their shares, the Delaware Court of Chancery is empowered to conduct a hearing upon the petition, and to determine those stockholders who have complied with Section 262 and who have become entitled to the appraisal rights provided thereby. The Delaware Court of Chancery may require the stockholders who have demanded appraisal for their shares to submit their stock certificates to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with that direction, the Delaware Court of Chancery may dismiss the proceedings as to that stockholder.

After determination of the stockholders entitled to appraisal of their shares, the Delaware Court of Chancery will appraise the "fair value" of the shares owned by those stockholders. This value will be exclusive of any element of value arising from the accomplishment or expectation of the Merger, but may include a fair rate of interest, if any, upon the amount determined to be the fair value. When the value is determined, the Delaware Court of Chancery will direct the payment of the value, with interest thereon accrued during the pendency of the proceeding, if the Delaware Court of Chancery so determines, to the stockholders entitled to receive the same, upon surrender by the holders of the certificates representing those shares. At any time before the entry of judgment in the proceedings, the surviving corporation may pay to each stockholder entitled to appraisal an amount in cash, in which case interest shall accrue thereafter only upon the sum of (i) the difference, if any, between the amount so paid and the fair value of the shares subject to appraisal as determined by the Delaware Court of Chancery and (ii) interest thereofore accrued, unless paid at that time.

In determining fair value, and, if applicable, a fair rate of interest, the Delaware Court of Chancery is required to take into account all relevant factors. In *Weinberger v. UOP, Inc.*, the Delaware Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that "proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court" should be considered, and that "fair price obviously requires consideration of all relevant factors involving the value of a company."

Section 262 provides that fair value is to be "exclusive of any element of value arising from the accomplishment or expectation of the merger." In *Cede & Co. v. Technicolor, Inc.*, the Delaware Supreme Court stated that this exclusion is a "narrow exclusion [that] does not encompass known elements of value," but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In *Weinberger*, the Delaware Supreme Court construed Section 262 to mean that "elements of future value, including the nature of the enterprise, which are known or susceptible of proof as of the date of the merger and not the product of speculation, may be considered."

You should be aware that the fair value of your shares as determined under Section 262 could be more than, the same as, or less than the value that you are entitled to receive under the terms of the Merger Agreement.

Costs of the appraisal proceeding may be imposed upon the surviving corporation and the stockholders participating in the appraisal proceeding by the Delaware Court of Chancery as the Court deems equitable in the circumstances. Upon the application of a stockholder, the Delaware Court of Chancery may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorneys' fees and the fees and expenses of experts, to be charged pro rata against the value of all shares entitled to appraisal. In the absence of such a determination of assessment, each party bears its own expenses. Any stockholder who had demanded appraisal rights will not, after the Effective Time, be entitled to vote shares subject to that demand for any purpose or to receive payments of dividends or any other distribution with respect to those shares, other than with respect to payment as of a record date prior to the Effective Time; however, if no petition for appraisal is filed within 120 days after the Effective Time, or if the stockholder delivers a written withdrawal of his or her demand for appraisal and an acceptance of the terms of the Merger within 60 days after the Effective Time, then the right of that stockholder to appraisal will cease and that stockholder will be entitled to receive the merger consideration for shares of his or her Tvardi capital stock pursuant to the Merger Agreement. Any withdrawal of a demand for appraisal made more than 60 days after the Effective Time may only be made with the written approval of the surviving corporation. No appraisal proceeding in the Delaware Court of Chancery will be dismissed as to any stockholder without the approval of the court.

Failure to follow the steps required by Section 262 for perfecting appraisal rights may result in the loss of appraisal rights. In view of the complexity of Section 262, stockholders who may wish to dissent from the Merger and pursue appraisal rights should consult their legal advisors.

THE MERGER AGREEMENT

The following is a summary of the material terms of the Merger Agreement. A copy of the Merger Agreement is attached as Annex A to this proxy statement/prospectus and is incorporated by reference. The Merger Agreement has been attached to this proxy statement/prospectus to provide you with information regarding its terms. It is not intended to provide any other factual information about Cara, Tvardi or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the Merger and the terms and conditions of the Merger Agreement. Capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Merger Agreement, except that references to Tvardi herein shall refer to "the Company" in the Merger Agreement and references to Cara herein shall refer to "Parent" in the Merger Agreement.

The Merger Agreement contains representations and warranties that Cara and Merger Sub, on the one hand, and Tvardi, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if such statements made in the representations and warranties prove to be incorrect. In addition, the assertions made in the representations and warranties prove to be incorrect. In addition, the assertions made in the representations with the signing of the Merger Agreement. While Cara and Tvardi do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules contain information that modifies, qualifies and creates exceptions to the representations and warranties as current characterizations of factual information about Cara, Tvardi or Merger Sub, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between Cara and Merger Sub on the one hand, and Tvardi on the other hand, and are modified by the disclosure schedules.

Structure

Under the Merger Agreement, Merger Sub, a wholly owned subsidiary of Cara formed in connection with the Merger, will merge with and into Tvardi, with Tvardi surviving as a wholly owned subsidiary of Cara. Substantially concurrently with the completion of the Merger, Cara will be renamed "Tvardi Therapeutics, Inc." and expects to trade on The Nasdaq Capital Market under the symbol "TVRD."

Completion and Effectiveness of the Merger

The Merger will be completed on the second business day after all of the conditions to the closing of the Merger (Closing; and the date on which Closing actually takes place, the Closing Date) are satisfied or waived, including the approval of the stockholders of Cara, unless earlier terminated in accordance with the terms of the Merger Agreement. For more information on termination rights, see the section titled "*The Merger Agreement — Termination and Termination Fees.*" The Merger is anticipated to occur after the Cara special meeting of stockholders, which is further described in the section titled "*The Special Meeting of Cara's Stockholders.*" Cara and Tvardi cannot predict the exact timing of Closing because it is subject to various conditions.

Merger Consideration and Exchange Ratio

Merger Consideration

At the Effective Time, each share of Tvardi capital stock outstanding immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion and excluding shares held by stockholders who have exercised and perfected appraisal rights and excluding shares held as treasury stock by Cara or held or owned by Cara, Merger Sub or any subsidiary of Cara or Tvardi), will be converted into the right to receive a number of shares of Cara common stock equal to the Exchange Ratio. The Convertible Notes will also be converted into the right to receive a number of shares of Cara common stock calculated based on a conversion price equal to 80% of the implied value of the combined company (as more fully described in the Section titled "Agreements Related to the Merger" beginning on page <u>163</u>).

No fractional shares of Cara common stock will be issued in connection with the Merger, and no certificates or scrip for any such fractional shares will be issued. Any holder of Tvardi capital stock who would otherwise be entitled to receive a fraction of a share of Cara common stock (after aggregating all fractional shares of Cara common stock issuable to such holder) will, in lieu of such fraction of a share be paid in cash the dollar amount (rounded to the nearest whole cent), without interest, determined by multiplying such fraction by the average closing trading price of a share of Cara common stock on Nasdaq for the five consecutive trading days ending three trading days immediately prior to the date of the public announcement of the Merger Agreement, which is equal to \$0.276.

Exchange Ratio

The Exchange Ratio formula is derived based upon an Tvardi fixed valuation of \$210.0 million and a Cara valuation of \$43.0 million, subject to certain adjustments, including based upon Cara Net Cash at Closing and Convertible Notes in the amount of approximately \$28.3 million.

Immediately following the Merger, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock, and the holders of the Convertible Notes are expected to hold approximately 15.54% of the shares of Cara common stock, in each case, on a fully diluted basis and subject to further adjustment as further described below. The expected post-Merger equity ownership split percentages are based on the assumed Exchange Ratio of 4.8997 and an assumed amount of Conversion Shares equal to approximately 46,115,173 and are subject to adjustments based on the final Exchange Ratio and final amount of Conversion Shares. The assumed Exchange Ratio was calculated assuming, among other things, that Cara Net Cash at the Closing will be between \$22.875 million and \$23.125 million and an amount of Conversion Shares equal to approximately 46,115,173. Such assumed Exchange Ratio is subject to certain adjustments, including based on the amount of Cara Net Cash at Closing, the final ratio for the reverse stock split of Cara common stock and the final amount of Conversion Shares. The Exchange Ratio formula is based upon a Tvardi fixed valuation of \$210.0 million and a Cara valuation of \$43.0 million, subject to certain adjustments, including based upon Cara Net Cash at Closing, and an assumed implied value of the combined company of \$282.0 million, subject to certain adjustments. The Exchange Ratio is the quotient obtained by dividing (a) the Tvardi Merger Shares by (b) the Tvardi Outstanding Shares, in which:

- "Aggregate Convertible Note Valuation" means the aggregate principal amount of the Convertible Notes plus all accrued and unpaid interest.
- *"Aggregate Post-Bridge Valuation"* means the sum of (i) the Tvardi Valuation, plus (ii) the Cara Valuation plus (iii) the Implied Note Valuation.
- "Aggregate Valuation" means the sum of (i) the Tvardi Valuation, plus (ii) the Cara Valuation plus (iii) the Aggregate Convertible Note Valuation.
- "Cara Allocation Percentage" means the Cara Valuation divided by the Aggregate Valuation.
- "Cara Equity Value" means \$20,000,000.
- "Cara Outstanding Shares" means, subject to Section 1.5(f) of the Merger Agreement (that addresses, among other things, the possibility to effect the Reverse Stock Split Proposal) and the immediately following sentence, the total number of shares of Cara common stock outstanding immediately prior to the Effective Time, but excluding any Conversion Shares, expressed on a fully diluted basis and using the treasury stock method (and shall include, for the avoidance of doubt, all in-the-money Cara options), but assuming, without limitation or duplication, the issuance of shares of Cara in respect of all Cara options, Cara RSUs and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time (assuming cashless exercise), whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger (but excluding any shares of Cara common stock reserved for issuance other than with respect to outstanding Cara options and Cara RSUs as of immediately prior to the Effective Time and as set forth above) and assuming issuance

of such shares at the Aggregate Post-Bridge Valuation. For the avoidance of doubt, no out-of-themoney Cara options shall be included in the total number of shares of Cara common stock outstanding for purposes of determining the Cara Outstanding Shares.

- "Cara Valuation" means (i) if Cara Net Cash is greater than \$23,125,000, the sum of (w) the Cara Equity Value plus (x) \$23,000,000 plus (y) the amount by which Cara Net Cash exceeds \$23,125,000, (ii) if Cara Net Cash is greater than or equal to \$22,875,000 but less than or equal to \$23,125,000, the sum of (x) the Cara Equity Value plus (y) \$23,000,000, or (iii) if Cara Net Cash is less than \$22,875,000, the sum of (w) the Cara Equity Value plus (x) \$23,000,000 minus (y) the amount by which \$22,875,000 exceeds Cara Net Cash.
- "Conversion Shares" means the product obtained by multiplying (a) the Post-Closing Cara Shares by (b) the quotient obtained by dividing (i) the Implied Note Valuation by (ii) the Aggregate Post-Bridge Valuation.
- *"Implied Note Valuation"* means the quotient obtained by dividing (a) (i) the principal amount of the Convertible Notes plus (ii) all accrued and unpaid interest by (b) 80%.
- "*Post-Closing Cara Shares*" means the quotient obtained by dividing the Cara Outstanding Shares by the Cara Allocation Percentage.
- *"Total Tvardi Merger Shares"* means the product determined by multiplying (a) the Post-Closing Cara Shares by (b) the Tvardi Allocation Percentage.
- "Tvardi Allocation Percentage" means 1.00 minus the Cara Allocation Percentage.
- "Tvardi Merger Shares" means the Total Tvardi Merger Shares less the Conversion Shares.
- *"Tvardi Outstanding Shares"* means the total number of shares of Tvardi capital stock outstanding immediately prior to the Effective Time, after giving effect to the Preferred Stock Conversion and excluding any Conversion Shares, expressed on a fully diluted and as-converted to Tvardi common stock basis, expressed on a fully diluted and as-converted to Tvardi common stock basis and using the treasury stock method, but assuming, without limitation or duplication, (i) the exercise of all Tvardi Options outstanding as of immediately prior to the Effective Time, and (ii) the issuance of shares of Tvardi capital stock in respect of all other outstanding options, restricted stock awards, restricted stock units, warrants or rights to receive such shares, whether conditional or unconditional and including any outstanding options, warrants, restricted stock awards, restricted stock units or rights triggered by or associated with the consummation of the Merger (but excluding any shares of Tvardi Capital stock reserved for issuance other than with respect to outstanding Tvardi Options under the Tvardi Plan as of immediately prior to the Effective Time).
- "Tvardi Valuation" means \$210,000,000.
- "Cara Net Cash" means, without duplication, (a) the sum of (i) Cara's cash and cash equivalents, and marketable securities in each case as of the Anticipated Closing Date, (ii) prepaid expenses and deposits, (iii) expenses paid, or liabilities incurred, prior to Closing, that are approved in writing prior to the Response Date by the insurance carrier prior to Closing (with such evidence delivered to Tvardi) to be covered pursuant to any directors' and officers' insurance policy in excess of any applicable deductible and reasonably expected to be received by Cara within 90 days of the Anticipated Closing Date, (iv) any tax receivables reasonably expected to be received by Cara within 90 days of the Anticipated Closing Date, (v) any net proceeds of the Asset Dispositions (which amount may be positive or negative) which Cara will pay or receive, as applicable, on or about the Anticipated Closing Date, (vi) (A) if the Cara Net Cash calculation is prepared pursuant to Section 1.6 of the Merger Agreement before February 28, 2025, if Cara delivers to Tvardi (I) the royalty report received from Marushi Pharmaceutical Co. Ltd. or its Affiliates and (II) a certificate signed by the Chief Financial Officer of Cara in a form reasonably acceptable toTvardi to the effect that the milestone has been earned pursuant to Cara's agreement with HCRX Investments Holdco, L.P. and Healthcare Royalty Partners IV, L.P. or their respective Affiliates (collectively, HCR), then the amount set forth in clause (vi) shall be up to \$2,500,000 as indicated in the certificate required by clause (II) above, (B) if the Cara Net Cash calculation is prepared pursuant to Section 1.6 of the Merger Agreement after February 28, 2025 but before May 1, 2025, if Cara delivers to Tvardi the report and certificate required

by clauses (I) and (II), respectively, and the officer's certificate delivered from Cara to HCR pursuant to Cara's agreement with HCR, then the amount set forth in clause (vi) shall be up to \$2,500,000 as indicated in the certificate required by clause (II) above, or (C) if the Cara Net Cash calculation is prepared pursuant to Section 1.6 of the Merger Agreement on or after May 1, 2025, then the amount set forth in clause (vi) shall be equal to \$0 and Cara shall only receive credit for any amounts collected from HCR on or prior to the Closing Date as indicated in the definition of "Cash and Cash Equivalents" in clause (i) above, and (vii) profit sharing payments received by Cara at least 15 calendar days prior to the Cara special meeting from CSL Vifor or its Affiliates (collectively CSL), which amount shall be net of taxes and, for the avoidance of doubt, shall be equal to \$0 unless included in the definition of "Cash and Cash Equivalents" in clause (i) above, minus (b) the sum of (i) Cara's accounts payable, accrued expenses (including legal settlements that are not covered by any directors' and officers' insurance policy, Cara's unpaid Transaction Expenses (as defined in "- Expenses") and the costs of any tail policy associated with any directors' and officers' insurance policy to be bound at the Closing) and other bona fide current and long-term liabilities payable in cash that would be required to be set forth in a balance sheet prepared in accordance with GAAP), (ii) notice payments, fines or other payments to be made by Cara in order to terminate, assign or fully perform all Specified Cara Contracts and to discharge of all other Liabilities of Cara as contemplated by Section 8.6 of the Merger Agreement (for any existing agreement to which Cara is a party and to wind down any current and future clinical trial obligations and research and development activities), (iii) 50% of the aggregate costs (excluding any legal fees incurred by Cara) related to any outstanding stockholder litigation brought or threatened in writing against Cara or its directors or officers relating to the Contemplated Transactions (not covered by any directors' and officers' insurance policy) (Cara Litigation Cost); provided that in no event shall Cara pay the Cara Litigation Cost more than once, (iv) all costs and expenses of continuing to fund Cara's operations, including all activities required to continue to develop the Potentially Transferable Assets (including without limitation any PDUFA fees that become due and payable), including (A) unpaid costs and expenses incurred or reasonably expected to be incurred by Cara in connection with the Asset Dispositions (including, if applicable, any such amounts that would come due post-Closing) and (B) unpaid costs and expenses incurred or reasonably expected to be incurred by Cara in connection with the realization of potential milestone payments to be received from HCR or profit sharing payments to be received from CSL, (v) the fees and expenses of the Accounting Firm in accordance with Section 1.6(e) of the Merger Agreement, (vi) 50% of all fees and expenses incurred in relation to the printing and filing with the SEC of the Registration Statement and Proxy Statement and any amendments and supplements thereto and paid to a financial printer or the SEC, and (vii) any bonus, severance, change in control or retention payments or similar payment obligations (including payments pursuant to "single trigger" or "double-trigger" provisions triggered at and as of the Closing) that become due or payable to any director, officer, employee or consultant of Cara or any of its Subsidiaries or other Person in connection with the consummation of the Contemplated Transactions. Notwithstanding the foregoing, in no case shall Cara Net Cash be reduced for any costs or expenses, including attorney's fees or settlement costs, incurred in connection with any Dissenting Shares

The following table illustrates how the Exchange Ratio and post-Merger equity ownership of Tvardi's pre-Merger equityholders and Cara's pre-Merger equityholders may change if Cara Net Cash is between \$20 million and \$25 million at Closing, in each case calculated as of the Anticipated Closing Date.

		Post-Merger Ownership			
Cara Net Cash at Closing (\$ in millions)	Exchange Ratio	Cara Equity Holders	Tvardi Equity Holders	Holders of Convertible Notes	
\$20 million	5.2674	14.34%	72.99%	12.67%	
\$20.5 million	5.2024	14.49%	72.86%	12.65%	
\$21 million	5.1389	14.64%	72.73%	12.63%	
\$21.5 million	5.0769	14.79%	72.60%	12.60%	
\$22 million	5.0164	14.95%	72.47%	12.58%	
\$22.5 million	4.9574	15.10%	72.34%	12.56%	

		Post-Merger Ownership			
Cara Net Cash at Closing (\$ in millions)	Exchange Ratio	Cara Equity Holders	Tvardi Equity Holders	Holders of Convertible Notes	
\$23.0 million	4.8997	15.25%	72.21%	12.54%	
\$23.5 million	4.8434	15.40%	72.09%	12.52%	
\$24.0 million	4.7883	15.55%	71.96%	12.50%	
\$24.5 million	4.7344	15.70%	71.83%	12.47%	
\$25.0 million	4.6818	15.84%	71.70%	12.45%	

Treatment of Tvardi Stock Options

Under the terms of the Merger Agreement, each option to purchase shares of Tvardi common stock that is outstanding and unexercised immediately prior to the Effective Time, if any, whether or not vested, will be converted into and become an option to purchase shares of Cara common stock. Cara will assume the Tvardi Plan and all such Tvardi stock options in accordance with the terms of the Tvardi Plan and the terms of the stock option agreement by which such option is evidenced.

Accordingly, from and after the Effective Time: (i) each outstanding Tvardi stock option assumed by Cara may be exercised solely for shares of Cara common stock; (ii) the number of shares of Cara common stock subject to each outstanding Tvardi stock option assumed by Cara will be determined by multiplying (A) the number of shares of Tvardi common stock that were subject to such Tvardi stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Cara common stock; (iii) the per share exercise price for the Cara common stock issuable upon exercise of each Tvardi stock option assumed by Cara will be determined by dividing (A) the per share exercise price of Cara common stock subject to such Tvardi stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any Tvardi stock option assumed by Cara will continue in full force and effect and the term, exercisability, vesting schedule, accelerated vesting provisions, and any other provisions of such Tvardi stock option will otherwise remain unchanged; provided, however, that the Cara Board or a committee thereof will succeed to the authority and responsibility of the Tvardi Board or any committee thereof with respect to each Tvardi stock option assumed by Cara.

Directors and Executive Officers of the Combined Company Following the Merger

The Merger Agreement provides that the parties will take all necessary action so that immediately after the Effective Time, the Combined Company Board is comprised of seven members, with six such members designated by Tvardi and one such members designated by Cara. Mr. Alibhai, Chief Executive Officer of Tvardi, will serve as the Chief Executive Officer of the combined company, Mr. Conn, Chief Financial Officer of Tvardi will serve as Chief Financial Officer of the combined company, Dr. Kauh who serves as Chief Medical Officer of Tvardi, will serve in the same role at the combined company, Dr. Larson who serves as Senior Vice President, Research & Development of Tvardi, will serve in the same role at the combined company and Dr. Chen who serves as Vice President, Chemistry, Manufacturing and Controls of Tvardi, will serve in the same role at the combined company. For more information about the directors and executive officers of the combined company following the Merger, please see the sections titled "*The Merger* — *Executive Officers of the Combined Company Following the Merger*" and "*The Merger* — *Directors of the Combined Company Following the Merger*."

Conditions to the Completion of the Merger

The obligations of each party to consummate the Contemplated Transactions are subject to the satisfaction or, to the extent permitted by applicable law, the written waiver by each of the parties of the following conditions:

• there must not have been any temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Contemplated Transactions issued by any court of

competent jurisdiction or other governmental body of competent jurisdiction and that remains in effect, and no law may have made the consummation of the Contemplated Transactions illegal;

- the Cara stockholders must have approved (i) the issuance of Cara common stock or other securities of Cara that represent (or are convertible into) more than 20% of the shares of Cara common stock outstanding immediately prior to the Merger to the holders of Tvardi capital stock and Tvardi stock options in connection with the Contemplated Transactions and the change of control of Cara resulting from the Contemplated Transactions, in each case pursuant to the Nasdaq rules, (ii) the amendment to Cara's certificate of incorporation to effect the Reverse Stock Split and (iii) the amendment to Cara's certificate of incorporation to effect the Authorized Share Increase;
- Tvardi must have delivered an action by written consent (Tvardi Written Consent) executed by the holders of (a) a majority of the then outstanding shares of Tvardi Series A Preferred Stock voting as a separate class; (b) a majority of the then outstanding shares of Tvardi Series B Preferred Stock voting as a separate class; and (d) a majority of the then outstanding shares of Tvardi Series B Preferred Stock on an as-converted to Tvardi common stock basis (collectively, the Required Tvardi Stockholder Vote): (i) adopting and approving the Merger Agreement and the Contemplated Transactions, (ii) acknowledging that the approval given thereby is irrevocable and that such stockholder is aware of its rights to demand appraisal for its shares pursuant to Section 262 of the DGCL and that such stockholder 's approval of the Merger such stockholder is not entitled to appraisal rights and thereby waives any right to receive payment of the fair value of its shares of Tvardi capital stock under the DGCL, and (iv) electing an automatic conversion of each share of Tvardi preferred stock into shares of Tvardi common stock immediately prior to the Effective Time in accordance with the relevant provisions of Tvardi's organizational documents, and such Required Tvardi Stockholder Vote shall remain in full force and effect and shall not have been revoked;
- the existing shares of Cara common stock must have been continually listed on Nasdaq as of and from the date of the Merger Agreement through the Closing Date and the shares of Cara common stock to be issued in the Merger pursuant to the Merger Agreement must have been approved for listing (subject to official notice of issuance) on Nasdaq as of Closing;
- this Registration Statement must have become effective in accordance with the Securities Act and must not be subject to any stop order or proceeding (or threatened proceeding by the SEC) seeking a stop order with respect to the Registration Statement that not been withdrawn; and
- Cara Net Cash must have been finally determined in accordance with the Merger Agreement.

In addition, the obligation of Cara and Merger Sub to consummate the Merger is further subject to the satisfaction or waiver of the following conditions:

- the representations and warranties of Tvardi set forth in the Merger Agreement under Section 2.8(b) must have been true and correct in all respects as of the date of the Merger Agreement and must be true and correct as of the Closing Date with the same force and effect as if made on and as of such date;
- the representations and warranties of Tvardi set forth in the Merger Agreement under Sections 2.1 (Due Organization; Subsidiaries), 2.3 (Authority; Binding Nature of Agreement), 2.4 (Vote Required), 2.6(a) and (c) (Capitalization) and 2.20 (No Financial Advisors) must have been true and correct in all material respects as of the date of the Merger Agreement and must be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties must have been true and correct in all material respects as of such date);
- the representations and warranties of Tvardi set forth in the Merger Agreement (other than the Tvardi representations and warranties listed above) must have been true and correct as of the date of the Merger Agreement and must be true and correct on and as of the Closing Date with the same force and effect as if made on and as of the Closing Date except (a) in each case, or in the aggregate, where the failure to be so true and correct would not reasonably be expected to have an Tvardi

Material Adverse Effect (as defined below) (without giving effect to any references therein to any Tvardi Material Adverse Effect or other materiality qualifications) or (b) for those representations and warranties which address matters only as of a particular date (which representations must have been true and correct, subject to the qualifications set forth in the preceding clause (a), as of such particular date);

- Tvardi must have performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it under the Merger Agreement at or prior to the Effective Time;
- Cara must have received from Tvardi (i) an officer's certificate certifying (x) that certain conditions set forth in the Merger Agreement have been duly satisfied and (y) that the information set forth in an allocation certificate delivered by Tvardi containing information regarding Tvardi's capitalization is true and accurate in all respects; and (ii) a copy of such allocation certificate;
- Cara must have received (i) an original signed statement from Tvardi that Tvardi is not, and has not been at any time during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code, a "United States real property holding corporation," as defined in Section 897(c)(2) of the Code, conforming to the requirements of Treasury Regulations Section 1.1445-2(c)(3) and 1.897-2(h), and (ii) an original signed notice from Tvardi to be delivered to the IRS in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2), together with written authorization for Cara to deliver such notice to the IRS on behalf of Tvardi following Closing, each dated as of the Closing Date, duly executed by an authorized officer of Tvardi, and in form and substance reasonably acceptable to Cara;
- since the date of the Merger Agreement, there must not have occurred an Tvardi Material Adverse Effect that is continuing;
- certain of Tvardi's investor agreements must have been terminated (or will be terminated as of the Closing); and
- Cara must have received duly executed copies of the required Lock-Up Agreements from certain stockholders of Tvardi and each executive officer and director of Tvardi who is elected or appointed, as applicable, as an executive officer or director of Cara as of immediately following Closing, each of which must be in full force and effect as of Closing.

In addition, the obligation of Tvardi to consummate the Merger is further subject to the satisfaction or waiver of the following conditions:

- the representations and warranties of Cara set forth in the Merger Agreement under Section 3.8(b) must have been true and correct in all respects as of the date of the Merger Agreement and must be true and correct as of the Closing Date with the same force and effect as if made on and as of such date;
- the representations and warranties of Cara set forth in the Merger Agreement under Sections 3.1(a) (Due Organization; Subsidiaries), 3.3 (Authority; Binding Nature of Agreement), 3.4 (Vote Required), 3.6(a) and (c) (Capitalization) and 3.21 (No Financial Advisors) must have been true and correct in all material respects as of the date of the Merger Agreement and must be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties must have been true and correct in all material respects as of such date);
- the representations and warranties of Cara set forth in the Merger Agreement (other than the Cara representations and warranties listed above) must have been true and correct as of the date of the Merger Agreement and must be true and correct on and as of the Closing Date with the same force and effect as if made on and as of the Closing Date except (a) in each case, or in the aggregate, where the failure to be so true and correct would not reasonably be expected to have an Cara Material Adverse Effect (as defined below) (without giving effect to any references therein to any Cara Material Adverse Effect or other materiality qualifications) or (b) for those representations and

warranties which address matters only as of a particular date (which representations must have been true and correct, subject to the qualifications set forth in the preceding clause (a), as of such particular date);

- Cara and Merger Sub must have performed or complied with in all material respects all of their agreements and covenants required to be performed or complied with by each of them under the Merger Agreement at or prior to the Effective Time;
- Tvardi must have received from Cara (i) an officer's certificate confirming that certain conditions of the Merger Agreement have been duly satisfied; (ii) a certificate containing information regarding Cara's capitalization; (iii) the Cara closing financial certificate certifying Cara Net Cash as of the Anticipated Closing Date, a draft of which must have been provided at least five business days prior to Closing, which certificate will be accompanied by such supporting documentation, information and calculations as are reasonably requested by Tvardi to verify and determine the information contained therein; and (iv) and a written resignation executed by the directors of Cara who will not continue as directors of Cara after Closing;
- since the date of the Merger Agreement, there must not have occurred a Cara Material Adverse Effect that is continuing;
- Cara Net Cash must be greater than or equal to \$18 million;
- Tvardi must have received satisfactory evidence that (a) specified Cara contracts have been terminated, assigned or fully performed by Cara, (b) all obligations of Cara thereunder have been fully satisfied, waived or otherwise discharged and (c) the Asset Disposition will be consummated substantially concurrently with the Closing; and
- Cara must have received the Lock-Up Agreements executed by certain officers, directors and stockholders of Cara each of which must be in full force and effect as of immediately following the Effective Time.

"Cara Material Adverse Effect" means any effect, change, event, circumstance or development (collectively, Effect) that, considered together with all other Effects, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities or results of operations of Cara or its subsidiaries, taken as a whole; provided, however, that any Effect, individually or together with other Effects, arising or resulting from the following will not be taken into account in determining whether there has been a Cara Material Adverse Effect: (a) general business, political or economic conditions generally affecting the industry in which Cara or any of its subsidiaries operate, (b) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions, (c) changes in financial, banking or securities markets, (d) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (e) any chance in the stock price or trading volume of Cara common stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Cara common stock may be taken into account in determining whether a Cara Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (f) the failure of Cara to meet internal or analysts' expectations or projections or the results of operations of Cara, it being understood, however, that any Effect causing or contributing to the failure of Cara to meet internal or analysts' expectations or projections or the results of operations of Cara may be taken into account in determining whether a Cara Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition, (g) any changes in or affecting clinical trial programs or studies conducted by or on behalf of Cara or its subsidiaries, including any adverse data, event or outcome arising out of or related to any such programs or studies, (h) the announcement of the Merger Agreement or the pendency of the Contemplated Transactions, (i) the Asset Dispositions, (j) any reduction in the amount of Cara's cash and cash equivalents as a result of expenditures made by Cara related to wind down activities of Cara associated with the termination of its research and development activities (including the termination of ongoing contractual obligations relating to Cara current products or product candidates), (k) the taking of any action expressly required to be taken by the Merger Agreement, except in each case, with respect to clauses (a) through (d), to

the extent disproportionately affecting Cara and its subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which Cara and its subsidiaries operate.

"Tvardi Material Adverse Effect" means any Effect that, considered together with all other Effects, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities or results of operations of Tvardi, taken as a whole; provided, however, that any Effect, individually or together with other Effects, arising or resulting from the following will not be taken into account in determining whether there has been an Tvardi Material Adverse Effect: (a) general business, political or economic conditions generally affecting the industry in which Tvardi operates, (b) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions. (c) changes in financial, banking or securities markets. (d) any change in, or any compliance with or action taken for the purpose of complying with, any law or GAAP (or interpretations of any law or GAAP), (e) the announcement of the Merger Agreement or the pendency of the Contemplated Transactions, (f) resulting from the taking of any action expressly required to be taken by the Merger Agreement, or (g) continued losses from operations or decreases in cash balances of Tvardi; except with respect to clauses (a) through (d), to the extent such Effect disproportionately affects Tvardi, taken as a whole, relative to other similarly situated companies in the industries in which Tvardi operates, in which case such Effect shall be taken into account to the extent of such disproportionate effect on the Tvardi.

Calculation of Cara Net Cash

At least 15 calendar days prior to the Cara special meeting of stockholders, Cara and Tvardi will agree upon the Anticipated Closing Date. At least 15 calendar days prior to the Cara special meeting of stockholders, Cara will deliver to Tvardi the Net Cash Schedule setting forth Cara's estimated calculation of Cara Net Cash, including each component thereof, as of the Anticipated Closing Date, prepared and certified by Cara's Chief Financial Officer (or, if there is no Chief Financial Officer, the principal accounting officer of Cara), and shall make available to Tvardi the work papers and back-up materials used or useful in preparing the Net Cash Schedule and, as reasonably requested by Tvardi, Cara's accountants and counsel at reasonable times and upon reasonable notice. Within three business days after delivery of the Net Cash Schedule (Response Date), Tvardi will have the right to dispute any part of the Net Cash Schedule by delivering a written notice to that effect to Cara (a Dispute Notice). Any Dispute Notice will identify in reasonable detail the nature of any proposed revisions to the Cara Net Cash calculation.

If on or prior to the Response Date, Tvardi (i) notifies Cara in writing that it has no objections to the Cara Net Cash calculation or (ii) fails to deliver a Dispute Notice, then the Cara Net Cash calculation as set forth in the Net Cash Schedule will be deemed to have been finally determined for purposes of the Merger Agreement and to represent Cara Net Cash as of the Anticipated Closing Date for purposes of the Merger Agreement.

If Tvardi delivers a Dispute Notice on or prior to the Response Date, then representatives of both parties will promptly meet and attempt in good faith to resolve the disputed item(s) and negotiate an agreedupon determination of Cara Net Cash, which agreed upon Cara Net Cash amount will be deemed to have been finally determined for purposes of the Merger Agreement and to represent the Cara Net Cash, as of the Anticipated Closing Date for purposes of the Merger Agreement.

If Cara and Tvardi are unable to negotiate an agreed-upon determination of Cara Net Cash, as of the Anticipated Closing Date, within three calendar days after delivery of the Dispute Notice (or such other period as Cara and Tvardi may mutually agree upon), then Cara and Tvardi will jointly select an independent auditor of recognized national standing (Accounting Firm) to resolve any remaining disagreements as to the Cara Net Cash calculation. Cara will promptly deliver to the Accounting Firm the work papers and back-up materials used in preparing the Net Cash Schedule, and Cara and Tvardi will use commercially reasonable efforts to cause the Accounting Firm to make its determination within 10 calendar days of accepting its selection. Cara and Tvardi will be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; *provided, however*, that no such presentation or discussion will occur without the presence of a representative of each of Cara and Tvardi. The determination of the Accounting Firm will be limited to the disagreements

submitted to the Accounting Firm. The determination of the amount of Cara Net Cash, made by the Accounting Firm will be final and binding upon the parties and deemed to have been finally determined for purposes of the Merger Agreement and to represent Cara Net Cash as of the Anticipated Closing Date for purposes of the Merger Agreement, and the parties will delay the Closing until the resolution of the Cara Net Cash calculation. The fees and expenses of the Accounting Firm will be allocated between Cara and Tvardi in the same proportion that the disputed amount of Cara Net Cash that was unsuccessfully disputed by such party (as finally determined by the Accounting Firm) bears to the total disputed amount of Cara Net Cash. If the determination of Cara Net Cash as of the Anticipated Closing Date is done in accordance with this paragraph, the parties will not be required to determine Cara Net Cash, again even though the Closing may occur later than the Anticipated Closing Date, except that either party may request a re-determination of Cara Net Cash if the Closing Date is more than five business days after the Anticipated Closing Date.

Asset Disposition

Cara must use commercially reasonable efforts to sell, transfer, license, assign or otherwise divest its intellectual property and other assets and technology in existence on the date of the Merger Agreement (Potentially Transferrable Assets) to one or more third parties in one or a series of transactions concurrently with, or immediately following, Closing (Potential Asset Dispositions); provided, that any such Potential Asset Disposition will require, to the extent consistent with applicable laws, the prior written consent of Tvardi (which consent shall be in the sole discretion of Tvardi) if such Potential Asset Disposition would create any post-disposition liabilities or indemnity obligations for Cara following Closing; provided, however, that the prior written consent of Tvardi will not be required in connection with any Potential Asset Disposition if Cara agrees that the maximum aggregate dollar value of any post-disposition liabilities or indemnity obligation to Cara Net Cash as set forth in the Merger Agreement. In no event will Cara enter into any Potential Asset Disposition that would result in excess of \$100,000 of indemnity obligations or post-disposition Liabilities to, or obligations of, Cara following the Closing.

On December 17, 2024, Cara and Royalty Sub, entered into an APA with CSL Vifor, pursuant to which, at the consummation of the transaction, Sellers will sell to CSL Vifor and CSL Vifor will acquire from Sellers certain assets and rights for the development, manufacture and commercialization of difelikefalin as well as certain associated liabilities for a purchase price of \$900,000 (subject to certain adjustments with respect to inventory). See "Asset Sale" beginning on page 165 of this proxy statement/prospectus for a more detailed description of this Asset Disposition.

Representations and Warranties

The Merger Agreement contains customary representations and warranties of the parties. Tvardi represents and warrants to the following matters:

- Due Organization; Subsidiaries
- Organizational Documents
- · Authority; Binding Nature of Agreement
- · Vote Required
- Non-Contravention; Consents
- · Capitalization
- Financial Statements
- · Absence of Changes
- · Absence of Undisclosed Liabilities
- Title to Assets
- · Real Property; Leasehold
- · Intellectual Property

- Agreements, Contracts and Commitments
- Compliance; Permits; Restrictions
- Legal Proceedings; Orders
- Tax Matters
- Employee and Labor Matters; Benefit Plans
- Environmental Matters
- Insurance
- No Financial Advisors
- Disclosure
- Transactions with Affiliates
- Anti-Bribery
- Disclaimer of Other Representations and Warranties

Cara and Merger Sub represent and warrant to the following matters:

- Due Organization; Subsidiaries
- Organizational Documents
- Authority; Binding Nature of Agreement
- Vote Required
- Non-Contravention; Consents
- Capitalization
- SEC Filings; Financial Statements
- Absence of Changes
- Absence of Undisclosed Liabilities
- Title to Assets
- Real Property; Leasehold
- Intellectual Property
- Agreements, Contracts and Commitments
- Compliance; Permits; Restrictions
- · Legal Proceedings; Orders
- Tax Matters
- Employee and Labor Matters; Benefit Plans
- Environmental Matters
- Transactions with Affiliates
- Insurance
- No Financial Advisors
- Disclosure
- Anti-Bribery
- Valid Issuance

- · Opinion of Financial Advisor
- · Disclaimer of Other Representations and Warranties

The representations and warranties of Tvardi, Cara and Merger Sub contained in the Merger Agreement or any certificate or instrument delivered pursuant to the Merger Agreement will terminate at the Effective Time.

Non-Solicitation

Cara and its subsidiaries and Tvardi and their respective representatives are prohibited by the terms of the Merger Agreement, other than, in the case of Cara, with respect to any Asset Disposition, from, directly or indirectly, (i) soliciting, initiating or knowingly encouraging, inducing or facilitating the communication, making, submission or announcement of any Acquisition Proposal (as defined below) or Acquisition Inquiry (as defined below) or taking any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnishing any non-public information regarding such party to any person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engaging in discussions (other than to inform any person of the existence of these prohibitions) or negotiations with any person with respect to any Acquisition Proposal; (v) executing or entering into any letter of intent or any contract contemplating or otherwise relating to any Acquisition Transaction (as defined below) (other than, in the case of Cara, a confidentiality agreement permitted as described below); or (vi) publicly proposing to do any of the foregoing.

Pursuant to the terms of the Merger Agreement, each of Cara and Tvardi agreed to immediately cease and cause to be terminated any existing discussions, negotiations and communications with any person relating to any Acquisition Proposal or Acquisition Inquiry (other than, in the case of Cara, any Asset Dispositions) as of the date of the Merger Agreement, immediately terminate access to any non-public information provided to such person via an electronic or physical data room and within three business days after the date of the Merger Agreement, request the destruction or return of any of such party's nonpublic information provided to such person as soon as practicable after the date of the Merger Agreement.

Subject to certain restrictions and prior to obtaining the Required Cara Stockholder Vote (as defined below), Cara and its subsidiaries may furnish non-public information regarding Cara or any of its subsidiaries to, and enter into discussions or negotiations with, any person in response to a bona fide Acquisition Proposal by such person, which the Cara Board determines in good faith, after consultation with its outside financial advisor and outside legal counsel, constitutes, or is reasonably likely to result in, a Superior Offer (as defined below) (and is not withdrawn) if: (A) none of Cara, any of its subsidiaries or any of their respective representatives have breached the non-solicitation restrictions in the Merger Agreement in any material respect. (B) the Cara Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action would be inconsistent with the fiduciary duties of the Cara Board under applicable law; (C) Cara receives from such person an executed confidentiality agreement containing provisions (including nondisclosure provisions, use restrictions, non-solicitation provisions, no hire and "standstill" provisions), in the aggregate, at least as favorable to it as those contained in the confidentiality agreement entered into between Cara and Tvardi in connection with the Merger; (D) substantially contemporaneously with furnishing any such nonpublic information to such person, Cara gives Tvardi notice of Cara's intention to furnish nonpublic information to, or enter into discussions with, such person and furnishes such nonpublic information to Tvardi (to the extent such information has not been previously furnished by Cara to Tvardi).

If Cara any of its subsidiaries, Tvardi, or any of their respective representatives, receives an Acquisition Proposal or Acquisition Inquiry during the period following the date of the Merger Agreement through Closing, then such party will promptly (and in no event later than one business day after such party becomes aware of such Acquisition Proposal or Acquisition Inquiry) (i) advise the other party orally and in writing of such Acquisition Proposal or Acquisition Inquiry) (ii) advise the other party orally and in writing such Acquisition Proposal or Acquisition Inquiry), (ii) in the case of a written Acquisition Proposal or Acquisition Inquiry), (ii) in the case of a written Acquisition Proposal or any of its subsidiaries or Tvardi, as the case may be, any of their respective representatives, including any



subsequent modifications or amendments, and (iii) in the case of an oral Acquisition Proposal or Acquisition Inquiry, provide a written summary of the terms thereof. Each party will keep the other party reasonably and promptly informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry and any material modification, amendment or proposed material modification thereto (including any revision in the amount, form or mix of consideration) and of all verbal or written communications related thereto, together with copies of new written documentation and correspondence to or from such party, any of its subsidiaries or any of their respective representatives as well as written summaries of any material oral communications).

"Acquisition Inquiry" means, with respect to a party, an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by Tvardi or any of its affiliates, on the one hand, or Cara or any of its affiliates, on the other hand, to the other party) that could reasonably be expected to lead to an Acquisition Proposal; provided, however, that the term Acquisition Inquiry does not include the Merger, the other Contemplated Transactions or any transactions related to the Asset Dispositions.

"Acquisition Proposal" means, with respect to a party, any offer or proposal, whether written or oral (other than an offer or proposal made or submitted by or on behalf of Tvardi or any of its affiliates, on the one hand, or by or on behalf of Cara or any of its affiliates, on the other hand, to the other party) contemplating or otherwise relating to any Acquisition Transaction with such party, other than the Asset Dispositions.

"Acquisition Transaction" means any transaction or series of related transactions (other than the Asset Dispositions) involving:

- any merger, consolidation, amalgamation, share exchange, business combination, issuance of securities, acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or other similar transaction: (i) in which a party is a constituent entity; (ii) in which a person or "group" (as defined in the Exchange Act) of persons directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of a party or any of its subsidiaries; or (iii) in which a party or any of its subsidiaries issues securities of any class of voting securities of such party or any of its subsidiaries; provided, however, that the conversion of the Convertible Notes into shares of Cara common stock pursuant to the Merger Agreement will not be, nor will securities to be acquired thereby, by deemed to trigger an Acquisition Transaction; or
- any sale, lease, exchange, transfer, license, acquisition or disposition of any business or businesses or assets that constitute or account for 20% or more of the consolidated book value or the fair market value of the assets of a party and its subsidiaries, taken as a whole.

"Superior Offer" means an unsolicited bona fide written Acquisition Proposal (with all references to 20% in the definition of Acquisition Transaction being treated as references to greater than 50% for these purposes) that: (a) was not obtained or made as a result of a breach of (or in violation of) the Merger Agreement; and (b) is on terms and conditions that the Cara Board determines in good faith, based on such matters that it deems relevant (including the likelihood of consummation thereof and the financing terms thereof), as well as any written offer by the Company to amend the terms of the Merger Agreement, and following consultation with its outside legal counsel and outside financial advisors are more favorable, from a financial point of view, to Cara's stockholders than the terms of the Contemplated Transactions and is not subject to any financing condition (and if financing is required, such financing is then fully committed to the third party).

Cara Stockholder Meeting

Promptly after the Registration Statement has been declared effective by the SEC under the Securities Act, Cara will take all action necessary under applicable law to call, give notice of and hold a meeting of the holders of Cara common stock for the purpose of seeking approval of the Merger Agreement and the Contemplated Transactions, including: (i) the issuance of Cara common stock or other securities of Cara that represent (or are convertible into) more than 20% of the shares of Cara common stock outstanding immediately prior to the Merger to the holders of Tvardi capital stock and Tvardi stock options in connection

with the Contemplated Transactions and the change of control of Cara resulting from the Contemplated Transactions, in each case pursuant to the Nasdaq rules, (ii) the amendment of Cara's certificate of incorporation to effect the Reverse Stock Split, (iii) the amendment of Cara's certificate of incorporation to effect the Authorized Share Increase, (iv) the Equity Plan Proposal, (v) the ESPP Proposal and (vi) any other proposals the parties deem necessary or desirable to consummate the Contemplated Transactions (the proposals set forth in the foregoing clauses (i) through (iii), the Cara Stockholder Matters).

The Cara special meeting will be held as promptly as practicable after the Registration Statement is declared effective under the Securities Act and, in any event, no later than 45 calendar days after the effective date of the Registration Statement. Cara will take reasonable measures to ensure that all proxies solicited in connection with the Cara special meeting are solicited in compliance with all applicable laws. If, on or before the date of the Cara special meeting, Cara reasonably believes that it (i) will not receive proxies sufficient to obtain the required approvals of the Required Cara Closing Stockholder Matters (Required Cara Stockholder Vote), whether or not a quorum would be present or (ii) will not have sufficient shares of Cara common stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Cara special meeting, Cara may postpone or adjourn, or make one or more successive postponements or adjourned more than an aggregate of 30 calendar days in connection with any postponements.

Cara agreed that, subject to certain exceptions in the Merger Agreement: (i) the Cara Board will recommend that the holders of Cara common stock vote to approve the Cara Stockholder Matters and the Equity Plan Proposal and the ESPP Proposal and will use commercially reasonable efforts to solicit such approval within the timeframe set forth above, (ii) this proxy statement/prospectus will include a statement to the effect that the Cara Board recommends that Cara's stockholders vote to approve the Cara Stockholder Matters and the Equity Plan Proposal and the ESPP Proposal (the recommendation of the Cara Board with respect to the Cara Stockholder Matters being referred to as the Cara Board Recommendation); (iii) the Cara Board Recommendation will not be withheld, amended, withdrawn or modified (and the Cara Board will not publicly propose to withhold, amend, withdraw or modify the Cara Board Recommendation), and no resolution by the Cara Board or any committee thereof to withdraw or modify the Cara Board Recommend) any Acquisition Proposal shall be adopted or proposed; and (iv) the Cara Board will not publicly announce an intention or resolution to effect any of the foregoing (the actions set forth in the foregoing clause (iii), collectively, a Cara Board Adverse Recommendation Change).

The terms of the Merger Agreement provide that, subject to the limitations set forth in the Merger Agreement, if at any time prior to the approval of the Cara Stockholder Matters at the Cara special meeting by the Required Cara Stockholder Vote, Cara receives a bona fide Acquisition Proposal (which did not arise out of a material breach of the non-solicitation provisions of the Merger Agreement) from any person that has not been withdrawn and after consultation with outside legal counsel, the Cara Board determines, in good faith, that such Acquisition Proposal is a Superior Offer, the Cara Board may make a Cara Board Adverse Recommendation Change if and only if: (A) the Cara Board determines in good faith, after consultation with Cara's outside legal counsel and financial advisor, that the failure to do so would be inconsistent with the fiduciary duties of the Cara Board to Cara's stockholders under applicable law; (B) Cara has given Tvardi prior written notice of its intention to consider making a Cara Board Adverse Recommendation Change at least four business days prior to making any such Cara Board Adverse Recommendation Change (a Cara Determination Notice, and such period, the Cara Notice Period) (which notice will not constitute a Cara Board Adverse Recommendation Change); and (C)(1) Cara provided to Tvardi a description in reasonable detail of the reasons for such Cara Board Adverse Recommendation Change (as defined in the Merger Agreement), the identity of the party making the Acquisition Proposal, a summary of the material terms and conditions of the Acquisition Proposal and written copied of any relevant proposed transaction documents (including with respect to financing arrangements) in accordance with the Merger Agreement, (2) Cara has given Tvardi the three business days after a Cara Determination Notice to propose revisions to the terms of the Merger Agreement or make another proposal and has made its representatives reasonable available to negotiate in good faith with Tvardi (to the extent Tvardi desires to negotiate) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by Tvardi, if any, after consultation

with outside legal counsel, the Cara Board determines, in good faith, that such Acquisition Proposal is a Superior Offer and that the failure to make the Cara Board Adverse Recommendation Change would be inconsistent with the fiduciary duties of the Cara Board to Cara's stockholders under applicable law; provided that during any Cara Notice Period, Tvardi shall be entitled to deliver to Cara one or more counterproposals to such Acquisition Proposal and Cara will, and will cause its representatives to, negotiate with Tvardi in good faith (to the extent Tvardi desires to negotiate) to enable Tvardi to propose in writing an offer binding on Tvardi to effect such adjustments to the terms and conditions of the Merger Agreement so that the applicable Acquisition Proposal ceases to constitute a Superior Offer. The provisions of the Merger Agreement described in this paragraph also apply to any material change to the facts and circumstances relating to such Acquisition Proposal or any amendment to such Acquisition Proposal (including any revision in the amount, form or mix of consideration), and require a new Cara Determination Notice and Cara will be required to provide Tvardi with notice of such material change or amendment, except that the references to four business days will be deemed to be two business days.

The terms of the Merger Agreement also provide that, other than in connection with an Acquisition Proposal, the Cara Board may make a Cara Board Adverse Recommendation Change in response to a Cara Change in Circumstance (as defined below), if and only if: (A) the Cara Board determines in good faith, after consultation with the Cara's outside legal counsel, that the failure to do so would be inconsistent with the fiduciary duties of the Cara Board to Cara's stockholders under applicable law; (B) Cara has given Tvardi a Cara Determination Notice at least four business days prior to making any such Cara Board Adverse Recommendation Change; and (C) (1) Cara has specified the Cara Change in Circumstance in reasonable detail, including the material facts and circumstances related to the applicable Cara Change in Circumstance, (2) Cara has given Tvardi four business days after the Cara Determination Notice to propose revisions to the terms of the Merger Agreement or make another proposal, and has made its representatives reasonably available to negotiate in good faith with Tvardi (to the extent Tvardi desires to do so) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by Tvardi, if any, after consultation with outside legal counsel, the Cara Board determines, in good faith, that the failure to make the Cara Board Adverse Recommendation Change in response to such Cara Change in Circumstance would be inconsistent with the fiduciary duties of the Cara Board to Cara's stockholders under applicable law. The provisions of the Merger Agreement described in this paragraph also apply to any material change to the facts and circumstances relating to such Cara Change in Circumstance and require a new Cara Determination Notice and Cara will be required to provide Tvardi with notice of such material change, except that the references to four business days will be deemed to be two business days.

"Cara Change in Circumstance" means a change in circumstances (other than any such event, development or change to the extent related to (A) any Acquisition Proposal, Acquisition Inquiry or the consequences thereof, or (B) the fact, in and of itself, that Cara meets or exceeds internal budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations) that affects the business, assets or operations of Cara or any of its subsidiaries that occurs or arises after the date of the Merger Agreement.

Tvardi Stockholder Action by Written Consent

The Merger Agreement contemplates that promptly after this Registration Statement is declared effective under the Securities Act, and in any event no later than three business days thereafter, Tvardi will prepare, with the cooperation of Cara, and cause to be mailed to its stockholders an information statement to solicit the approval by written consent from the Company Signatories (within seven business days after this Registration Statement is declared effective), including Tvardi's stockholders sufficient for the Required Tvardi Stockholder Vote in lieu of a meeting pursuant to Section 228 of the DGCL, for purposes of approving the Tvardi Stockholder Matters.

Tvardi agreed that: (i) the Tvardi Board will recommend that the Tvardi stockholders vote to approve the Tvardi Stockholder Matters and will use reasonable best efforts to solicit such approval from the Company's stockholders within the timeframe set forth above (the recommendation of the Tvardi Board that Tvardi's stockholders vote to adopt and approve the Tvardi Stockholder Matters being referred to as the Tvardi Board Recommendation); and (ii) the Tvardi Board Recommendation will not be withdrawn or

modified (and the Tvardi Board will not publicly propose to withdraw or modify the Tvardi Board Recommendation), and no resolution by the Tvardi Board or any committee thereof to withdraw or modify the Tvardi Board Recommendation or to adopt, approve or recommend (or publicly propose to adopt, approve or recommend) any Acquisition Proposal will be adopted or proposed.

Appraisal Rights

Under the DGCL, Cara stockholders are not entitled to appraisal rights in connection with the Merger.

Tvardi stockholders are entitled to statutory appraisal rights in connection with the Merger under Section 262 of the DGCL.

Covenants; Operation of Business Pending the Merger

During the period from the date of the Merger Agreement and continuing until the earlier of the termination of the Merger Agreement or the Effective Time, except (i) as set forth in Cara's disclosure schedule, (ii) expressly permitted or required in accordance with the Merger Agreement including in connection with the Asset Dispositions, (iii) as required by applicable law, or (iv) as may be consented to in writing by Tvardi (not be unreasonably withheld, conditioned or delayed), each of Cara and its subsidiaries has agreed to (A) conduct its business and operations in the ordinary course of business (which includes actions required to effect the Asset Dispositions or effect the winding down of Cara's prior research and development activities) and in compliance in all material respects with all applicable laws and the requirements of all of its material contracts and (B) continue to pay material outstanding accounts payable and other material current liabilities (including payroll) in the ordinary course of business, and will not:

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares
 of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or
 other securities (except repurchases from terminated employees, directors or consultants of Cara or
 in connection with the payment of the exercise price and/or withholding taxes incurred upon the
 exercise, settlement or vesting of any award or purchase rights granted under Cara's 2014 Equity
 Incentive Plan and Cara's 2019 Inducement Plan (collectively, Cara Plans) in accordance with the
 terms of such award in effect on the date of the Merger Agreement);
- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Cara or any of its subsidiaries (except for Cara common stock issued upon the valid exercise of Cara options upon settlement of Cara RSUs);
 (B) any option, warrant or right to acquire any capital stock or any other security; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Cara or any of its subsidiaries;
- (A) amend the terms of any outstanding Cara Options to extend the exercise period or the exercise price of any such Cara Option or (B) permit the net settlement of any Cara Options in any manner in which cash of Cara is to be remitted or paid by Cara rather than the relevant holder of any such Cara Options;
- except as required to give effect to anything in contemplation of Closing, amend any of its or its subsidiaries' organizational documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;
- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;
- (A) lend money to any person, (B) incur or guarantee any indebtedness for borrowed money,
 (C) guarantee any debt securities of others, (D) other than the incurrence or payment of Transaction Expenses (as defined in "— *Expenses*"), make any capital expenditure in excess of \$5,000, or
 (E) forgive any loans to any persons, including Cara's employees, officers, directors or affiliates;
- other than as required by applicable law or the terms of any Cara benefit plan as in effect on the date of the Merger Agreement: (A) adopt, terminate, establish or enter into any Cara benefit plan;



(B) cause or permit any Cara benefit plan to be amended; (C) pay any bonus or make any profitsharing or similar payment to, or increase the amount of the wages, salary, fringe benefits, commissions, bonus, or other compensation or benefits payable to any of its directors, officers, consultants, or employees; (D) hire any officer or employee whose annual base salary is or is expected to be more than \$200,000 per year, who is entitled to severance benefits or who is not hired on an at-will basis; (E) increase the severance or change of control benefits offered to any current or new employees, directors or consultants (other than acceleration of the Cara options or Cara RSUs as contemplated by the Merger Agreement); or (F) grant any new, or increase any existing, severance, retention benefits, change in control award, or similar compensation or benefit to any person;

- recognize any labor union or labor organization;
- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any encumbrance with respect to such material assets or properties;
- sell, assign, transfer, license, sublicense or otherwise dispose of any Cara intellectual property or any Cara in-licensed intellectual property;
- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income or other material tax liability or submit any voluntary disclosure application, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the ordinary course of business the principal subject matter of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than pursuant to an extension of time to file any tax return granted in the ordinary course of business of not more than seven months), or adopt or change any material accounting method in respect of taxes;
- enter into, materially amend or terminate any Cara material contract or contract that would be deemed a Cara material contract if entered into prior to the date of the Merger Agreement;
- other than as required by law or GAAP, take any action to change accounting policies or procedures;
- initiate or settle any legal proceeding;
- (A) fail to maintain any material insurance policies in full force and effect prior to the renewal period of any such material insurance policies or (B) fail to use commercially reasonable efforts to renew any such material insurance policies following the applicable expiration or acquire substantially similar insurance policies;
- enter into or amend a contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions;
- enter into a new line of business or start to conduct a line of business; or
- agree, resolve or commit to do any of the foregoing.

During the period from the date of the Merger Agreement and continuing until the earlier of the termination of the Merger Agreement or the Effective Time, except (i) as set forth in Tvardi's disclosure schedule, (ii) expressly permitted or required in accordance with the Merger Agreement, (iii) as required by applicable law, or (iv) as may be consented to in writing by Cara (not be unreasonably withheld, conditioned or delayed), Tvardi has agreed to (A) conduct its business and operations in the ordinary course of business and in compliance in all material respects with all applicable laws and the requirements of all of its material contracts and (B) continue to pay material outstanding accounts payable and other material current liabilities (including payroll) in the ordinary course of business, and will not:

• declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Tvardi or in connection with the payment of the exercise price or withholding taxes incurred upon the exercise,



settlement or vesting of any award granted under the Tvardi Plans in accordance with the terms of such award in effect on the date of the Merger Agreement);

- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with
 respect to: (A) any capital stock or other security of Tvardi (except for shares of Tvardi common
 stock issued upon the valid exercise of Tvardi Options); (B) any option, warrant or right to acquire
 any capital stock or any other security other than stock options or restricted stock unit awards
 granted to employees and service providers in the ordinary course of business which are included in
 the calculation of the Tvardi Outstanding Shares; or (C) any instrument convertible into or
 exchangeable for any capital stock or other security of Tvardi;
- except as required to give effect to anything in contemplation of the Closing, amend any of its organizational documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, in connection with the Contemplated Transactions;
- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;
- (A) lend money to any person (except for the advancement of reasonable and customary expenses to
 employees and directors in the ordinary course of business), (B) incur or guarantee any indebtedness
 for borrowed money, (C) guarantee any debt securities of others, (D) other than the incurrence or
 payment of Transaction Expenses (as defined in "— *Expenses*"), make any capital expenditures in
 excess of \$250,000 of the budgeted capital expenditure amounts set forth in Tvardi's operating
 budget delivered to Cara on the date of the Merger Agreement (Tvardi Budget), or (E) forgive any
 loans to any persons, including Tvardi's employees, officers, directors or affiliates;
- other than as required by applicable law or the terms of any Tvardi benefit plan as in effect on the date of the Merger Agreement: (A) adopt, terminate, establish or enter into any Tvardi benefit plan; (B) cause or permit any Tvardi benefit plan to be amended in any material respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees other than increases in base salary and annual cash bonus opportunities and payments made in the ordinary course of business consistent with past practice; (D) increase the severance or change-of-control benefits offered to any current or new employees, directors or consultants; or (E) hire, terminate or give notice of termination to any officer other than for cause;
- recognize any labor union or labor organization;
- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any encumbrance with respect to such material assets or properties, except in the ordinary course of business;
- sell, assign, transfer, license, sublicense or otherwise dispose of any Tvardi intellectual property (other than pursuant to non-exclusive licenses in the ordinary course of business) or any Tvardi inlicensed intellectual property;
- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income or other material tax liability or submit any voluntary disclosure application, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the ordinary course of business the principal subject matter of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than pursuant to an extension of time to file any tax return granted in the ordinary course of business of not more than seven months), or adopt or change any material accounting method in respect of taxes;
- enter into, materially amend or terminate any Tvardi material contract or contract that would be deemed a Tvardi material contract if entered into prior to the date of the Merger Agreement (other than in connection with the ordinary course of business);

- except as otherwise set forth in the Tvardi Budget and the incurrence or payment of any Transaction Expenses (as defined in "— *Expenses*"), make any expenditures or discharge or satisfy any liabilities, in each case, in amounts that exceed the aggregate amount of the Tvardi Budget by \$1,500,000;
- other than as required by law or GAAP, take any action to change accounting policies or procedures;
- initiate or settle any legal proceeding;
- (a) fail to maintain any material insurance policies in full force and effect prior to the renewal period of any such material insurance policies or (b) fail to use commercially reasonable efforts to renew any such material insurance policies following the applicable expiration or acquire substantially similar insurance policies;
- enter into or amend a contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions;
- enter into a new line of business in a new geographic area where it was not previously conduced; or
- agree, resolve or commit to do any of the foregoing.

Termination and Termination Fees

The Merger Agreement may be terminated prior to the Effective Time (whether before or after the required stockholder approvals to consummate the Merger have been obtained, unless otherwise specified below):

(a) by mutual written consent of Cara and Tvardi;

(b) by either Cara or Tvardi if the Contemplated Transactions have not been consummated by June 30, 2025 (End Date) (subject to possible extension as provided in this paragraph, the End Date); provided, however, that the right to terminate the Merger Agreement under this paragraph will not be available to a party if such party's action or failure to act has been a principal cause of the failure of the Contemplated Transactions to occur on or before the End Date and such action or failure to act constitutes a breach of the Merger Agreement; provided, further, however, that, in the event that the SEC has not declared the Registration Statement effective under the Securities Act by the date which is 30 calendar days prior to the End Date, then Cara will be entitled to extend the End Date for an additional 60 calendar days by written notice to Tvardi;

(c) by either Cara or Tvardi if a court of competent jurisdiction or other governmental body has issued a final and non-appealable order, decree or ruling, or has taken any other action, having the effect of permanently restraining, enjoining or otherwise prohibiting the Contemplated Transactions;

(d) by Cara if the Tvardi Written Consent executed by each Company Signatory has not been obtained within seven business days of the date of the Registration Statement becoming effective in accordance with the provisions of the Securities Act; provided, however, that once the Tvardi Written Consent has been obtained, Cara may not terminate the Merger Agreement pursuant to this paragraph;

(e) by either Cara or Tvardi if (i) the Cara special meeting (including any adjournments and postponements thereof) was held and completed and Cara's stockholders shall have taken a final vote on the Cara Stockholder Matters and (ii) the Cara Stockholder Matters were not approved at such Cara special meeting by the Required Cara Stockholder Vote; provided, however, that the right to terminate the Merger Agreement pursuant to this paragraph will not be available to Cara where the failure to obtain the Required Cara Stockholder Vote was caused by the action or failure to act of Cara and such action or failure to act constitutes a material breach by Cara of the Merger Agreement;

(f) by Tvardi (at any time prior to the approval of the Cara Stockholder Matters by the Required Cara Stockholder Vote) if a Cara Triggering Event (as defined below) has occurred;

(g) by Cara (at any time prior to the Required Tvardi Stockholder Vote being obtained) if an Tvardi Triggering Event (as defined below) has occurred;

(h) by Tvardi, upon a breach of any representation, warranty, covenant or agreement set forth in the Merger Agreement by Cara or Merger Sub or if any representation or warranty of Cara or Merger Sub has become inaccurate, in either case, such that certain closing conditions set forth in the Merger Agreement would not be satisfied as of the time of such breach or as of the time such representation or warranty has become inaccurate; provided that Tvardi is not then in material breach of any representation, warranty, covenant or agreement under the Merger Agreement; provided, further, that if such inaccuracy in Cara's or Merger Sub's representations and warranties or breach by Cara or Merger Sub is curable by the End Date by Cara or Merger Sub, then the Merger Agreement will not terminate pursuant to this paragraph as a result of such particular breach or inaccuracy until the earlier of (i) the End Date and (ii) the expiration of a 30 calendar day period commencing upon delivery of written notice from Tvardi to Cara of such breach or inaccuracy and its intention to terminate pursuant to this paragraph (it being understood that the Merger Agreement will not terminate pursuant to this paragraph as a result of such breach or inaccuracy and its intention to this paragraph as a result of such particular breach or Merger Sub is cured prior to such terminate pursuant to this paragraph.

(i) by Cara, upon a breach of any representation, warranty, covenant or agreement set forth in the Merger Agreement by Tvardi or if any representation or warranty of Tvardi has become inaccurate, in either case, such that certain closing conditions set forth in the Merger Agreement would not be satisfied as of the time of such breach or as of the time such representation or warranty has become inaccurate; provided that neither Cara nor Merger Sub is then in material breach of any representation, warranty, covenant or agreement under the Merger Agreement; provided, further, that if such inaccuracy in Tvardi's representations and warranties or breach by Tvardi is curable by End Date by Tvardi then the Merger Agreement will not terminate pursuant to this paragraph as a result of such particular breach or inaccuracy until the earlier of (i) the End Date and (ii) the expiration of a 30 calendar day period commencing upon delivery of written notice from Cara to Tvardi of such breach or inaccuracy and its intention to terminate pursuant to this paragraph (it being understood that the Merger Agreement will not terminate pursuant to this paragraph (it being understood that the Merger Agreement will not terminate pursuant to this paragraph (it being understood that the Merger Agreement will not terminate pursuant to this paragraph as a result of such particular breach or inaccuracy if such breach by Tvardi is cured prior to such termination becoming effective).

The party desiring to terminate the Merger Agreement will give the other party written notice of such termination, specifying the provisions of the Merger Agreement pursuant to which such termination is made and the basis therefor described in reasonable detail.

"Tvardi Triggering Event" will be deemed to have occurred if: (a) the Tvardi Board has made an Tvardi Board Adverse Recommendation Change; (b) the Tvardi Board or any committee thereof has publicly approved, endorsed or recommended any Acquisition Proposal; or (c) following the date of the Merger Agreement, Tvardi has entered into any letter of intent or similar document or any contract relating to any Acquisition Proposal.

"Cara Triggering Event" will be deemed to have occurred if: (a) Cara has failed to include in the proxy statement/prospectus the Cara Board Recommendation or has made a Cara Board Adverse Recommendation Change; (b) the Cara Board or any committee thereof has publicly approved, endorsed or recommended any Acquisition Proposal; (c) following the date of the Merger Agreement, Cara has entered into any letter of intent or similar document or any contract relating to any Acquisition Proposal (other than a confidentiality agreement permitted pursuant to the Merger Agreement) in violation of the terms of the Merger Agreement; (d) Cara or any director or officer of Cara has willfully and intentionally breached the provisions set forth in the non-solicitation or Cara stockholders' meeting provisions of the Merger Agreement or (e) the Cara Board shall have failed to publicly reaffirm the Cara Board Recommendation within 10 business days after Tvardi so requests in writing; *provided* that Tvardi may only make such request once every 30 days unless there has been a publicly disclosed change regarding an Acquisition Proposal.

Cara must pay Tvardi a nonrefundable termination fee of \$2.25 million if (i) (A) the Merger Agreement is terminated pursuant to clause (b), (e) or (h) above, (B) an Acquisition Proposal with respect to Cara has been publicly announced, disclosed or otherwise communicated to Cara or the Cara Board at any time after the date of the Merger Agreement but prior to the termination of the Merger Agreement (which has not been withdrawn) and (C) within 12 months after the date of such termination, Cara enters into a definitive agreement with respect to a subsequent transaction or consummates a subsequent transaction in respect of such Acquisition Proposal, or (ii). the Merger Agreement

is terminated by Tvardi pursuant to clause (f) above (or at the time the Merger Agreement is terminated, Tvardi has the right to terminate the Merger Agreement pursuant to clause (f) above).

Tvardi must pay Cara a nonrefundable termination fee of \$2.25 million if (i) (A) the Merger Agreement is terminated by Cara pursuant to clause (b), (d) or (i) above, (B) an Acquisition Proposal with respect to Tvardi has been publicly announced, disclosed or otherwise communicated to Tvardi or the Tvardi Board at any time after the date of the Merger Agreement but prior to obtaining the Required Company Stockholder Vote (which shall not have been withdrawn, (1) in the case of a termination pursuant to clauses (b) or (i) above, at the time the Required Company Stockholder Vote is obtained and (2) in the case of a termination pursuant to clause (d) above, at the time of such termination) and (C) within 12 months after the date of such termination, Tvardi enters into a definitive agreement with respect to a subsequent transaction or consummates a subsequent transaction in respect of such Acquisition Proposal or in respect of any other Acquisition Proposal; or (ii) the Merger Agreement is terminated by Cara pursuant to clause (g) above (or at the time the Merger Agreement is terminated, Cara has the right to terminate the Merger Agreement pursuant to clause (g) above).

If the Merger Agreement is terminated pursuant to clauses (e), (f) or (h) above or in the event of the failure of Tvardi to consummate the transactions to be contemplated at the Closing solely as a result of a Cara Material Adverse Effect as set forth in the Merger Agreement (provided, that at such time all other conditions precedent to Cara's obligation to close set forth in the Merger Agreement have been satisfied by Tvardi, are capable of being satisfied by Tvardi or have been waived by Cara), then Cara will reimburse Tvardi for all reasonable out-of-pocket fees and expenses incurred by Tvardi in connection with the Merger Agreement and the Contemplated Transactions, up to a maximum of \$750,000, by wire transfer of same-day funds within ten business days following the date on which Tvardi submits to Cara true and correct copies of reasonable documentation supporting such expenses; provided, however, that such expenses shall not include any amounts for financial advisors to Tvardi except for reasonably documented out-of-pocket expenses otherwise reimbursable by Tvardi to such financial advisors. To the extent any such expenses are paid, such amounts will be credited against any termination fee that becomes payable by Cara to Tvardi thereafter.

If the Merger Agreement is terminated pursuant to clauses (d), (g) or (i) above or in the event of the failure of Cara to consummate the transactions to be consummated to the Closing solely as a result of an Tvardi Material Adverse Effect as set forth in the Merger Agreement (provided, that at such time all other conditions precedent to Tvardi's obligation to close set forth in the Merger Agreement have been satisfied by Cara, are capable of being satisfied by Cara or have been waived by Tvardi), then Tvardi will reimburse Cara for all reasonable out-of-pocket fees and expenses incurred by Cara in connection with the Merger Agreement and the Contemplated Transactions, up to a maximum of \$750,000, by wire transfer of same-day funds within ten business days following the date on which Cara submits to Tvardi true and correct copies of reasonable documentation supporting such expenses; provided, however, that such expenses shall not include any amounts for financial advisors to Cara except for reasonably documented out-of-pocket expenses otherwise reimbursable by Cara to such financial advisors. To the extent any such expenses are paid, such amounts will be credited against any termination fee that becomes payable by Tvardi to Cara thereafter.

Other Agreements

Director Indemnification and Insurance

The Merger Agreement provides that, subject to certain limitations as set forth in the Merger Agreement, from the Effective Time through the sixth anniversary of the date on which the Effective Time occurs, Cara and the surviving company will indemnify each person who is, has been at any time prior to the date of the Merger Agreement, or who becomes prior to the Effective Time, a director, officer, fiduciary or agent of Cara or any of its subsidiaries or Tvardi.

The Merger Agreement also provides that the provisions relating to the indemnification, advancement of expenses and exculpation of present and former directors and officers of Cara or any of its subsidiaries set forth in the organizational documents of Cara or any of its subsidiaries will not be amended, modified or repealed for a period of six years from the Effective Time in any manner that would adversely affect the rights of individuals who, at or prior to the Effective Time, were officers or directors of Cara or any of its subsidiaries, unless required by applicable law. After Closing, the organizational documents of the surviving corporation will contain provisions no less favorable with respect to the provisions relating to the indemnification, advancement of expenses and exculpation of present and former directors and officers presently set forth in Tvardi's organizational documents as of the date of the Merger Agreement. Cara has agreed to purchase a six year "tail policy" for the non-cancellable extension of Cara's existing directors' and officers' liability insurance policies and Cara's and any of its subsidiaries' existing directors' and officers' insurance policies and Cara's existing fiduciary liability insurance policies (if any), in each case, for a claims reporting or discovery period of at least six years from and after the Effective Time with respect to any claim related to any period of time at or prior to the Effective Time.

Listing

Cara common stock currently is listed on The Nasdaq Capital Market under the symbol "CARA." Cara has agreed to use commercially reasonable efforts (i) to maintain its existing listing on Nasdaq until the Closing Date and obtain approval of the listing of the combined company on Nasdaq, (ii) without derogating from the requirements of the foregoing clause (i) and to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Cara common stock to be issued in connection with the Contemplated Transactions, and to cause such shares to be approved for listing (subject to official notice of issuance), (iii) to effect the Reverse Stock Split and (iv) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial Nasdaq Listing Application for the Cara common stock on Nasdaq and to cause such listing application to be conditionally approved prior to the Effective Time.

The parties will use commercially reasonable efforts to coordinate with respect to compliance with Nasdaq rules and regulations and will reasonably promptly inform the other party of all verbal or written communications between Nasdaq and such party or its representatives. Tvardi will cooperate with Cara as reasonably requested by Cara with respect to the Nasdaq Listing Application and promptly furnish to Cara all information concerning Tvardi and its stockholders that may be required or reasonably requested in connection with any action contemplated by the foregoing paragraph.

Tvardi Financial Statements

Tvardi shall, to the extent required, use commercially reasonable efforts to, (i) no later than March 31, 2025, furnish to Cara audited financial statements of Tvardi for the fiscal year ended 2024, and (ii) no later than May 14, 2025, furnish to Cara unaudited interim financial statements for each interim period completed prior to the Closing that would be required to be included in the Registration Statement or any periodic report due prior to the Closing if Tvardi were subject to the periodic reporting requirements under the Securities Act or the Exchange Act.

Expenses

Pursuant to the Merger Agreement, all the Transaction Expenses (as defined below) will be paid by the party incurring such expense, whether or not the Merger is consummated; provided, that Cara and Tvardi shall each pay 50% of all fees and expenses incurred in relation to (i) the printing and filing with the SEC of this Registration Statement and any amendments and supplements thereto and paid to a financial printer or the SEC, and (ii) the proxy solicitation firm engaged in connection with the Cara special meeting. Notwithstanding the foregoing, in connection with a disagreement regarding Cara Net Cash, the fees and expenses of the Accounting Firm will be allocated between Tvardi and Cara in the proportion that the unsuccessfully disputed amount of Cara Net Cash bears to the total disputed amount of Cara Net Cash.

"Transaction Expenses" means, with respect to each party, all fees and expenses incurred by such party at or prior to the Effective Time in connection with the Contemplated Transactions and the Merger Agreement, including (a) any fees and expenses of legal counsel and accountants and the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of such party; (b) fees paid to the SEC in connection with filing the Registration Statement, the proxy statement/prospectus, and any amendments and supplements hereto or thereto, with the SEC; (c) any fees and expenses in connection with the printing, mailing and distribution of the Registration Statement and any amendments and supplements hereto; and (d) any fees and expenses payable to Nasdaq.

Amendment of Merger Agreement

The Merger Agreement may be amended by the parties at any time with the written approval of Tvardi, Merger Sub and Cara, except that after the Merger Agreement has been adopted and approved by a party's stockholders, no amendment which by law requires further approval by the stockholders of that party will be made without such further stockholder approval.

AGREEMENTS RELATED TO THE MERGER

Support Agreements

Concurrently with the execution of the Merger Agreement, executive officers and directors of Cara entered into the Cara Support Agreements in favor of Tvardi relating to the Merger. The Cara Support Agreements provide, among other things, that such officers, directors and stockholders will vote all of their shares of Cara common stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the Cara Proposals, and the other Contemplated Transactions, (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any Acquisition Proposal.

Concurrently with the execution of the Merger Agreement, executive officers, directors and certain stockholders of Tvardi entered the Tvardi Support Agreements in favor of Cara relating to the Merger. The Tvardi Support Agreements provide, among other things, that such executive officers, directors and stockholders vote all of their shares of Tvardi capital stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the Tvardi Stockholder Matters, and the other Contemplated Transactions, (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any Acquisition Proposal.

Lock-Up Agreements

Concurrently with the execution of the Merger Agreement, certain executive officers, directors, and stockholders of Tvardi entered into the Lock-Up Agreements, pursuant to which such persons accepted certain restrictions on transfers of the shares of Cara common stock held by such persons for the 180-day period following the Effective Time. In addition, the director of Cara designated prior to Closing, to serve on the Combined Company Board is expected to enter into the Lock-Up Agreement.

Convertible Notes

In multiple closings to be held between December 4, 2024 and December 13, 2024, Tvardi issued and sold or will issue and sell Convertible Notes to several investors in an aggregate amount of approximately \$28.3 million, which accrue simple interest at 8% per annum and mature on December 31, 2026. Upon the Closing of the Merger with Cara, the outstanding principal balance of such notes and all accrued and unpaid interest will be automatically converted into Conversion Shares, at a conversion price equal to 80% of the implied valuation of the combined company in the Merger. The Conversion Shares shall be calculated by multiplying the Post-Closing Cara Shares by (a) the quotient obtained by dividing (i) the Implied Note Valuation by (ii) the Aggregate Post-Bridge Valuation. The Post-Closing Shares means the quotient obtained by dividing the Cara Outstanding Shares by the Cara Allocation Percentage. The Implied Note Valuation means the quotient obtained by dividing (a) the principal amount of the Convertible Notes plus all accrued and unpaid interest by (b) 80%. The Aggregate Post-Bridge Valuation means the sum of (i) the Tvardi Valuation, plus (ii) the Cara Valuation plus (iii) the Implied Note Valuation. The Conversion Shares issued with respect to the 20% discount under the terms of the Convertible Notes (Note Conversion Discount Shares) shall dilute the pre-Merger equityholders of Tvardi as part of calculating the Exchange Ratio. The remaining Conversion Shares shall dilute the pre-Merger Cara equityholders and the pre-Merger Tvardi equityholders on a pro rata basis. Immediately following the conversion of the Convertible Notes, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre- Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock, and the holders of the Convertible Notes are expected to hold approximately 12.54% of the shares of Cara common stock, in each case of Cara and Tvardi, on a fully diluted basis and subject to further adjustment as further described below. The expected post-Merger equity ownership split percentages are based on the assumed Exchange Ratio of 4.8997 and an amount of Conversion Shares equal to approximately 46,115,173 and are subject to adjustments based on the final Exchange Ratio and final amount of Conversion Shares. For more information about the calculation of the Conversion Shares or the Exchange Ratio see the section titled "The Merger Agreement — Merger Consideration and Exchange Ratio".

In the event the Merger does not Close, the Convertible Notes are convertible as follows:

- In the event of a subsequent equity offering of Tvardi in which Tvardi raises at least \$15,000,000, not including the conversion of the Convertible Notes, into equity securities of Tvardi issued in such equity offering, at a conversion price equal to the lesser of (i) the price paid per share for equity securities by the investors in such financing multiplied by 0.8, and (ii) the quotient resulting from dividing \$252,000,000 by the number of fully diluted shares of common stock of the Company immediately prior to the financing and prior to the conversion of the Convertible Notes;
- In the event of a subsequent equity offering of Tvardi in which Tvardi raises less than \$15,000,000, the noteholders may elect to make the conversion as set forth above; and
- In the event Tvardi completes an initial public offering (IPO) of its common stock, into shares of Tvardi common stock at a conversion price equal to the lesser of (i) 80% of the initial public offering price per share in the IPO and (ii) the price obtained by dividing \$300,000,000 by the number of fully diluted shares of the Company's common stock immediately prior to the IPO and prior to the conversion of the Convertible Notes;



ASSET SALE

On December 17, 2024, Cara and its subsidiary, Royalty Sub, entered into an APA with CSL Vifor, pursuant to which, at the consummation of the transaction, Sellers will sell to CSL Vifor and CSL Vifor will acquire from Sellers certain assets and rights for the development, manufacture and commercialization of difelikefalin as well as certain associated liabilities for a purchase price of \$900,000 (subject to certain adjustments with respect to inventory). Pursuant to the APA, in connection with the consummation of the Asset Disposition, CSL Vifor and HCR have entered into a letter agreement with Cara providing that CSL Vifor and HCR will, subject to the satisfaction of conditions to closing under the APA, enter into an amended and restated purchase agreement to amend and replace the Original HCR Agreement, by and among Royalty Sub, HCRX and HCR IV. Upon entering into the amended and restated purchase agreement, effective as of the closing of the Asset Disposition: (i) CSL Vifor will be obligated to make certain payments to HCR from and after the date thereof relating to certain revenue and/or royalties from difelikefalin, (ii) each of the Contribution Agreement, the License Agreement and the Pledge Agreement (each as defined in the Original HCR Agreement) shall be terminated, and (iii) Sellers shall have no further payment or other obligations to HCR under the Original HCR Agreement. Additionally, pursuant to the APA, at the consummation of the Asset Disposition, Cara has agreed to pay CSL Vifor \$3.0 million to compensate CSL Vifor for the estimated incremental future expenses to be incurred by CSL Vifor as a result of the transfer of the assets to be acquired and the liabilities to be assumed by it in connection with the Asset Disposition.

The Asset Disposition is subject to certain conditions to closing, including either (i) the consummation of the Merger concurrently with the Asset Disposition or (ii) the receipt of the requisite stockholder approval needed to approve the Asset Disposition in the event that the Merger is terminated. Other conditions to closing include there being no preliminary or permanent injunctions prohibiting the Asset Disposition, there being no proceedings pending by a governmental authority seeking to enjoin the Asset Disposition and Sellers receiving certain required third party consents in connection with the Asset Disposition.

The APA provides for certain termination rights of Sellers and CSL Vifor, including the right of either CSL Vifor or Cara to terminate the APA if (a) there is a permanent and nonappealable prohibition on the consummation of the Asset Disposition, (b) the Asset Disposition has not occurred by June 30, 2025 (which date shall be automatically extended in one-month increments until October 30, 2025 in certain instances if the Merger is not closed by June 30, 2025) or (c) if a meeting of Cara's stockholders has been held for the stockholders to consider and vote upon the APA and the Asset Disposition and the stockholder have not voted in favor of adopting the APA and approving the Asset Disposition at such stockholder meeting. Either party may also terminate the APA if the other party breaches its obligations under the APA in certain instances and subject to customary cure protections.

The APA contains representations, warranties, and covenants of the parties, including, among others, a covenant that requires (i) Sellers to operate their business in the ordinary course during the period between the execution of the APA and consummation of the Asset Disposition and to not engage in certain kinds of activities or transactions during such period (subject to either prior consent of CSL Vifor or customary limited exceptions), (ii) the parties to use their reasonable best efforts to complete certain transition steps in connection with the consummation of the Asset Disposition, and (iii) Sellers to use their commercially reasonable efforts to obtain any needed consents and provide any needed notices in connection with the Asset Disposition.

MATTERS BEING SUBMITTED TO A VOTE OF CARA'S STOCKHOLDERS

PROPOSAL NO. 1 (THE STOCK ISSUANCE PROPOSAL): APPROVAL OF THE ISSUANCE OF SHARES OF CARA COMMON STOCK PURSUANT TO THE MERGER

At the Cara special meeting, Cara's common stockholders will be asked to approve (i) the issuance of Cara common stock to Tvardi's stockholders pursuant to the Merger Agreement, which shares of Cara common stock to be issued pursuant to the Merger will represent more than 20% of the shares of Cara common stock outstanding immediately prior to the Merger and (ii) the change of control resulting from the Merger, pursuant to Rules 5635(a) and 5635(b) of Nasdaq, respectively. Immediately following the Merger, the pre-Merger equityholders of Cara are expected to hold approximately 15.25% of the shares of Cara common stock, the pre-Merger equityholders of Tvardi are expected to hold approximately 72.21% of the shares of Cara common stock, in each case, on a fully diluted basis, subject to certain assumptions, including Cara Net Cash at Closing being between \$22.875 million and \$23.125 million. Cara will assume unexercised options to purchase shares of Cara common stock.

The terms of, reasons for and other aspects of the Merger Agreement, the Merger, the issuance of Cara common stock pursuant to the Merger Agreement and the change of control resulting from the Merger are described in detail in the other sections in this proxy statement/prospectus.

Required Vote; Recommendation of the Cara Board

The affirmative vote of a majority of the votes cast by holders of shares present at the meeting (by virtual attendance) or represented by proxy and voting on the matter at the Cara special meeting is required to approve Proposal No. 1. Abstentions and broker non-votes will have no effect on the outcome of this proposal. It is anticipated that Proposal No. 1 will be a non-discretionary proposal considered non-routine under the rules of the NYSE, which generally controls the ability of brokers to vote or not vote shares held in street name on certain matters, and thus may result in broker non-votes.

THE CARA BOARD UNANIMOUSLY RECOMMENDS THAT CARA'S COMMON STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 1 TO APPROVE THE ISSUANCE OF SHARES OF CARA COMMON STOCK PURSUANT TO THE MERGER AND THE CHANGE OF CONTROL RESULTING FROM THE MERGER. THE APPROVAL OF PROPOSAL NO. 1 IS REQUIRED TO CONSUMMATE THE MERGER.

PROPOSAL NO. 2 (THE EQUITY PLAN PROPOSAL): APPROVAL OF EQUITY PLAN PROPOSAL

Overview

Cara stockholders are also being asked to consider and vote upon the Equity Plan Proposal to approve the combined company's 2025 Equity Incentive Plan, which we refer to herein as the "2025 Plan." The Cara Board approved the 2025 Plan on , subject to stockholder approval at the Cara special meeting. If stockholders approve the Equity Plan Proposal, the 2025 Plan will become effective on the consummation of the Merger. If the 2025 Plan is not approved by the stockholders, it will not become effective and no awards will be granted thereunder. If stockholders approve the Equity Plan Proposal, but the Merger is not consummated, the 2025 Plan will not come into effect. The 2025 Plan is described in more detail below.

If the 2025 Plan is approved by the Cara stockholders and the closing of the Merger occurs, effective from and after the closing, no new grants will be made under Cara's 2014 Equity Incentive Plan (2014 Plan); in any event, any outstanding awards granted under the 2014 Plan will remain outstanding and will continue to be governed by the terms of the 2014 Plan and the relevant award agreements.

General Information

The purpose of the 2025 Plan is to provide a means whereby the combined company can secure and retain the services of employees, directors and consultants, to provide incentives for such persons to exert maximum efforts for the success of the combined company and its affiliates and to provide a means by which such persons may be given an opportunity to benefit from increases in value of the combined company's common stock through the granting of awards under the 2025 Plan.

Approval of the 2025 Plan by Cara stockholders is required, among other things, in order to comply with stock exchange rules requiring stockholder approval of equity compensation plans and allow the grant of incentive stock options (ISOs), restricted stock unit (RSU) awards and other awards under the 2025 Plan. If the Equity Plan Proposal is approved by Cara stockholders, the 2025 Plan will become effective as of the date of the consummation of the Merger. In the event that our stockholders do not approve the Equity Plan Proposal, the 2025 Plan will not become effective.

The combined company's equity compensation program, as implemented under the 2025 Plan, will allow the combined company to be competitive with comparable companies in its industry by giving it the resources to attract and retain talented individuals to achieve its business objectives and build shareholder value. It is critical to the combined company's long-term success that the interests of employees and other service providers are tied to its success as "owners" of the business. Approval of the 2025 Plan will allow the combined company to grant stock options and other equity awards at levels it determines to be appropriate in order to attract new employees and other service providers, retain existing employees and service providers and to provide incentives for such persons to exert maximum efforts for the combined company to utilize a broad array of equity incentives with flexibility in designing equity incentives, including traditional stock option grants, stock appreciation rights, restricted stock awards, RSU awards, other stock awards and performance awards to offer competitive equity compensation packages in order to retain and motivate the talent necessary for the combined company.

If the request to approve the 2025 Plan is approved by our stockholders, a number of shares of combined company common stock will be available for grant under the 2025 Plan equal to the product of (i) ten percent (10%), multiplied by (ii) the total number of shares of Common Stock (as defined in the 2025 Plan) determined as of immediately following the closing of the Merger, subject to adjustment for specified changes in the combined company's capitalization. The Tvardi options that are converted into combined company stock as part of the Merger are not counted against the foregoing equity pool established by the 2025 Plan. In addition, as further described below under the section titled "*Description of the 2025 Plan* — *Authorized Shares*," during each of the calendar years 2026 through 2030 the share reserve is subject to annual increases of up to five percent (5%) of the total number of shares of the Fully Diluted Common Stock (as defined in the 2025 Plan) outstanding on a fully diluted basis as of December 31 of the preceding year (at the discretion of the combined company's board of directors and without any further action by

the combined company's stockholders). The Cara Board believes this pool size is necessary to provide sufficient reserved shares for a level of grants that will attract, retain, and motivate employees and other participants.

Description of the 2025 Plan

A summary description of the material features of the 2025 Plan is set forth below. The following summary does not purport to be a complete description of all the provisions of the 2025 Plan and is qualified by reference to the 2025 Plan, a copy of which is attached to this proxy statement/prospectus as *Annex D* and incorporated by reference in its entirety. *Annex D* reflects the change in name of Cara to Tvardi Therapeutics, Inc., as the 2025 Plan will not be effective unless and until the Merger closes. Cara stockholders should refer to the 2025 Plan for more complete and detailed information about the terms and conditions of the 2025 Plan.

Eligibility. Any individual who is an employee of the combined company or any of its affiliates, or any person who provides services to the combined company or its affiliates, including members of the combined company's board of directors, is eligible to receive awards under the 2025 Plan at the discretion of the plan administrator. If this Proposal is approved by the stockholders, all nonemployee directors of the combined company (presently expected to be six individuals), all of the combined company's employees, and consultants (as of) will be eligible to receive awards following the consummation of the Merger.

Awards. The 2025 Plan provides for the grant of ISOs to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, RSU awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of the combines company's affiliates.

Authorized Shares. Initially, the maximum number of shares of combined company common stock that may be issued under the 2025 Plan after it becomes effective will not exceed a number of shares of combined company common stock equal to the product of (i) ten percent (10%), multiplied by (ii) the total number of shares of the Common Stock determined as of immediately following the closing of the Merger (the Share Reserve). The Tvardi options that are converted into combined company stock as part of the Merger are not counted in the Share Reserve. In addition, the Share Reserve may be increased at the discretion of the combined company's board of directors (and without any further action by the combined company's stockholders) on January 1 of each year for a period of five years, commencing on January 1. 2026 and ending on January 1, 2030, in an amount not to exceed five percent (5%) of the total number of shares of the Fully Diluted Common Stock determined on December 31 of the preceding year, if the combined company's board of directors acts prior to January 1 of a given year to provide that the increase for such year will occur and to determine the applicable number of additional shares of combined company common stock. In the absence of action by the combined company's board of directors, no such increase will automatically occur. The maximum number of shares of combined company common stock that may be issued on the exercise of ISOs under the 2025 Plan is equal to three multiplied by the Share Reserve. As of , the record date for the Cara special meeting, the closing price of Cara common stock as

reported on Nasdaq was \$ per share.

Shares subject to stock awards granted under the 2025 Plan that expire or terminate without being exercised or otherwise issued in full or that are paid out in cash rather than in shares do not reduce the Share Reserve. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation do not reduce the Share Reserve. If any shares of combined company common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by the combined company (1) because of the failure to meet a contingency or vest, (2) to satisfy the exercise, strike or purchase price of an award, or (3) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert back to the Share Reserve and will again become available for issuance under the 2025 Plan.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any period commencing on the date of the combined company's annual meeting of stockholders for a particular year and ending on the day immediately prior to

the date of the combined company's annual meeting of stockholders for the next subsequent year, including stock awards granted and cash fees paid to such non-employee director, will not exceed \$750,000 in total value, or in the event such non-employee director is first appointed or elected to the combined company's board of directors during such annual period, \$1,000,000 in total value (in each case, calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes). Compensation will count towards this limit for the annual period in which it was granted or earned, and not later when distributed, in the event it is deferred.

Plan Administration. The combined company's board of directors, or a duly authorized committee thereof, will administer the 2025 Plan and is referred to as the "plan administrator" herein. The combined company's board of directors may also delegate to one or more persons or bodies the authority to do one or more of the following: (i) designate recipients (other than officers) of specified stock awards, provided that no person or body may be delegated authority to grant a stock award to themself; (ii) determine the number of shares subject to such stock award; and (iii) determine the terms of such stock awards. Under the 2025 Plan, the combined company's board of directors has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value and exercise price, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award, subject to the limitations of the 2025 Plan.

Under the 2025 Plan, the combined company's board of directors also generally has the authority to effect, without the approval of stockholders but with the consent of any materially adversely affected participant, (1) the reduction of the exercise, purchase, or strike price of any outstanding option or stock appreciation right; (2) the cancellation of any outstanding option or stock appreciation right and the grant in substitution therefore of other awards, cash, or other consideration; or (3) any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements approved by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2025 Plan, provided that the exercise price of a stock option cannot be less than 100% of the fair market value of a share of combined company common stock on the date of grant. Options granted under the 2025 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2025 Plan, up to a maximum of 10 years. Unless the terms of a participant's stock option agreement provide otherwise or as otherwise provided by the plan administrator, if a participant's service relationship with the combined company or any of the combined company's affiliates ceases for any reason other than disability, death, or cause, the participant may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. Unless the terms of a participant's stock option agreement provide otherwise or as otherwise provided by the plan administrator, if a participant's service relationship with the combined company or any of the combined company's affiliates ceases due to death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary of the participant may generally exercise any vested options for a period of 18 months following the date of death. Unless the terms of a participant's stock option agreement provide otherwise or as otherwise provided by the plan administrator, if a participant's service relationship with the combined company or any of the combined company's affiliates ceases due to disability, the participant may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

The plan administrator will determine the manner of payment of the exercise of a stock option, which may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of combined company common stock previously owned by the participant, (4) a net exercise of the option if it is an NSO or (5) other legal consideration approved by the plan administrator.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of combined company common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of the combined company's stock plans may not exceed \$100,000.



Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of the combined company's total combined voting power or that of any of the combined company's parent or subsidiary corporations unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. RSU awards are granted under RSU award agreements approved by the plan administrator. RSU awards may be granted in consideration for any form of legal consideration that may be acceptable to the plan administrator and permissible under applicable law. The plan administrator determines the terms and conditions of RSU awards, including vesting and forfeiture terms, as well as the manner of settlement, which may be by cash, delivery of shares of combined company common stock, a combination of cash and shares of combined company common stock, or in any other form of consideration set forth in the RSU award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a RSU award. Except as otherwise provided in the applicable award agreement or by the plan administrator, RSU awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements approved by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, services to us, or any other form of legal consideration that may be acceptable to the plan administrator and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with the combined company ends for any reason, the combined company may reacquire any or all of the shares of combined company common stock held by the participant that have not vested as of the date the participant terminates service with the combined company through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements approved by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which cannot be less than 100% of the fair market value of combined company common stock on the date of grant. A stock appreciation right granted under the 2025 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. Stock appreciation rights may be settled in cash or shares of combined company common stock or in any other form of payment, as determined by the plan administrator and specified in the stock appreciation right agreement.

The plan administrator determines the term of stock appreciation rights granted under the 2025 Plan, up to a maximum of 10 years. Unless the terms of a participant's stock appreciation rights agreement provide otherwise or as otherwise provided by the plan administrator, if a participant's service relationship with the combined company or any of its affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. Unless the terms of a participant's stock appreciation rights agreement provide otherwise or as otherwise provided by the plan administrator, if a participant's service relationship with the combined company or any of its affiliates ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2025 Plan permits the plan administrator to grant performance awards, which may be settled in stock, cash or other property. Performance awards may be structured so that the stock, cash or a combination of stock and cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period as determined by the plan

administrator. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, combined company common stock.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to combined company common stock. The plan administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Changes to Capital Structure. In the event there is a specified type of change in the capital structure of the combined company, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2025 Plan, (2) the class of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards, and (5) the performance goals of any award if the change in the capital structure affects such goals.

Corporate Transactions. The following applies to stock awards under the 2025 Plan in the event of a Corporate Transaction (as defined in the 2025 Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with the combined company or one of its affiliates.

In the event of a Corporate Transaction (as defined in the 2025 Plan), stock awards outstanding under the 2025 Plan may be assumed or continued, or substitute awards may be issued, by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by the combined company with respect to the stock award may be assigned to the combined company's successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or issue substitute awards for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the Corporate Transaction (as defined in the 2025 Plan), or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level unless otherwise provided in the award agreement) to a date prior to the effective time of the Corporate Transaction (as defined in the 2025 Plan) (contingent upon the effectiveness of the Corporate Transaction) (as defined in the 2025 Plan), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction (as defined in the 2025 Plan), and any reacquisition or repurchase rights held by the combined company with respect to such stock awards will lapse (contingent upon the effectiveness of the Corporate Transaction (as defined in the 2025 Plan)), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction (as defined in the 2025 Plan), except that any reacquisition or repurchase rights held by the combined company with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the Corporate Transaction (as defined in the 2025 Plan).

In the event a stock award will terminate if not exercised prior to the effective time of a Corporate Transaction (as defined in the 2025 Plan), the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the holder would have received upon the exercise of the award (including, at the discretion of the plan administrator, any unvested portion of such award), over (ii) any per share exercise price payable by such holder. If the exercise price with respect to a stock award is greater than the value of the property the holder would have received upon the exercise of such award (including, at the discretion of the Tvardi Board, any unvested portion of such award), then such award may be cancelled at the effective time for no consideration.

Change in Control. Awards granted under the 2025 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined in the 2025 Plan) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Transferability. A participant may not transfer stock awards under the 2025 Plan other than by will, the laws of descent and distribution, or as otherwise provided under the 2025 Plan.

Recoupment. Awards granted under the 2025 Plan are subject to recoupment in accordance with any clawback policy adopted by the combined company's board of directors. In addition, the plan administrator may impose other clawback, recovery or recoupment provisions in an award agreement as the plan administrator determines necessary or appropriate, including a reacquisition right in respect of previously acquired shares of our common stock or other cash or property upon the occurrence of cause.

Plan Amendment or Termination. The combined company's board of directors has the authority to amend, suspend, or terminate the 2025 Plan at any time, provided that such action does not materially impair (within the meaning of the 2025 Plan) the existing rights of any participant without such participant's written consent. Certain material amendments also require approval of the combined company's stockholders. No ISOs may be granted after the tenth anniversary of the date that the Cara Board adopts the 2025 Plan. No stock awards may be granted under the 2025 Plan while it is suspended or after it is terminated.

Material U.S. Federal Income Tax Consequences

The following is a summary of the principal U.S. Federal Income Tax consequences to participants and the combined company with respect to participation in the 2025 Plan, which will not become effective until the date of the consummation of the Merger. No awards will be issued under the 2025 Plan prior to the date of the consummation of the Merger. This summary is not intended to be exhaustive and does not discuss the income tax laws of any local, state or foreign jurisdiction in which a participant may reside. The information is based upon current U.S. Federal Income Tax rules and therefore is subject to change when those rules change. Because the tax consequences to any participant may depend on such participant's particular situation, each participant should consult the participant's tax adviser regarding the federal, state, local and other tax consequences of the grant, exercise, vesting or settlement of an award or the disposition of stock acquired under the 2025 Plan. The 2025 Plan is not qualified under the provisions of Section 401(a) of the Code and is not subject to any of the provisions of the Employee Retirement Income Security Act of 1974, as amended.

Tax Consequences to the Participants

Nonstatutory Stock Options. Generally, there is no taxation to the participant upon the grant of an NSO. Upon exercise, a participant will recognize ordinary income equal to the excess, if any, of the fair market value of the underlying stock on the date of exercise of the stock option over the exercise price. If the participant is employed by the combined company or one of its affiliates, that income will be subject to withholding taxes. The participant's tax basis in those shares will be equal to their fair market value on the date of exercise of the stock option, and the participant's capital gain holding period for those shares will begin on the day after they are transferred to the participant.

Incentive Stock Options. The 2025 Plan provides for the grant of stock options that are intended to qualify as "incentive stock options," as defined in Section 422 of the Code. A participant generally is not subject to ordinary income tax upon the grant or exercise of an ISO. If the participant holds a share received upon exercise of an ISO for more than two years from the date the stock option was granted and more than one year from the date the stock option was exercised, which is referred to as the required holding period, then the difference, if any, between the amount realized on a sale or other taxable disposition of that share and the exercise price paid by the participant for that share will be long-term capital gain or loss. If, however, a participant disposes of a share acquired upon exercise of an ISO before the end of the required holding period, which is referred to as a disqualifying disposition, then the participant generally will recognize ordinary income in the year of the disqualifying disposition equal to the excess, if any, of the fair market value of the share on the date of exercise of the stock option over the exercise price. However, if the sales proceeds are less than the fair market value of the share on the date of exercise of the stock option, the amount of ordinary income recognized by the participant will not exceed the gain, if any, realized on the sale. If the amount realized on a disqualifying disposition exceeds the fair market value of the share on the date of exercise of the stock option, that excess will be short-term or long-term capital gain, depending on whether the holding period for the share exceeds one year. For purposes of the alternative minimum tax, the amount by which the fair market value of a share of stock acquired upon exercise of an ISO exceeds the exercise price of the stock option generally will be an adjustment included in the participant's alternative

minimum taxable income for the year in which the stock option is exercised. If, however, there is a disqualifying disposition of the share in the year in which the stock option is exercised, there will be no adjustment for alternative minimum tax purposes with respect to that share. In computing alternative minimum taxable income, the tax basis of a share acquired upon exercise of an ISO is increased by the amount of the adjustment taken into account with respect to that share for alternative minimum tax purposes in the year the stock option is exercised.

Restricted Stock Awards. Generally, a participant who is granted a restricted stock award will recognize ordinary income at the time the stock is received equal to the excess, if any, of the fair market value of the stock received over any amount paid by the participant in exchange for the stock. If, however, the stock is subject to restrictions constituting a substantial risk of forfeiture when it is received (for example, if the employee is required to work for a period of time in order to have the right to transfer or sell the stock), the participant generally will not recognize income until the restrictions constituting the substantial risk of forfeiture lapse, at which time the participant will recognize ordinary income equal to the excess, if any, of the fair market value of the stock on the date of such lapse over any amount paid by the participant in exchange for the stock. A participant may, however, file an election with the Internal Revenue Service, within 30 days following the date of grant, to recognize ordinary income, as of the date of grant, equal to the excess, if any, of the fair market value of the stock on the date the award is granted over any amount paid by the participant for the stock. The participant's basis for the determination of gain or loss upon the subsequent disposition of shares acquired from a restricted stock award will be the amount paid for such shares plus any ordinary income recognized either when the stock is received or when the restrictions constituting a substantial risk of forfeiture lapse.

Restricted Stock Unit Awards. Generally, a participant who is granted an RSU award will recognize ordinary income at the time the stock is delivered equal to (i) the excess, if any, of the fair market value of the stock received over any amount paid by the participant in exchange for the stock or (ii) the amount of cash paid to the participant. The participant's basis for the determination of gain or loss upon the subsequent disposition of shares acquired from an RSU award will be the amount paid for such shares plus any ordinary income recognized when the stock is delivered, and the participant's capital gain holding period for those shares will begin on the day after they are transferred to the participant.

Stock Appreciation Rights. Generally, a participant who is granted a stock appreciation right will recognize ordinary income equal to the fair market value of the stock or cash received upon such exercise.

Performance Awards and Other Stock Awards. Generally, a participant who is granted a performance award or other stock award will recognize ordinary income equal to the fair market value of the stock received over any amount paid by the participant in exchange for such stock, or the amount of cash paid to the participant.

Tax Consequences to the Combined Company

General. In each case described above, the combined company will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the participant with respect to the stock award at the same time the participant recognizes such ordinary income. The combined company's ability to realize the benefit of any tax deductions depends on the combined company's generation of taxable income as well as the requirement of reasonableness and the satisfaction of the combined company's tax reporting obligations.

Compensation of Covered Employees. The ability of the combined company to obtain a deduction for amounts paid under the 2025 Plan could be limited by Section 162(m) of the Code. Section 162(m) of the Code limits the combined company's ability to deduct compensation, for U.S. Federal Income Tax purposes, paid during any year to a "covered employee" (within the meaning of Section 162(m) of the Code) in excess of \$1 million.

Golden Parachute Payments. The ability of the combined company (or the ability of one of its subsidiaries) to obtain a deduction for future payments under the 2025 Plan could also be limited by the golden parachute rules of Section 280G of the Code, which prevent the deductibility of certain "excess parachute payments" made in connection with a change in control of an employer-corporation.



New Plan Benefits

The awards, if any, that will be made to eligible persons under the 2025 Plan are subject to the discretion of the compensation committee of the combined company's board of directors. Therefore, Cara cannot currently determine the benefits or number of shares subject to awards that may be granted in the future.

Registration with the SEC

If the 2025 Plan is approved by Cara stockholders and becomes effective, the combined company intends to file a registration statement on Form S-8 registering the shares reserved for issuance under the 2025 Plan as soon as reasonably practicable after the combined company becomes eligible to use such form.

Required Vote; Recommendation of the Cara Board

The affirmative vote of a majority of the votes cast by holders of shares present at the meeting (by virtual attendance) or represented by proxy and voting on the matter at the Cara special meeting is required to approve Proposal No. 2. Abstentions and broker non-votes will have no effect on the outcome of this proposal. It is anticipated that Proposal No. 2 will be a non-discretionary proposal considered non-routine under the rules of NYSE, which generally controls the ability of brokers to vote or not vote shares held in street name on certain matters, and thus may result in broker non-votes.

The Equity Plan Proposal is conditioned upon the consummation of the Merger. Therefore, if approval of the Merger is not obtained, the Equity Plan Proposal will have no effect, even if approved by Cara stockholders.

The Merger cannot be consummated without the approval of the Stock Issuance Proposal, Reverse Stock Split Proposal and the Authorized Share Proposal at the Cara special meeting.

THE CARA BOARD UNANIMOUSLY RECOMMENDS THAT THE CARA STOCKHOLDERS VOTE "FOR" THE APPROVAL OF THE EQUITY PLAN PROPOSAL.

When you consider the recommendation of the Cara Board in favor of approval of the 2025 Plan, you should keep in mind that certain of Cara's directors and officers have interests in the 2025 Plan that are different from in addition to, or in conflict with your interests as a stockholder, including, among other things, the existence of financial and personal interests, which may result in a conflict of interest on the part of such director(s) between what he, she or they may believe is in the best interests of Cara and its stockholders and what he, she or they may believe is best for himself or themselves in determining to recommend that stockholders vote for the proposals. In addition, Cara's officers have interests in the Merger that may conflict with your interests as a stockholder. See the section titled *"The Merger — Interests of Cara Directors and Executive Officers in the Merger"* for a further discussion of these considerations.

PROPOSAL NO. 3 (THE ESPP PROPOSAL): APPROVAL OF ESPP PROPOSAL

Overview

Cara's stockholders are also being asked to consider and vote upon the ESPP Proposal to approve the combined company's 2025 Employee Stock Purchase Plan, which we refer to herein as the "ESPP." The Cara Board approved the ESPP on , subject to stockholder approval at the Cara special meeting. If Cara stockholders approve the ESPP Proposal, the ESPP will become effective on the consummation of the Merger. If the ESPP is not approved by the stockholders, it will not become effective. If stockholders approve the ESPP Proposal, but the Merger is not consummated, the ESPP will not come into effect. The ESPP is described in more detail below.

General Information

The purpose of the ESPP is to provide a means whereby the combined company can align the long-term financial interests of its employees with the financial interests of its stockholders. In addition, the combined company board of directors believes that the ability to allow employees to purchase shares of combined company common stock following the consummation of the Merger will help the combined company to attract, retain, and motivate employees and encourage employees to devote their best efforts to the combined company's business and financial success.

Approval of the ESPP by combined company stockholders will allow the combined company to provide its employees with the opportunity to acquire an ownership interest in the combined company through their participation in the ESPP, thereby encouraging them to remain in service and more closely aligning their interests with those of the combined company's stockholders.

Description of the ESPP

The material features of the ESPP are described below. The following description of the ESPP is a summary only. This summary is not a complete statement of the ESPP and is qualified in its entirety by reference to the complete text of the ESPP, a copy of which is attached hereto as *Annex E* and incorporated into this proxy statement/prospectus by reference. *Annex E* reflects the change in name of Cara to Tvardi Therapeutics, Inc., as the ESPP will not be effective unless and until the Merger closes. Cara stockholders should refer to the ESPP for more complete and detailed information about the terms and conditions of the ESPP.

As stated above, the purpose of the ESPP is to provide a means by which eligible employees of the combined company and certain designated companies may be given an opportunity to purchase shares of combined company common stock following the consummation of the Merger, to assist the combined company in retaining the services of eligible employees, to secure and retain the services of new employees and to provide incentives for such persons to exert maximum efforts for the combined company's success. The ESPP includes two components: a 423 Component and a Non-423 Component. The combined company intends that the share purchase rights under the 423 Component will qualify as options issued under an "employee stock purchase plan" as that term is defined in Section 423(b) of the Code. The share purchase rights under the Non-423 Component will not qualify as options that are subject to Section 423(b) of the Code. Except as otherwise provided in the ESPP or determined by the combined company's board of directors, the Non-423 Component will operate and be administered in the same manner as the 423 Component.

Share Reserve. Following the consummation of the Merger, the maximum number of shares of combined company common stock that may be issued under the ESPP will not exceed the number of shares of combined company common stock equal to one percent (1%) of the Common Stock (as defined in the ESPP) determined as of immediately following the closing of the Merger, subject to adjustment for specified changes in the combined company's capitalization (the "Initial Share Reserve"). Additionally, the number of shares of combined company common stock reserved for issuance under the ESPP will automatically increase on January 1 of each year for a period of up to ten years, beginning on January 1, 2026 and continuing through and including January 1, 2035, by an amount equal to the lesser of (i) one percent (1%) of the total number of shares of the Fully Diluted Common Stock (as defined in the ESPP) determined on December 31 of the preceding year, and (ii) a number of shares equal to three times the Initial Share Reserve.

Notwithstanding the foregoing, the combined company's board of directors may act prior to January 1st of a given year to provide that the increase for such year will be a lesser number of shares. Shares issuable under the ESPP may be shares of authorized but unissued or reacquired combined company common stock, including shares purchased by the combined company on the open market. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP. As of the record date for the Cara special meeting, the closing price of Cara common stock as reported on Nasdaq was \$ per share.

Administration. The combined company's board of directors, or a duly authorized committee thereof, will administer the ESPP.

Eligibility. The combined company's employees and the employees of any of its designated affiliates, will be eligible to participate in the ESPP, provided they may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by the administrator: (1) customary employment with the combined company or one of its affiliates for more than 20 hours per week and more than five months per calendar year or (2) continuous employment with the combined company or one of its affiliates for a minimum period of time, not to exceed two years, prior to the first date of an offering. In addition, the combined company's board of directors may also exclude from participation in the ESPP or any offering, employees who are "highly compensated employees" (within the meaning of Section 423(b)(4) (D) of the Code) or a subset of such highly compensated employees. If this Proposal No. 3 is approved by the Cara stockholders, all employees of the combined company and its related corporations (as of will be eligible to participate in the ESPP following the consummation of the Merger. An employee may not be granted rights to purchase stock under the 423 Component of the ESPP (a) if such employee immediately after the grant would own stock (including stock issuable upon exercise of all such employee's purchase rights) possessing 5% or more of the total combined voting power or value of all classes of combined company common stock or (b) to the extent that such rights would accrue at a rate that exceeds \$25,000 worth of combined company common stock for each calendar year that the rights remain outstanding. The combined company's board of directors may approve different eligibility rules for the Non-423 Component.

Offerings. The 423 Component of the ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Code. The administrator may specify offerings under the 423 Component with a duration of not more than 27 months and may specify one or more shorter purchase periods within each offering. For the Non-423 Component, the administrator may specify offerings, and purchase periods within each offering, as determined by the administrator. Each offering will have one or more purchase dates on which shares of combined company common stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the other terms of offerings under the ESPP. The administrator has the discretion to structure an offering so that if the fair market value of a share of combined company common stock on any purchase date during the offering period is less than or equal to the fair market value of a share of combined company common stock or many common stock on the first day of the offering period, then that offering will terminate immediately, and the participants in such terminated offering will be automatically enrolled in a new offering that begins immediately after such purchase date.

A participant may not transfer purchase rights under the ESPP other than by will, the laws of descent and distribution, or as otherwise provided under the ESPP.

Payroll Deductions. The ESPP permits participants to purchase shares of combined company common stock through payroll deductions, subject to such limitations as the administrator specifies. The administrator may limit a participant's payroll deductions to a certain percentage or amount of pay, or by limiting the number of shares that may be purchased during the offering.

Purchase Price. Unless otherwise determined by the administrator, the purchase price of the shares will be 85% of the lesser of the fair market value of combined company common stock on the first day of an offering or on the applicable date of purchase.

Withdrawal. Participants may withdraw from an offering by delivering a withdrawal form to the combined company and terminating their contributions. Such withdrawal may be elected at any time prior to the end of an offering, except as otherwise provided by the administrator. Upon such withdrawal, the combined company will distribute to the employee such employee's accumulated but unused contributions

without interest (unless otherwise required by law), and such employee's right to participate in that offering will terminate. However, an employee's withdrawal from an offering does not affect such employee's eligibility to participate in any other offerings under the ESPP.

Termination of Employment. A participant's rights under any offering under the ESPP will terminate immediately if the participant either (i) is no longer employed by the combined company or any of its parent or subsidiary companies (subject to any post-employment participation period required by law) or (ii) is otherwise no longer eligible to participate. In such event, the combined company will distribute to the participant such participant's accumulated but unused contributions, without interest (unless otherwise required by law).

Corporate Transactions. In the event of certain specified significant corporate transactions, such as a Merger or change in control, a successor corporation may assume, continue, or substitute each outstanding purchase right. If the successor corporation does not assume, continue, or substitute for the outstanding purchase rights, the offering in progress will be shortened and a new purchase date will be set. The participants' purchase rights will be exercised on the new purchase date and such purchase rights will terminate immediately thereafter.

Amendment and Termination. The combined company's board of directors has the authority to amend, suspend, or terminate the ESPP, at any time and for any reason, provided certain types of amendments will require the approval of the combined company's stockholders. Any benefits, privileges, entitlements and obligations under any outstanding purchase rights granted before an amendment, suspension or termination of the ESPP will not be materially impaired by any such amendment, suspension or termination except (i) with the consent of the person to whom such purchase rights were granted, (ii) as necessary to facilitate compliance with any laws, listing requirements, or governmental regulations, or (iii) as necessary to obtain or maintain favorable tax, listing, or regulatory treatment. The ESPP will remain in effect until terminated by the combined company's board of directors in accordance with the terms of the ESPP.

Material U.S. Federal Income Tax Consequences

The following is a summary of the principal U.S. Federal Income Tax consequences to participants and the combined company with respect to participation in the ESPP. This summary is not intended to be exhaustive and does not discuss the income tax laws of any local, state or foreign jurisdiction in which a participant may reside. The information is based upon current U.S. Federal Income Tax rules and therefore is subject to change when those rules change. Because the tax consequences to any participant may depend on such participant's particular situation, each participant should consult the participant's tax adviser regarding the federal, state, local, and other tax consequences of the grant or exercise of a purchase right or the sale or other disposition of combined company common stock acquired under the ESPP. The ESPP is not qualified under the provisions of Section 401(a) of the Code and is not subject to any of the provisions of the Employee Retirement Income Security Act of 1974, as amended. The combined company's generation of taxable income, the requirement of reasonableness, the deduction limits under Section 162(m) of the Code and the satisfaction of tax reporting obligations.

423 Component. Rights granted under the 423 Component of the ESPP are intended to qualify for favorable U.S. Federal Income Tax treatment associated with rights granted under an employee stock purchase plan which qualifies under the provisions of Section 423 of the Code.

A participant will be taxed on amounts withheld for the purchase of shares combined company common stock as if such amounts were actually received. Otherwise, no income will be taxable to a participant as a result of the granting or exercise of a purchase right until a sale or other disposition of the acquired shares. The taxation upon such sale or other disposition will depend upon the holding period of the acquired shares.

If the shares are sold or otherwise disposed of more than two years after the beginning of the offering period and more than one year after the shares are transferred to the participant, then the lesser of the following will be treated as ordinary income: (i) the excess of the fair market value of the shares at the time

of such sale or other disposition over the purchase price; or (ii) the excess of the fair market value of the shares as of the beginning of the offering period over the purchase price (determined as of the beginning of the offering period). Any further gain or any loss will be taxed as a long-term capital gain or loss.

If the shares are sold or otherwise disposed of before the expiration of either of the holding periods described above, then the excess of the fair market value of the shares on the purchase date over the purchase price will be treated as ordinary income at the time of such sale or other disposition. The balance of any gain will be treated as capital gain. Even if the shares are later sold or otherwise disposed of for less than their fair market value on the purchase date, the same amount of ordinary income is attributed to the participant, and a capital loss is recognized equal to the difference between the sales price and the fair market value of the shares on such purchase date. Any capital gain or loss will be short-term or long-term, depending on how long the shares have been held.

There are no U.S. Federal Income Tax consequences to the combined company by reason of the grant or exercise of rights under the 423 Component. The combined company is entitled to a deduction to the extent amounts are taxed as ordinary income to a participant for shares sold or otherwise disposed of before the expiration of the holding periods described above.

Non-423 Component. A participant will be taxed on amounts withheld for the purchase of shares of combined company common stock as if such amounts were actually received. Under the Non-423 Component, at the time of exercise of the purchase rights, a participant will recognize ordinary income equal to the excess, if any, of the fair market value of the underlying stock on the date of exercise of the purchase right over the purchase price. Such income will be subject to withholding taxes. The participant's tax basis in those shares will be equal to their fair market value on the date of exercise of the purchase right, and the participant's capital gain holding period for those shares will begin on the day after they are transferred to the participant.

There are no U.S. Federal Income Tax consequences to the combined company by reason of the grant of rights under the Non-423 Component. The combined company is entitled to a deduction to the extent amounts are taxed as ordinary income to a participant at the time of exercise of the purchase rights.

New Plan Benefits

Participation in the ESPP is voluntary and each eligible employee will make such employee's own decision regarding whether and to what extent to participate in the ESPP. Therefore, Cara cannot currently determine the benefits or number of shares subject to purchase rights and a new plan benefits table is thus not provided.

Required Vote; Recommendation of the Cara Board

The affirmative vote of a majority of the votes cast by holders of shares present at the meeting (by virtual attendance) or represented by proxy and voting on the matter at the Cara special meeting is required to approve Proposal No. 3. Abstentions and broker non-votes will have no effect on the outcome of this proposal. It is anticipated that Proposal No. 3 will be a non-discretionary proposal considered non-routine under the rules of NYSE, which generally controls the ability of brokers to vote or not vote shares held in street name on certain matters, and thus may result in broker non-votes.

The ESPP Proposal is conditioned upon the consummation of the Merger. Therefore, if approval of the Merger is not obtained, the ESPP Proposal will have no effect, even if approved by Cara stockholders.

The Merger cannot be consummated without the approval of the Stock Issuance Proposal, Reverse Stock Split Proposal and the Authorized Share Proposal at the Cara special meeting.

THE CARA BOARD UNANIMOUSLY RECOMMENDS THAT THE CARA STOCKHOLDERS VOTE "FOR" THE APPROVAL OF THE ESPP PROPOSAL.

When you consider the recommendation of the Cara Board in favor of approval of the ESPP, you should keep in mind that certain of Cara's directors and officers have interests in the ESPP that are different from, in addition to, or in conflict with, your interests as a stockholder, including, among other

things, the existence of financial and personal interests, which may result in a conflict of interest on the part of such director(s) between what he, she or they may believe is in the best interests of Cara and its stockholders and what he, she or they may believe is best for himself or themselves in determining to recommend that stockholders vote for the proposals. In addition, Cara's officers have interests in the Merger that may conflict with your interests as a stockholder. See the section titled "*The Merger — Interests of Cara Directors and Executive Officers in the Merger*" for a further discussion of these considerations.

Equity Compensation Plan Information

The following table provides information as of December 31, 2023 with respect to the shares of Cara common stock that may be issued under Cara's existing equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights ⁽²⁾	Number of securities remaining available for future issuance under equity compensation plans (excluding securities in first column) ⁽⁴⁾
Equity compensation plans approved by security holders ⁽¹⁾	8,463,971 ⁽³⁾	\$12.21	1,252,843
Equity compensation plans not approved by security holders	_	\$ —	300,000 ⁽⁵⁾
Total	8,463,971	\$12.21	1,552,843

(1) Includes the 2014 Plan.

(2) Cara grants full value RSUs which skew the weighted average exercise price down since there is no strike price. Excluding RSUs, Cara had 7,897,647 securities issued from plans approved by security holders, comprised of stock options, with a weighted average exercise price of \$12.99 per share.

- (3) This amount included 407,000 performance-based RSUs that, if and when vested, would be settled in shares of Cara's common stock. For these performance-based RSUs, the amounts reported in the table reflect maximum levels of performance. Subsequent to December 31, 2023, the actual level of achievement of the performance metrics for these awards was determined, with the awards vesting in part, with the balance of the awards being forfeited.
- (4) All of these shares are available for future issuance under the 2014 Plan. Further, pursuant to the terms of the 2014 Plan, the aggregate number of shares of common stock reserved for issuance under the 2014 Plan automatically increases on January 1 of each year, through and including January 1, 2024, by 3% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Cara Board. Accordingly, on January 1, 2024, the number of shares of common stock available for issuance under the 2014 Plan increased by 1,634,421 shares. This increase is not reflected in the table above.
- (5) Includes shares of common stock issuable pursuant to Cara's 2019 Inducement Plan (2019 Plan).

PROPOSAL NO. 4 (THE REVERSE STOCK SPLIT PROPOSAL): APPROVAL OF AN AMENDMENT TO THE CARA AMENDED AND RESTATED CERTIFICATE OF INCORPORATION EFFECTING THE REVERSE STOCK SPLIT AT A RATIO IN THE RANGE FROM -FOR-1 TO -FOR-1

General

At the Cara special meeting, Cara's common stockholders will be asked to approve an amendment to the amended and restated certificate of incorporation of Cara effecting the Reverse Stock Split of Cara common stock at a ratio anywhere in the range between one new share for every shares and one new share for every shares outstanding. Prior to the effectiveness of the Merger, Cara and Tvardi will mutually agree upon the exact reverse split ratio within such range. Upon the effectiveness of the amendment to the amended and restated certificate of incorporation of Cara effecting the Reverse Stock Split, or the split effective time, the issued shares of Cara common stock immediately prior to the split effective time will be reclassified into a smaller number of shares within the specified range, such that a stockholder of Cara will own one new share of Cara common stock for the specified number of shares of issued common stock held by that stockholder immediately prior to the split effective time. The full text of the proposed amendment to Cara's amended and restated certificate of incorporation is attached to this proxy statement as Annex F.

If Proposal No. 4 is approved, the Reverse Stock Split would become effective immediately prior to the effectiveness of the Merger. Cara may effect only one reverse stock split in connection with this Proposal No. 4. Cara and Tvardi's mutual decision will be based on a number of factors, including market conditions, existing and expected trading prices for Cara common stock and the listing requirements of Nasdaq.

If Proposal No. 4 is not approved and the Merger is not effected, the Cara Board may still choose to implement the Reverse Stock Split in order to effectively increase the per share price of Cara common stock.

The form of the amendment to the amended and restated certificate of incorporation of Cara to effect the Reverse Stock Split, as more fully described below, will effect the Reverse Stock Split but will not change the number of authorized shares of common stock or preferred stock, or the par value of Cara common stock or preferred stock.

Purpose

The Cara Board approved the proposal approving the amendment to the amended and restated certificate of incorporation of Cara effecting the Reverse Stock Split for the following reasons:

- the Cara Board believes effecting the Reverse Stock Split may be an effective means of satisfying the Nasdaq initial listing requirements for Cara common stock following the closing of the Merger;
- the Cara Board believes that the Reverse Stock Split will result in a number of authorized but unissued shares of Cara common stock sufficient for the issuance of shares of Cara common stock to Tvardi's stockholders pursuant to the Merger Agreement; and
- the Cara Board believes a higher stock price may help generate investor interest in Cara and help Cara attract and retain employees.

If the Reverse Stock Split successfully increases the per share price of Cara common stock, the Cara Board believes this increase may increase trading volume in Cara common stock and facilitate future financings by the combined company.

Nasdaq Requirements for Listing on Nasdaq

Cara common stock is listed on The Nasdaq Capital Market under the symbol "CARA." Cara intends to file an initial listing application with Nasdaq, as described below, to seek a listing upon the closing of the Merger. According to Nasdaq rules, an issuer must, in a case such as this, apply for initial inclusion following a transaction whereby the issuer combines with a non-Nasdaq entity, resulting in a change of control of the issuer and potentially allowing the non-Nasdaq entity to obtain a Nasdaq listing. Accordingly, the listing standards of Nasdaq will require Cara to have, among other things, a \$4.00 per share minimum bid price upon the closing of the Merger. Therefore, the Reverse Stock Split may be necessary in order to consummate the Merger.

One of the effects of the Reverse Stock Split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in Cara's management being able to issue more shares without further stockholder approval. For example, before the Reverse Stock Split, as of December 1, 2024, Cara's authorized shares of common stock immediately prior to the closing of the Merger and without giving effect to the Authorized Share Proposal is 200,000,000 compared to shares issued and outstanding of 54,855,514. If Cara effects the Reverse Stock Split using a -for-1 ratio, its authorized shares of common stock immediately prior to the closing of the Merger would still be compared to shares issued and outstanding of approximately . Cara currently has no plans to issue shares, other than in connection with the Merger and to satisfy obligations under the Cara employee stock options from time to time as the options are exercised. The Reverse Stock Split will not affect the number of authorized shares of Cara common stock which will continue to be authorized pursuant to the certificate of incorporation of Cara.

Potential Increased Investor Interest

On December 17, 2024, Cara common stock closed at \$0.2497 per share. An investment in Cara common stock may not appeal to brokerage firms that are reluctant to recommend lower priced securities to their clients. Investors may also be dissuaded from purchasing lower priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower priced stocks. Also, the Cara Board believes that most investment funds are reluctant to invest in lower priced stocks.

There are risks associated with the Reverse Stock Split, including that the Reverse Stock Split may not result in an increase in the per share price of Cara common stock.

Cara cannot predict whether the Reverse Stock Split will increase the market price for Cara common stock in the future. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of Cara common stock after the Reverse Stock Split will rise in proportion to the reduction in the number of shares of Cara common stock outstanding before the Reverse Stock Split;
- the Reverse Stock Split will result in a per share price that will attract brokers and investors who do not trade in lower priced stocks;
- the Reverse Stock Split will result in a per share price that will increase the ability of Cara to attract and retain employees;
- the market price per share will either exceed or remain in excess of the \$1.00 minimum bid price as required by Nasdaq for continued listing, or that Cara will otherwise meet the requirements of Nasdaq for inclusion for trading on Nasdaq, including the \$4.00 minimum bid price upon the closing of the Merger.

The market price of Cara common stock will also be based on performance of Cara and other factors, some of which are unrelated to the number of shares outstanding. If the Reverse Stock Split is effected and the market price of Cara common stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of Cara may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of Cara common stock could be adversely affected by the reduced number of shares that would be outstanding after the Reverse Stock Split.

Criteria to be Used for Determining Which Reverse Stock Split Ratio to Implement

In determining which reverse stock split ratio to implement, if any, following receipt of stockholder approval of the Reverse Stock Split Proposal, Cara and/or Tvardi may consider, among other things, various factors, such as:

• the historical trading price and trading volume of Cara common stock;

- the then-prevailing trading price and trading volume of Cara common stock and the expected impact of the reverse stock split on the trading market for Cara common stock in the short- and long-term;
- the ability of Cara to continue its listing on The Nasdaq Capital Market;
- which reverse stock split ratio would result in the least administrative cost to Cara; and
- prevailing general market and economic conditions.

The failure of Cara stockholders to approve the Reverse Stock Split Proposal could have serious, adverse effects on Cara and its stockholders. Cara could be delisted from Nasdaq if shares of Cara common stock may begin to trade below the requisite \$1.00 per share bid price needed to maintain its listing. If Nasdaq delists Cara common stock, Cara shares may then trade on the OTC Bulletin Board or other small trading markets, such as the pink sheets. In that event, Cara common stock could trade thinly as a microcap or penny stock, adversely decrease to nominal levels of trading and be avoided by retail and institutional investors, resulting in the impaired liquidity of Cara common stock and making it difficult to raise additional capital if needed.

Principal Effects of the Reverse Stock Split

The amendment to the amended and restated certificate of incorporation of Cara effecting the Reverse Stock Split would revise Section A of Article IV of the amended and restated certificate of incorporation of Cara to read in its entirety as follows (with the time and ratio chosen within the range described above filled in):

The Company is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Company is authorized to issue is two hundred five million (205,000,000) shares. Two hundred million (200,000,000) shares shall be Common Stock, each having a par value of one-tenth of one cent (\$0.001). Five million (5,000,000) shares shall be Preferred Stock, each having a par value of one-tenth of one cent (\$0.001). Effective at on (the Effective Time) pursuant to Section 242 of the DGCL, each) shares of the Corporation's (Common Stock, par value of \$0.001 per share, issued and outstanding immediately prior to the Effective Time shall automatically without further action on the part of the Company or any holder of such Common Stock, be reclassified, combined, converted and changed into one (1) fully paid and nonassessable share of Common Stock, par value of \$0.001 per share, subject to the treatment of fractional share interests as described below (the Reverse Stock Split). Notwithstanding the immediately preceding sentence, no fractional shares shall be issued as a result of the reverse stock split. Instead, any stockholder who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split shall be entitled to receive a cash payment equal to the product of such resulting fractional interest in one share of Common Stock multiplied by the closing trading price of a share of Common Stock on the last trading day immediately prior to the date on which the Effective Time occurs. Each certificate that immediately prior to the Effective Time represented shares of Common Stock (Old Certificates), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional share interests as described above.

The Reverse Stock Split will be effected simultaneously for all outstanding shares of Cara common stock. The Reverse Stock Split will affect all of Cara's stockholders uniformly and will not affect any stockholder's percentage ownership interest in Cara, except to the extent that the Reverse Stock Split results in any of Cara's stockholders owning a fractional share. Shares of Cara common stock issued pursuant to the Reverse Stock Split will remain fully paid and nonassessable. The Reverse Stock Split does not affect the total proportionate ownership of Cara following the Merger. The Reverse Stock Split will not affect Cara continuing to be subject to the periodic reporting requirements of the Exchange Act.

As an example, the following table illustrates the effects of a -for-1 to -for-1 reverse stock split (without giving effect to the treatment of fractional shares):

	Prior to Reverse Stock Split		
Common stock outstanding			

Common stock issuable pursuant to outstanding equity awards⁽¹⁾

(1) Includes RSUs. Substantially all options underlying these awards have an exercise price higher than
 \$ per share, the closing price of Cara common stock on

In addition, if the reverse stock split is implemented, it will increase the number of Cara stockholders who own "odd lots" of fewer than 100 shares of common stock. Brokerage commission and other costs of transactions in odd lots are generally higher than the costs of transactions of more than 100 shares of common stock. Accordingly, the reverse stock split may not achieve the desired results of increasing marketability and liquidity of Cara common stock that have been described above.

After the effective date of the reverse stock split, Cara common stock would have a new committee on uniform securities identification procedures (CUSIP number), a number used to identify Cara common stock.

Cara common stock is currently registered under Section 12(b) of the Exchange Act, and Cara is subject to the periodic reporting and other requirements of the Exchange Act. The proposed reverse stock split will not affect the registration of the common stock under the Exchange Act.

Procedure for Effecting the Reverse Stock Split and Exchange of Stock Certificates

If Cara's common stockholders approve the amendment to the amended and restated certificate of incorporation of Cara effecting the Reverse Stock Split, and if the Cara Board still believes that a reverse stock split is in the best interests of Cara and its stockholders, Cara will file the amendment to the amended and restated certificate of incorporation with the Secretary of State of the State of Delaware at such time as the Cara Board has determined to be the appropriate split effective time. The Cara Board may delay effecting the Reverse Stock Split without resoliciting stockholder approval. Beginning at the split effective time, each certificate representing pre-split shares will be deemed for all corporate purposes to evidence ownership of post-split shares.

Beneficial Owners of Common Stock. Upon the implementation of the reverse stock split, Cara intends to treat shares held by stockholders in "street name" (i.e., through a bank, broker, custodian or other nominee), in the same manner as registered stockholders whose shares are registered in their names. Banks, brokers, custodians or other nominees will be instructed to effect the reverse stock split for their beneficial holders holding Cara common stock in street name. However, these banks, brokers, custodians or other nominees than registered stockholders for processing the reverse stock split and making payment for fractional shares. If a stockholder holds shares of Cara common stock with a bank, broker, custodian or other nominee and has any questions in this regard, stockholders are encouraged to contact their bank, broker, custodian or other nominee.

Registered Holders of Common Stock in Book-Entry Form. Certain of Cara's registered holders of common stock hold some or all of their shares electronically in book-entry form with Cara's transfer agent, Equiniti Trust Company, LLC. These stockholders do not hold physical stock certificates evidencing their ownership of Cara common stock. However, they are provided with a statement reflecting the number of shares of Cara common stock registered in their accounts. If a stockholder holds registered shares in book-entry form with Cara's transfer agent, no action needs to be taken to receive post-reverse stock split shares or payment in lieu of fractional shares, if applicable. If a stockholder is entitled to post-reverse stock split shares, a transaction statement will automatically be sent to the stockholder's address of record indicating the number of shares of Cara common stock held following the reverse stock split.

Registered Holders of Common Stock in Certificate Form. As soon as practicable after the split effective time, Cara's stockholders will be notified that the Reverse Stock Split has been effected. Cara expects that the Cara transfer agent will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-split shares will be asked to surrender to the exchange agent certificates representing pre-split shares held in certificated form in exchange for certificates representing post-split shares in accordance with the procedures to be set forth in a letter of transmittal to be sent by Cara. No new certificates will be issued to a stockholder until such stockholder has surrendered such stockholder's outstanding certificate(s) together with the properly completed and executed letter of transmittal to the exchange agent. Any pre-split shares submitted for transfer, whether pursuant to a sale or other disposition, or otherwise, will automatically be exchanged for post-split shares. **Stockholders should not destroy any stock certificate(s) and should not submit any certificate(s) unless and until requested to do so.**

Fractional Shares

No fractional shares will be issued in connection with the Reverse Stock Split. Stockholders of record who otherwise would be entitled to receive fractional shares because they hold a number of pre-split shares not evenly divisible by the number of pre-split shares for which each post-split share is to be reclassified, will be entitled, upon surrender to the exchange agent of certificates representing such shares, to a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of the common stock on Nasdaq on the date immediately preceding the split effective time. The ownership of a fractional interest will not give the holder thereof any voting, dividend, or other rights except to receive payment therefor as described herein.

By approving the amendment to the amended and restated certificate of incorporation of Cara effecting the Reverse Stock Split, stockholders will be approving the combination of a whole number of shares of Cara common stock between to into one share of Cara common stock, with the actual ratio to be mutually agreed upon by Cara and Tvardi prior to the effectiveness of the Merger.

Stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where Cara is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by Cara or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

Accounting Consequences

The par value per share of Cara common stock will remain unchanged at \$0.001 per share after the reverse stock split. As a result, at the reverse stock split effective time, the stated capital on Cara's balance sheet attributable to Cara common stock will be reduced proportionately based on the reverse stock split ratio, from its present amount, and the additional paid-in capital account will be increased for the amount by which the stated capital is reduced. After the reverse stock split (and disregarding the impact of shares of Cara common stock issued in the merger), net income or loss per share, and other per share amounts will be increased because there will be fewer shares of Cara common stock outstanding. In future financial statements, net income or loss per share and other per share amounts for periods ending before the reverse stock split will be recast to give retroactive effect to the reverse stock split.

Potential Anti-Takeover Effect

Although the increased proportion of unissued authorized shares to issued shares could, under certain circumstances, have an anti-takeover effect, for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the Cara Board or contemplating a tender offer or other transaction for the combination of Cara with another company, the Reverse Stock Split Proposal is not being proposed in response to any effort of which Cara is aware to accumulate shares of Cara common stock or obtain control of Cara, other than in connection with the Merger, nor is it part of a plan by management to recommend a series of similar amendments to the Cara Board and stockholders. Other than the proposals being submitted to Cara's common stockholders for their consideration at the Cara

special meeting, the Cara Board does not currently contemplate recommending the adoption of any other actions that could be construed to affect the ability of third parties to take over or change control of Cara.

Material U.S. Federal Income Tax Consequences of the Reverse Stock Split

The following is a discussion of material U.S. Federal Income Tax consequences of the Reverse Stock Split that are applicable to U.S. holders (as defined below) of Cara common stock, but does not purport to be a complete analysis of all potential tax effects. This summary is based upon current provisions of the Code, existing Treasury regulations, judicial decisions, and published rulings and administrative pronouncements of the IRS, all in effect as of the date hereof and all of which are subject to differing interpretations or change. Any such change or differing interpretation, which may be retroactive, could alter the tax consequences to Cara stockholders as described in this summary.

This summary does not address U.S. Federal Income Tax consequences that may be relevant to particular Cara stockholders in light of their personal circumstances or to Cara stockholders who are subject to special treatment under U.S. Federal Income Tax laws, such as Cara stockholders who: do not hold their Cara common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment); are banks, insurance companies, tax-exempt entities, mutual funds, financial institutions, real estate investment trusts, regulated investment companies, government entities or brokerdealers; hold their Cara common stock as "qualified small business stock" under Section 1202 of the Code or as "Section 1244 stock" under Section 1244 of the Code; hold their Cara common stock as part of a hedging, "straddle," conversion or other integrated transaction or are treated as having sold their Cara common stock pursuant to the constructive sale provisions of the Code; are not U.S. holders (as defined below); acquired their Cara common stock pursuant to the exercise of compensatory options, or in other compensatory transactions; acquired their Cara common stock pursuant to the exercise of warrants or conversion rights under convertible instruments; are subject to special tax accounting rules under Section 451(b) of the Code; hold their Cara common stock through individual retirement or other taxdeferred accounts; acquired their Cara common stock in a transaction subject to the gain rollover provisions of Section 1045 of the Code; have a functional currency other than the U.S. dollar; or are partnerships or entities or arrangements classified as partnerships or disregarded entities for U.S. Federal Income Tax purposes, S corporations, or other pass-through entities (including hybrid entities) and investors therein.

Cara stockholders subject to particular U.S. or non-U.S. Tax rules that are described in this paragraph are urged to consult their own tax advisors regarding the consequences to them of the Reverse Stock Split.

If an entity that is treated as a partnership for U.S. Federal Income Tax purposes holds Cara common stock, the U.S. Federal Income Tax treatment of a partner in the partnership will depend upon the status of the partner, the activities of the partnership and certain determinations made at the partner level. If you are a partnership or a partner of a partnership holding Cara capital stock or any other person not addressed by this discussion, you should consult your tax advisors regarding the tax consequences of the Reverse Stock Split.

In addition, the following discussion does not address: (a) the tax consequences of transactions effectuated before, after or at the same time as the Reverse Stock Split, whether or not they are in connection with the Reverse Stock Split; (b) any U.S. federal non-income tax consequences of the Reverse Stock Split, including estate, gift or other tax consequences; (c) any state, local or non-U.S. tax consequences of the Reverse Stock Split; or (d) the Medicare contribution tax on net investment income. No ruling from the IRS or opinion of counsel, has been or will be requested in connection with the Reverse Stock Split. Cara stockholders should be aware that the IRS could adopt a position which could be sustained by a court contrary to that set forth in this discussion.

Definition of "U.S. Holder"

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of Cara common stock that is, for U.S. Federal Income Tax purposes:

• an individual who is a citizen or resident of the United States;

- a corporation or any other entity taxable as a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- a trust if either (i) a court within the United States is able to exercise primary supervision over the administration of such trust, and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) are authorized or have the authority to control all substantial decisions of such trust, or (ii) the trust was in existence on August 20, 1996 and has a valid election in effect under applicable Treasury Regulations to be treated as a United States person for U.S. Federal Income Tax purposes; or
- an estate, the income of which is subject to U.S. Federal Income Tax regardless of its source.

Treatment of U.S. Holders in the Reverse Stock Split

Cara intends to treat the Reverse Stock Split as a "recapitalization" for U.S. Federal Income Tax purposes within the meaning of Section 368(a) of the Code. Assuming the Reverse Stock Split qualifies as a recapitalization within the meaning of Section 368(a) of the Code, a U.S. holder will not recognize gain or loss upon the Reverse Stock Split, except with respect to cash received in lieu of a fractional share of Cara common stock (which fractional share will be treated as received and then exchanged for such cash). A U.S. holder's aggregate tax basis in the shares of Cara common stock received pursuant to the Reverse Stock Split will equal the aggregate tax basis of the shares of the Cara common stock surrendered (excluding any portion of such basis that is allocated to any fractional share of Cara common stock), and such U.S. holder's holding period in the shares of Cara common stock received will include the holding period in the shares of Cara common stock surrendered. Treasury Regulations provide detailed rules for allocating the tax basis and holding period of the shares of Cara common stock surrendered to the shares of Cara common stock received in a recapitalization pursuant to the Reverse Stock Split. U.S. holders of shares of Cara common stock acquired on different dates and at different prices should consult their tax advisors regarding the allocation of the tax basis and holding period of such shares.

A U.S. holder that receives cash in lieu of a fractional share of Cara common stock pursuant to the Reverse Stock Split will generally recognize capital gain or loss in an amount equal to the difference between the amount of cash received and the U.S. holder's tax basis in the shares of Cara common stock surrendered that is allocated to such fractional share of Cara common stock. Any such gain or loss will be long-term capital gain or loss if, as of the effective time of the Reverse Stock Split, the U.S. holder's holding period for such fractional share exceeds one year. Long-term capital gains of certain non-corporate taxpayers, including individuals, are generally taxed at preferential rates. The deductibility of capital losses is subject to limitations.

Information Reporting and Backup Withholding

If the Reverse Stock Split qualifies as a recapitalization within the meaning of Section 368(a) of the Code, each U.S. holder who receives shares of Cara common stock in the Reverse Stock Split is required to retain permanent records pertaining to the Reverse Stock Split, and make such records available to any authorized IRS officers and employees. Such records should specifically include information regarding the amount, basis, and fair market value of all transferred property, and relevant facts regarding any liabilities assumed or extinguished as part of such reorganization. U.S. holders who owned immediately before the Reverse Stock Split at least five percent (by vote or value) of the total outstanding stock of Cara is required to attach a statement to their tax returns for the year in which the Reverse Stock Split is consummated that contains the information listed in Treasury Regulation Section 1.368-3(b). Such statement must include the U.S. holder's tax basis in such holder's Cara common stock surrendered in the Reverse Stock Split, the fair market value of such stock, the date of the Reverse Stock Split and the name and employer identification number of Cara. U.S. holders are urged to consult with their tax advisors to comply with these rules.

A U.S. holder may be subject to information reporting and backup withholding for U.S. Federal Income Tax purposes on cash paid in lieu of fractional shares in connection with the Reverse Stock Split. Backup withholding will not apply, however, to a U.S. holder who (i) furnishes a correct taxpayer identification number and certifies the holder is not subject to backup withholding on IRS Form W-9 or a substantially similar form, or (ii) certifies the holder is otherwise exempt from backup withholding. If a U.S. holder

does not provide a correct taxpayer identification number on IRS Form W-9 or other proper certification, the stockholder may be subject to penalties imposed by the IRS. Any amounts withheld under the backup withholding rules may be refunded or allowed as a credit against the federal income tax liability of a U.S. holder of Cara capital stock, if any, provided the required information is timely furnished to the IRS. U.S. holders should consult their tax advisors regarding their qualification for an exemption from backup withholding, the procedures for obtaining such an exemption, and in the event backup withholding is applied, to determine if any tax credit, tax refund or other tax benefit may be obtained.

The foregoing summary is of a general nature only and is not intended to be, and should not be construed to be, legal, business or tax advice to any particular Cara stockholder. This summary does not take into account your particular circumstances and does not address consequences that may be particular to you. Therefore, you should consult your tax advisor regarding the particular consequences of the Reverse Stock Split to you.

Vote Required; Recommendation of the Cara Board

The affirmative vote of a majority of the votes cast by holders of shares present at the meeting (by virtual attendance) or by represented by proxy and voting on the matter at the Cara special meeting is required to approve Proposal No. 4. Abstentions and broker non-votes will have no effect on the outcome of this proposal. It is anticipated that Proposal No. 4 will be a non-discretionary proposal considered non-routine under the rules of the NYSE, which generally controls the ability of brokers to vote or not vote shares held in street name on certain matters, and thus may result in broker non-votes.

THE CARA BOARD RECOMMENDS THAT CARA'S COMMON STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 4 TO APPROVE THE AMENDMENT TO THE CARA AMENDED AND RESTATED CERTIFICATE OF INCORPORATION EFFECTING THE REVERSE STOCK SPLIT. THE APPROVAL OF EACH OF PROPOSAL NOS. 1, 4 AND 5 IS REQUIRED TO CONSUMMATE THE MERGER.

PROPOSAL NO. 5 (THE AUTHORIZED SHARE PROPOSAL): INCREASE IN AUTHORIZED SHARES

The Cara Board has determined that it is advisable to increase the authorized number of shares of Cara common stock from shares to shares, and has voted to recommend that the stockholders adopt an amendment to Cara's amended and restated certificate of incorporation effecting the proposed increase. The full text of the proposed amendment to Cara's amended and restated certificate of incorporation is attached to this proxy statement as Annex G.

As of December 1, 2024, 54,855,514 shares of Cara common stock were issued and outstanding (excluding treasury shares) and approximately an additional 5,045,128 shares of Cara common stock were reserved for issuance upon the conversion of existing securities and exercise of options granted under our various stock-based plans. Accordingly, a total of approximately 5,931,297 and 300,000 shares of Cara common stock are available for future issuance under the 2014 Plan and 2019 Plan, respectively. Additionally, Cara expects that it will issue 311,701,096 shares of Cara common stock in the Merger, including shares issuable upon conversion of the Convertible Notes, excluding any shares that may be issued in connection with the exercise of options assumed by Cara. Following the issuance of the shares of Cara common stock in the Merger, a total of approximately shares of Cara common stock is expected to be available for future issuance.

The Cara Board believes it continues to be in Cara's best interest to have sufficient additional authorized but unissued shares of Cara common stock available in order to provide flexibility for corporate action and strategic transactions in the future. Management believes that the availability of additional authorized shares for issuance from time to time in the Cara Board's discretion in connection with future financings, investment opportunities, stock splits or dividends or for other corporate purposes is desirable in order to avoid repeated separate amendments to Cara's amended and restated certificate of incorporation and the delay and expense incurred in holding special meetings of the stockholders to approve such amendments. We currently have no specific understandings, arrangements or agreements with respect to any future acquisitions that would require us to issue a material amount of new shares of Cara common stock. However, the Cara Board believes that the currently available unissued shares do not provide sufficient flexibility for corporate action in the future.

We will not solicit further authorization by vote of the stockholders for the issuance of the additional shares of Cara common stock proposed to be authorized, except as required by law, regulatory authorities or rules of Nasdaq or any other stock exchange on which the Cara common stock may then be listed. The issuance of additional shares of Cara common stock could have the effect of diluting existing stockholder earnings per share, book value per share and voting power. Cara stockholders do not have any preemptive right to purchase or subscribe for any part of any new or additional issuance of our securities.

Required Vote; Recommendation of the Cara Board

The affirmative vote of a majority of the votes cast by holders of shares present at the meeting (by virtual attendance) or by represented by proxy and voting on the matter at the Cara special meeting is required to approve Proposal No. 5. Abstentions and broker non-votes will have no effect on the outcome of this proposal. It is anticipated that Proposal No. 5 will be a non-discretionary proposal considered non-routine under the rules of the NYSE, which generally controls the ability of brokers to vote or not vote shares held in street name on certain matters, and thus may result in broker non-votes.

THE CARA BOARD UNANIMOUSLY RECOMMENDS THAT CARA'S COMMON STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 5 TO APPROVE THE AMENDMENT TO THE CARA AMENDED AND RESTATED CERTIFICATE OF INCORPORATION PROVIDING FOR AN INCREASE IN THE NUMBER OF AUTHORIZED SHARES OF CARA COMMON STOCK FROM SHARES TO SHARES. THE APPROVAL OF EACH OF PROPOSAL NOS. 1, 4 AND 5 IS REQUIRED TO CONSUMMATE THE MERGER.

PROPOSAL NO. 6 (THE ADJOURNMENT PROPOSAL): APPROVAL OF POSSIBLE ADJOURNMENT OF THE CARA SPECIAL MEETING

If Cara fails to receive a sufficient number of votes to approve the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal, Cara may propose to adjourn the Cara special meeting for the purpose of soliciting additional proxies to approve the Stock Issuance Proposal. Cara currently does not intend to propose adjournment at the Cara special meeting if there are sufficient votes to approve the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal.

If on the date of the Cara special meeting, or a date preceding the date on which the Cara special meeting is scheduled, Cara reasonably believes that (i) it will not receive proxies sufficient to obtain the required vote to approve the Stock Issuance Proposal, the Reverse Stock Split Proposal and/or the Authorized Share Proposal, whether or not a quorum would be present or (ii) it will not have sufficient shares of Cara common stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Cara special meeting, Cara may postpone or adjourn, or make one or more successive postponements or adjournments of, the Cara special meeting as long as the date of the Cara special meeting is not postponed or adjourned more than an aggregate of 30 calendar days in connection with any postponements or adjournments.

Required Vote; Recommendation of the Cara Board

The affirmative vote of a majority of shares present in person (by virtual attendance) or represented by proxy at the meeting and entitled to vote at the Cara special meeting is required to approve Proposal No. 6. Abstentions will have the same effect as a vote "Against" this proposal and broker non-votes will have no effect on the outcome of this proposal. It is anticipated that Proposal No. 6 will be a non-discretionary proposal considered non-routine under the rules of NYSE, which generally controls the ability of brokers to vote or not vote shares held in street name on certain matters, and thus may result in broker non-votes.

THE CARA BOARD UNANIMOUSLY RECOMMENDS THAT CARA STOCKHOLDERS VOTE "FOR" THE ADJOURNMENT PROPOSAL TO ADJOURN THE SPECIAL MEETING, IF NECESSARY, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF THE STOCK ISSUANCE PROPOSAL, THE REVERSE STOCK SPLIT PROPOSAL AND/OR THE AUTHORIZED SHARE PROPOSAL.



DESCRIPTION OF TVARDI'S BUSINESS

Unless otherwise indicated, all references to "Tvardi," the "company" or similar terms refer to Tvardi Therapeutics, Inc.

Overview

Tvardi is a clinical-stage biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting (STAT3) to treat fibrosis-driven diseases with significant unmet need. Based upon Tvardi's founder's seminal work and deep understanding of the transcription factor, STAT3, Tvardi has designed an innovative approach to directly inhibit STAT3, a highly validated, yet historically undruggable target. Leveraging this expertise, Tvardi is developing a pipeline of STAT3 inhibitors with a differentiated mechanism of action and convenient oral dosing. Tvardi's lead product candidate, TTI-101, is currently in Phase 2 clinical development for the treatment of fibrosis-driven diseases, with an initial focus on idiopathic pulmonary fibrosis (IPF), and hepatocellular carcinoma (HCC). Tvardi expects to report unblinded data from its Phase 2 IPF clinical trial in the second half of 2025 and anticipate preliminary topline data from its HCC Phase 1b/2 clinical trial in the second half of 2025.

Tvardi's approach is rooted in its expertise around STAT3's functional composition and its critical role in disease pathogenesis, as well as other essential biological functions. Tvardi's co-founder, David J. Tweardy, M.D., was one of the first to identify that STAT3, when activated by phosphorylation on tyrosine (Y) residue 705, referred to herein as (pY-STAT3), acts as a central catalyst across critical fibrotic signaling pathways and is key to the cellular processes associated with fibrosis-driven diseases. Intrinsically (within proliferative cells and the extracellular matrix (ECM), pY-STAT3 increases cell proliferation and survival and promotes the deposition of extracellular matrix proteins, while extrinsically (within the immune system), pY-STAT3 contributes to immune suppression. Collectively, persistent pY-STAT3 drives the development and progression of the pathogenic cascade of fibrosis. By targeting pY-STAT3, Tvardi's approach is designed to simultaneously modulate each of the key pathways of the fibrotic cascade, whereas previous approaches only targeted single pathways. Beyond its role in fibrosis, STAT3 also has an essential role in cellular respiration in the mitochondria. Tvardi's co-founder, David J. Tweardy, M.D., made the critical discovery that blocking pY-STAT3 could inhibit STAT3's role as a transcription factor without affecting its role in the mitochondria. Tvardi has leveraged this discovery to design its product candidates to inhibit STAT3 activation which, it believes, will lead to disease modifying activity without impairing essential biological functions.

Based on the strong biological rationale and data to date, Tvardi believes it has robust proof of concept to support the potential of its STAT3 inhibitors to treat fibrosis-driven diseases. In preclinical models, TTI-101 administration resulted in statistically significant reductions in levels of well-known biomarkers of fibrosis, most notably collagen type I alpha1 chain (COL1A1) (p≤0.05). In addition, TTI-101 administration decreased the amount of fibrotic tissue in the lungs, in a statistically significant manner ($p \le 0.05$), as measured by histologic evaluation of fibrosis severity, and returned oxygen saturation (SO₂), to near normal levels versus animals treated with placebo where SO₂ levels continued to decline. Tvardi is enrolling patients in its ongoing REVERT_{IPF} Phase 2, randomized, double-blind, placebo-controlled clinical trial of TTI-101 as monotherapy or in addition to nintedanib, a standard of care (SoC), therapy, to evaluate its safety, tolerability and preliminary efficacy in patients suffering from IPF. In addition, Tvardi has previously demonstrated, in a Phase 1 oncology clinical trial of TTI-101 as monotherapy enriched for patients with HCC, that TTI-101 was generally well-tolerated, targeted STAT3, lowering levels of pY-STAT3 in tumors, as evidenced by biopsy sample and demonstrated a disease control rate of 53% as measured by Response Evaluation Criteria in Solid Tumors Version 1.1, RECIST v1.1, leading to clinical responses in fibrosis-driven tumors. RECIST is a standard way to measure how well a cancer patient responds to treatment. Tvardi is currently enrolling patients in its REVERT_{LIVER CANCER} Phase 1b/2 clinical trial to investigate TTI-101 as monotherapy and in combination with standard of care in patients with HCC. The ongoing Phase 1b/2 design allows Tvardi to transition from a dose-finding and safety evaluation in the Phase 1b portion of the clinical trial, to a larger, Phase 2 portion of the clinical trial with primary efficacy endpoints, including overall response rate using RECIST v1.1. Tvardi's second product candidate, TTI-109, is also an oral, small molecule STAT3 inhibitor that is structurally related to, yet chemically distinct from, TTI-101 and is designed to enhance Tvardi's ability to target STAT3. Tvardi expects to submit an investigational new drug (IND), application for TTI-109 in the first half of 2025.

Tvardi's Pipeline

Tvardi's current pipeline is depicted below:



1. We plan to commence clinical trials in fibrosis and/or oncology pending IND submission and FDA feedback.

The U.S. Food and Drug Administration (FDA), has granted orphan drug designation for TTI-101 in both IPF and HCC as well as Fast-Track Designation for TTI-101 in HCC.

TTI-101 for the Treatment of IPF

In the United States, approximately 150,000 individuals have IPF, while globally the number is estimated to be three million. Currently, approved anti-fibrotic therapies, Esbriet and Ofev, had collective peak sales of \$4.9 billion, yet their use is limited as they do not reverse fibrosis or improve lung function. Based on the well-established role of pY-STAT3 in the pathogenesis of fibrosis, Tvardi believes TTI-101's differentiated mechanism of action has the potential to address this unmet need in IPF, if approved. In preclinical models, Tvardi observed that TTI-101 led to a reduction of fibrotic tissue in the lungs and improved lung function. Tvardi also observed dose-dependent decreases in validated biomarkers associated with cell proliferation (resulting in reduced deposition) as well as increase in the modulation and activity of T cells (responsible for increased cellular and extracellular degradation). Additionally, Tvardi's completed Phase 1 healthy volunteer drug-drug interaction clinical trial with IPF standard of care (SoC), therapies showed TTI-101 to be generally well-tolerated. No severe adverse events (SAEs), were reported. The most frequent treatment emergent adverse events (TEAEs), predominantly reported as mild in severity, resolved on study. Tvardi's clinical data, including robust pharmacokinetic (PK), pharmacodynamic (PD), and tolerability data, has allowed Tvardi to rapidly progress into a Phase 2 clinical trial in IPF.

Tvardi is currently enrolling its REVERT_{IPF} Phase 2, multicenter, randomized, double-blind, placebocontrolled clinical trial of TTI-101 to evaluate safety, tolerability and PK in patients suffering from IPF. Tvardi also plans to evaluate multiple efficacy measures, including the established Phase 3 efficacy endpoint of forced vital capacity (FVC). Approximately 75 patients are randomly assigned (1:1:1) to receive oral TTI-101 400 mg/day, TTI-101 800 mg/day or placebo for 12 weeks as monotherapy or in addition to SoC, nintedanib. The natural course of disease for patients suffering from IPF, even when treated with SoC, is a decline in lung function as measured by FVC. Preliminary blinded data from the two dose levels of TTI-101 and placebo in 38 patients to date have reported approximately 50% of patients' FVC values near or above baseline. Tvardi expects to report unblinded data from this clinical trial in the second half of 2025.

TTI-101 for the Treatment of HCC

HCC, a fibrosis-driven cancer, is the third-leading cause of cancer-related mortality in the United States and globally, with an estimated survival of six to 20 months following diagnosis. Treatment with the current SoC in first line remains suboptimal with an overall response rate (ORR), of 10% to 27%. Following progression on first-line therapies, response rates are further reduced (ORR of \leq 5%) for patients who go

on to receive second-line therapies. Overall response rate is defined as the proportion of patients who have achieved a partial response (\geq 30% decrease in the sum of the diameters of target lesions, as compared with the baseline sum of diameters) or a complete response (disappearance of all target lesions). Similar to its role in IPF, pY-STAT3 in HCC serves an integral role in both the intrinsic cellular processes that drive aberrant proliferation, survival, deposition and extrinsic processes that induce immune suppression. Greater than 95% of patients with HCC have pY-STAT3 in their tumors, the presence of which correlates closely with tumor vascularity and aggressiveness of disease and is significantly associated with poor overall survival.

In preclinical studies, TTI-101 demonstrated statistically significant changes in (1) microsteatosis score (abnormal liver fat accumulation) that was 89% lower in animals treated with TTI-101 versus placebo treated animals (p<0.001), (2) fibrosis, measured by histologic staining, that was 65% lower in animals treated with TTI-101 versus placebo treated animals (p<0.001) and (3) tumor growth, measured by comparing the average tumor volume determined by MRI, that was 57% lower in animals treated with TTI-101 versus placebo treated animals (p=0.04). Additionally, in a separate study, combination of TTI-101 with anti-PD-1 and bevacizumab demonstrated a statistically significantly larger reduction in tumor weight compared to anti-PD-1 and bevacizumab or saline that was statistically significant (p<0.01). Tvardi has also completed a Phase 1 dose-escalation and dose-expansion clinical trial for TTI-101 in advanced tumors, enriched for patients with HCC. TTI-101 was observed to lower levels of pY-STAT3 in tumors, as evidenced by biopsy samples and demonstrated a disease control rate of 53%, as measured by RECIST v1.1, leading to clinical responses in HCC and other tumor types. Tvardi also conducted a Phase 1b clinical trial in six hormone receptor — positive (HR+), human epidermal receptor 2 negative (HER2-), palbociclib-resistant breast cancer patients to evaluate TTI-101 in combination with palbociclib and aromatase inhibitor (AI). The recommended Phase 2 dose was selected and there were no clinically significant safety concerns or risks identified that were related to the use of TTI-101 in combination with palbociclib or AI. Given the evolving treatment landscape for metastatic breast cancer, Tvardi has discontinued all clinical development in metastatic breast cancer and have directed its resources to its current pipeline. Tvardi believes its results to date support TTI-101's differentiated mechanism of action to deliver therapeutic benefit as monotherapy and in combination with existing approved agents, if approved. If approved, Tvardi does not believe a commercial license, supply, and/or collaboration agreement with the marketers of existing SoC treatments would be needed, as these commercial therapies are available in the market.

Tvardi is currently enrolling its REVERT_{LIVER CANCER} Phase 1b/2, multicenter, open-label clinical trial, designed to investigate the safety and efficacy of TTI-101 across three cohorts of patients with HCC: as monotherapy and in combination with SoC treatments pembrolizumab or atezolizumab + bevacizumab. This is a combined Phase 1b and 2 trial in order to evaluate safety and tolerability of TTI-101 and to determine the recommended Phase 2 dose (RP2D), of orally administered TTI-101 as a single agent or in combination with pembrolizumab or atezolizumab/bevacizumab in Phase 1b. The primary endpoints for the Phase 1b portion include incidence of adverse events (AEs). Separately, the trial will evaluate safety and tolerability at the RP2D and assess preliminary efficacy in the Phase 2 portion of the trial. The primary endpoints for the Phase 2 portion include incidence of AEs and overall response rate using RECIST v1.1.

Tvardi plans to report preliminary topline data from this clinical trial in the second half of 2025.

TTI-109

Tvardi's second product candidate, TTI-109, is an oral, small-molecule, prodrug of, and mechanistically identical to, TTI-101. TTI-109 itself does not inhibit STAT3, but rapidly converts to TTI-101 in the blood. TTI-109 is designed to enhance its ability to target STAT3 as a more efficient delivery vehicle for TTI-101 with the potential to improve tolerability. In Tvardi's IND-enabling toxicology studies in rats and monkeys, TTI-109 has been observed to result in equal drug exposure as compared to TTI-101, with no toxicity observed. Tvardi has received pre-IND feedback from the FDA that its data package to date is sufficient to support a clinical trial of TTI-109 in oncology. To maximize the potential of TTI-109 in fibrosis-driven diseases, Tvardi is planning additional preclinical studies and a first-in-human IND submission for TTI-109 in the first half of 2025.

Tvardi's Team

Tvardi was founded in 2017 by world-renowned physician-scientists David J. Tweardy, M.D., and Ron DePinho, M.D. Dr. Tweardy is recognized for his work elucidating STAT3's contribution to inflammation,

fibrosis and oncogenesis. Discoveries by Dr. Tweardy and his lab included identification of the structural basis for the activation of STAT3, which led to the identification of TTI-101. Dr. DePinho is the Past President of The University of Texas MD Anderson Cancer Center and a member of the National Academy of Science and National Academy of Medicine. Dr. DePinho's groundbreaking research program has contributed to Tvardi's understanding of cancer and aging disorders.

Tvardi's management team is comprised of experienced entrepreneurs, innovative scientists and dedicated physicians with a mission to develop a new class of breakthrough medicines for fibrosis-driven disease. Imran Alibhai, Ph.D., Tvardi's Chief Executive Officer, brings approximately 20 years of experience in the biopharmaceutical industry as an executive, advisor and investor across public and private equities including fibrosis and oncology. Dr. Alibhai has held several executive positions at MPM Capital LLC, Alexandria Venture Investments, LLC, Peter J. Solomon Company and most recently as senior vice president and managing director at DNAtrix, Inc. John Kauh, M.D., Tvardi's Chief Medical Officer, is a board-certified medical oncologist with proven leadership in early- and late-phase drug development of multiple oncology programs including surufatinib (Sulanda) at HUTCHMED (China) Limited and ramucirumab (Cyramza) for HCC at Eli Lilly and Company. Dan Conn, J.D., M.B.A., Tvardi's Chief Financial Officer, has an extensive background in corporate law, finance and business management, having held multiple senior positions at Morgan Stanley, D.E. Shaw & Co., L.P., Brookfield Asset Management, Peter J. Solomon Company and most recently as chief executive officer and member of the board of directors at Christie's International Real Estate.

Tvardi's Strategy

Tvardi's goal is to leverage its expertise in STAT3 biology to discover and develop novel, oral, small molecule therapeutics for the treatment of patients suffering from fibrosis-driven diseases with significant unmet need. Tvardi aims to achieve this goal by executing on the following strategies.

- Become a leading STAT3 company to unlock its potential in fibrosis-driven diseases. As a central mediator across critical fibrotic signaling pathways, pY-STAT3 is key to many of the cellular processes that drive aberrant proliferation, survival, ECM, deposition and immune suppression. Based upon its founder's seminal work, Tvardi has made breakthrough discoveries that helped identify the structural basis and medicinal chemistry required to target the highly validated, yet historically undruggable, pY-STAT3. Tvardi leverages its deep understanding of STAT3 biology to design product candidates which specifically inhibit the activation of STAT3's nuclear functions without interfering with essential biological functions of STAT3. Tvardi believes its approach to directly inhibiting STAT3 enables it to develop product candidates with the potential to provide meaningful therapeutic benefit to patients with fibrosis-driven diseases, if approved.
- Rapidly advance TTI-101, Tyardi's oral, small molecule inhibitor of STAT3 through clinical trials for the treatment of IPF. Tvardi believes there is a critical need for a disease-modifying and well-tolerated oral agent to effectively treat IPF, a chronic, debilitating fibrotic lung disease with median survival time of less than five years from time of diagnosis. Tvardi's lead product candidate, TTI-101, has demonstrated downregulation of biomarkers of fibrosis across multiple preclinical models, supportive of STAT3 inhibition. In particular, in an established functional model of IPF, Tvardi observed dose-dependent, therapeutic reduction in fibrosis and improved lung function. Additionally, the robust PK, PD and safety data Tvardi has generated in oncology to date has allowed Tvardi to rapidly progress into a Phase 2 clinical trial in IPF. In August 2023, Tvardi dosed the first patient in its ongoing 12-week REVERT_{IPF} Phase 2 clinical trial for the treatment of patients suffering from IPF. Preliminary blinded data from the two dose levels of TTI-101 and placebo in 38 patients (randomized 1:1:1) to date indicated approximately 50% of participants reporting FVC values near or above baseline. The natural course of disease for patients suffering from IPF, regardless of SoC therapies, is a decline in lung function. Tvardi expects to report unblinded data from this clinical trial in the second half of 2025. Based on results from this Phase 2 clinical trial in IPF, it intends to further explore TTI-101 for use as monotherapy or in addition to SoC, nintedanib.
- **Progress TTI-101 through pivotal development for the treatment of fibrosis-driven cancers, with initial development in HCC.** As in IPF, STAT3 serves an integral role in the cellular processes that drive aberrant proliferation, survival, ECM deposition and immune suppression in HCC. Greater than



95% of patients with HCC have pY-STAT3 in their tumors, which correlates with a worse prognosis. Tvardi has prioritized HCC for its initial development within oncology and believes its results to date support TTI-101's differentiated mechanism of action to deliver therapeutic benefit as monotherapy and in combination with existing approved agents, if approved. Amongst patients with HCC (n=17), Tvardi's Phase 1 clinical trial data demonstrated a disease control rate of 53%, as measured by RECIST v1.1, after a median of two prior systemic therapies. Tvardi is currently conducting its REVERT_{LIVER CANCER} Phase 1b/2 clinical trial for TTI-101 in HCC both as monotherapy and in combination with pembrolizumab or atezolizumab + bevacizumab and expects to report preliminary topline data in the second half of 2025. Based on results from this Phase 2 clinical trial in HCC, Tvardi intends to further explore TTI-101 for use as monotherapy or in combination with existing SoC.

- Expand Tvardi's pipeline into additional indications where STAT3 activation plays a central role in disease pathogenesis. Tvardi intends to continue leveraging its deep expertise in STAT3 biology to develop multiple product candidates for a broad range of fibrosis-driven diseases. In addition to its development of TTI-101, Tvardi is advancing TTI-109 through IND-enabling studies. Tvardi plans to leverage the data from these preclinical studies to determine the optimal path forward for TTI-109, targeting an IND submission in the first half of 2025.
- Evaluate and pursue tailored strategies to maximize the impact of Tvardi's product candidates and benefit to patients. Tvardi retains exclusive worldwide rights to all of its product candidates. It intends to independently develop its product candidates in indications and geographies with clear clinical and regulatory approval pathways where it can commercialize successfully on its own, if approved. Tvardi may also seek to establish strategic partnerships around certain product candidates in disease areas or geographies that are better served by the resources or specific expertise of other biopharmaceutical companies. To better serve patients with rare fibrosis-driven diseases, such as IPF, Tvardi continues to grow and strengthen its relationship with key constituents such as physicians, caregivers and patient advocacy groups.

Overview of Fibrosis

Fibrosis is a pathological feature of most chronic inflammatory diseases and is characterized by the excessive accumulation of ECM components, including collagen and fibronectin in and around inflamed tissue, which can lead to permanent scarring, organ function decline and ultimately death. While fibrotic pathways are typically activated to serve as a natural mechanism for wound healing, normal tissue repair can evolve into a progressive irreversible fibrotic response if the tissue injury is severe or repetitive. Fibrosis-driven diseases can affect nearly all tissues and organs, compromising their normal function and contributing to the morbidity and mortality of aging-related disease worldwide. In the United States, fibrosis-driven diseases have led to an estimated 45% of all-cause mortality. The underlying principal mechanisms of fibrosis are similar across various tissue and cell types, and fibrosis plays a critical role in numerous debilitating diseases. However, the pathophysiology of fibrosis is a complex process driven by multiple signaling pathways and mediators including, but not limited to, IL-6 and TGF- β , leaving many patients suffering from fibrosis-driven diseases without adequate treatment options. As a central mediator across critical fibrotic signaling pathways, pY-STAT3 is key to many of the cellular processes that drive aberrant proliferation, survival, ECM deposition and immune suppression.

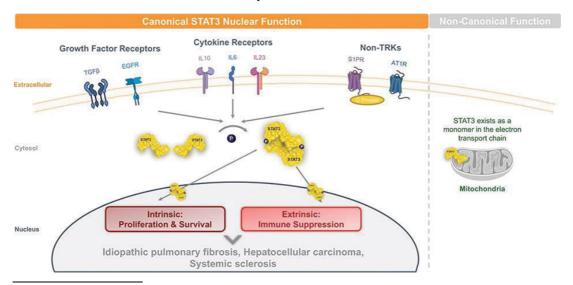
Role of STAT3 in Fibrosis-Driven Diseases

Activation of STAT3 plays multiple roles in cells, including cell survival and proliferation in response to injury in the canonical pathway and cellular respiration within the mitochondria in the non-canonical pathway. The canonical pathway is the primary STAT3 pathway linking to fibrosis. In the canonical pathway, STAT3 becomes phosphorylated on tyrosine residue Y705, pY-STAT3, forms a dimer, translocates into the nucleus and activates the transcription of responsive genes. In the non-canonical pathway, STAT3 becomes phosphorylated on serine residue S724, pS-STAT3, and translocates into mitochondria, playing a key role in the essential biological function of cellular respiration.

In the canonical pathway, STAT3 activation can be triggered by an inflammatory reaction to injury and is sustained to repair the wound. Upon achieving homeostasis or recovery, feedback loops inactivate



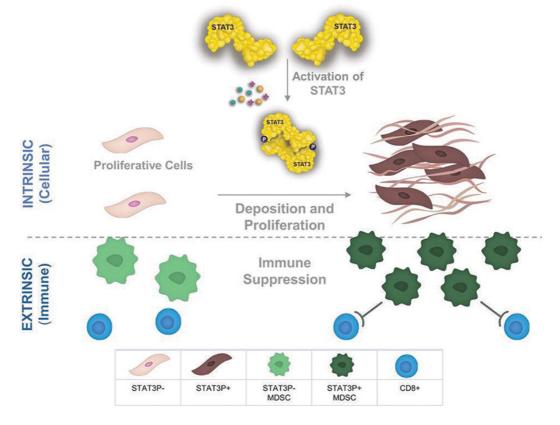
STAT3's response. Persistent STAT3 activation can lead to uncontrolled chronic inflammation and fibrosis leading to a variety of chronic, debilitating diseases. STAT3 can be activated by a variety of cytokines, growth factors and non-tyrosine receptor kinases (non-TRKs), including IL-6 and TGF- β , which lead to pY-STAT3.



STAT3's Canonical Function Plays a Central Role in Fibrosis-Driven Diseases

Source: Image adapted from "Therapeutically exploiting STAT3 activity in cancer — using tissue repair as a road map" by Jennifer Huynh, *et al.*, and "Contribution of STAT3 to Inflammatory and Fibrotic Diseases and Prospects" by Moses M. Kasembeli, *et al.*

The canonical STAT3 pathway associated with fibrosis-driven diseases can be broadly defined by a dual mechanism of action: intrinsic activity (within proliferative cells and the ECM) and extrinsic activity (within the immune system). Intrinsically (within proliferative cells and the ECM), pY-STAT3 increases cell proliferation and survival and promotes the deposition of ECM proteins, while extrinsically (within the immune system), pY-STAT3 contributes to immune suppression. Increased levels of extrinsic and intrinsic pY-STAT3 signaling result in fibrosis-driven diseases, including but not limited to IPF, HCC and systemic sclerosis (SSc).



The Dual Mechanism of Action of STAT3's Function in the Canonical Pathway

Critical and well-established signaling regulators of fibrosis, such as IL-6 and TGF- β , have been shown to induce pY-STAT3-dependent fibrotic conditions. pY-STAT3 is known to act both independently and in conjunction with other signaling networks that contribute to fibrosis. pY-STAT3 drives the development and progression of fibrosis through clotting and coagulation, inflammatory cell migration and fibroblast proliferation, ultimately leading to ECM deposition. STAT3's role as the central mediator in the pathogenesis of fibrosis has been validated in third-party preclinical haploinsufficiency models, where one of two alleles of STAT3 were knocked out. In these preclinical studies, haploinsufficient STAT3 mice did not develop lung fibrosis despite injury, whereas the knockout of IL-6 or TGF- β receptor (TGF- β R), still resulted in fibrosis. These preclinical studies suggest that targeting individual signaling pathways is insufficient to block the development of fibrosis, however inhibiting STAT3 activation can potentially prevent the initiation of fibrosis.

Clotting & Coagulation Haploinsufficiency of Feedback Loop STAT3 (STAT3+/-) protects mice from development of lung fibrosis vs. knockout Inflammatory **Cell Migration** of IL6 or TGFBR which still results in fibrosis 120 C 100-STATS 60 Fibroblast DUN-40-20-A0% -20 ILG" STAT3* WT Feedback Loops WT: Wild-type; ECM: E: trix: II 64: knock ut of IL6: STAT3: of STAT3 where one of t les of STAT3 is k

STAT3 Activation is a Central Catalyst in the Fibrotic Cascade

Tvardi's Approach to Targeting STAT3

STAT3, like many transcription factors, has historically been deemed undruggable due largely to its intracellular location and the failure to identify residues within its Src-homology (SH) 2 domain critical for its activation. Though STAT3 has been a recognized and interrogated target for drug development, there is yet to be an FDA-approved STAT3-targeting therapeutic. Prior approaches to target the STAT3 signaling pathway have largely been indirect, focused on upstream signaling mechanisms, including growth factors and cytokines, such as IL-6 and TGF- β , their receptors, or receptor-intrinsic or receptor-associated tyrosine kinases. Due to the adaptive nature of most signaling cascades, indirect approaches have led to off target effects or acquired resistance. As a result, Tvardi believes that direct targeting of STAT3 is the more robust approach to impacting downstream mediators of fibrosis within the STAT3 signaling pathway. Previous attempts to directly inhibit STAT3 have often demonstrated lack of selectivity, poor PK and/or poor absorption. In addition, some molecules identified to date are not reversible competitive inhibitors of STAT3; rather, their binding to STAT3 leads to its instability and degradation, which reduces non-canonical STAT3 functions within the mitochondria, resulting in off-target impacts and toxicities such as unresolving peripheral neuropathies and lactic acidosis. Other approaches to inhibit the translation of STAT3 have been hampered by safety concerns, such as high rates of thrombocytopenia (reduced platelet count) and transaminitis (elevated liver enzymes), poor PD and burdensome administration regimens requiring numerous intravenous infusions.

Tvardi's strategy for clinical development of therapies targeting inhibition of STAT3 activation is rooted in its deep understanding of STAT3 structure and function, and its critical role in disease pathogenesis. One of Tvardi's co-founders, Dr. Tweardy, was among the first to discover pY-STAT3 in normal blood cells. He pioneered the scientific community's understanding of STAT3 biology in hematopoiesis and determined that targeting residues within the STAT3 SH2 domain that are critical to the first step in its activation, pY-STAT3, was the key to selectively inhibiting STAT3's role as a transcription factor without affecting its role in the mitochondria. Tvardi believes its approach to directly inhibiting STAT3 enables Tvardi to develop product candidates with the potential to provide meaningful therapeutic benefit to patients with fibrosis-driven diseases, if approved.



Tvardi's Pipeline





1. We plan to commence clinical trials in fibrosis and/or oncology pending IND submission and FDA feedback.

Tvardi's lead product candidate, TTI-101, is an oral, small molecule inhibitor of STAT3 that Tvardi is initially developing in IPF and HCC. The FDA has granted orphan drug designation for TTI-101 in both IPF and HCC as well as Fast-Track Designation for TTI-101 in HCC.

Tvardi's TTI-101 Product Candidate

Tvardi's lead product, TTI-101, is an oral, small molecule inhibitor of STAT3 that specifically blocks pY-STAT3. TTI-101 binds tightly to the SH2 domain of STAT3, which specifically blocks its ability to bind to signaling complexes that contain tyrosine kinases. This is designed to prevent STAT3 from being phosphorylated at tyrosine (Y) 705 and further prevent STAT3 dimerization and nuclear translocation. The selective binding of TTI-101 to the SH2 domain thus inhibits STAT3's canonical nuclear function, while preserving its essential non-canonical functions associated with cellular respiration within the mitochondria.

Preclinical studies in fibrotic conditions and cancers indicate inhibition of STAT3 using TTI-101 can disrupt the STAT3 canonical pathway to address fibrosis-driven diseases. Specifically, preclinical IPF models using TTI-101 have demonstrated that STAT3 inhibition resulted in (1) an observed histologic reduction in lung fibrosis, quantified using Ashcroft score and Masson's trichrome from murine lung tissues, and (2) increase in lung function as measured by percent pulse oxygen saturation (SO₂). Preclinical nonalcoholic steatohepatitis (NASH), models demonstrated that treatment with TTI-101 reduced (1) elevated hepatic enzymes and microsteatosis, or abnormal liver fat accumulation, (2) hepatic fibrosis, measured by Masson's trichrome staining and (3) tumor growth as evidenced by reduction in average tumor volume determined by MRI. In SSc preclinical models, TTI-101 demonstrated an observed reduction in dermal fibrosis, measured by histological examination of skin sections stained with H&E and Masson's trichrome.

In a broad range of cancer models, TTI-101 demonstrated the capability to intrinsically induce apoptosis, or cell death, of tumor cells as evidenced by reduction in tumor weight or tumor volume and extrinsically overcome immune suppression in the tumor microenvironment as monotherapy and in combination with immune checkpoint inhibitors, as measured by immunohistochemical staining. Tvardi believes this preclinical data supports the development of TTI-101 across fibrosis-driven diseases. Tvardi also completed Phase 1 clinical trials of TTI-101 in advanced cancers and in healthy volunteers and are currently conducting two Phase 2 clinical trials of TTI-101 in IPF and HCC, respectively.

Tvardi's TTI-109 Product Candidate

Tvardi's second product candidate, TTI-109, is an oral, small-molecule, prodrug of, and mechanistically identical to, TTI-101. TTI-109 itself does not inhibit STAT3, but rapidly converts to TTI-101 in the blood. TTI-109 is designed to enhance its ability to target STAT3 as a more efficient delivery vehicle for TTI-101 with

the potential to improve tolerability. In Tvardi's IND-enabling toxicology studies in rats and monkeys, TTI-109 has been observed to result in equivalent drug exposure as compared to TTI-101, with no toxicity observed. Tvardi has received pre-IND feedback from the FDA that its data package to date is sufficient to support a clinical trial of TTI-109 in oncology. To maximize the potential of TTI-109 in fibrosis-driven diseases, Tvardi is planning additional preclinical studies and a first-in-human IND submission for TTI-109 in the first half of 2025.

Idiopathic Pulmonary Fibrosis

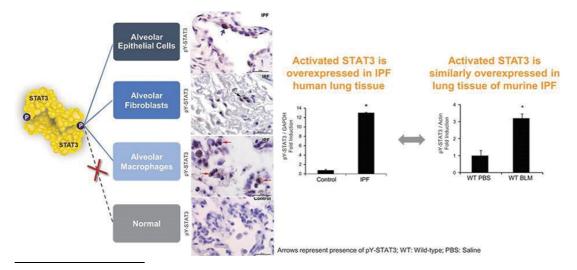
Background on Idiopathic Pulmonary Fibrosis

IPF is a rare, chronic, debilitating interstitial lung disease characterized by inflammation, progressive fibrosis and lung damage of unknown cause. As IPF progresses, it leads to thickening and stiffening of the lung tissue and eventually the inability of the lungs to transfer oxygen into the bloodstream. Patients suffering from IPF experience a poor quality of life and struggle with their daily routine due to constant shortness of breath, fatigue and weakness. In most patients suffering from IPF, the cause of death is IPF itself. Moreover, IPF is also associated with respiratory and non-respiratory comorbidities such as chronic obstructive pulmonary hypertension, obstructive sleep apnea, lung cancer, ischemic heart disease and gastro-esophageal reflux. Patients suffering from IPF have a poor life expectancy, and it is estimated that the five-year mortality rate of patients suffering from IPF ranges from 60% to 80%.

FVC, a measure of pulmonary function, is an important monitoring and prognostic tool for patients suffering from IPF and the established efficacy endpoint for IPF clinical trials. Patients suffering from IPF have demonstrated an annual decline of approximately 5% in FVC in placebo-treated groups of randomized control trials, while real world evidence suggests many patients decline more rapidly. According to a study titled "Three-Month FVC Change: A Trial Endpoint for Idiopathic Pulmonary Fibrosis Based on Individual Participant Data Meta-analysis" by Fasihul A. Khan, et al., meta-analyses of pooled patient data from twelve placebo cohorts from IPF clinical trials have demonstrated a median three-month decline of 2.3% in FVC. Additionally, there was a 15% increased risk for mortality per 2.5% relative FVC decline. Data further demonstrated that three-month declines in lung function, as measured by FVC, are highly predictive of 12-month change and represent major implications for overall disease progression and prognosis for patients suffering from IPF.

STAT3 plays a critical role as a central mediator underlying the pathogenesis of fibrosis in IPF. pY-STAT3 levels are often elevated in human lung tissue samples of patients suffering from IPF, driving the development and progression of fibrosis through clotting and coagulation, inflammatory cell migration, myofibroblast proliferation, ultimately leading to ECM deposition.

STAT3 is activated in the three major compartments of the lungs associated with IPF. Elevated levels of pY-STAT3, as measured immunolocalization expression by immunohistologic staining, have been observed in human lung tissue samples of patients suffering from IPF and not observed in non-fibrotic, healthy control lungs. Specifically, pY-STAT3 was observed in the alveolar epithelial cells, alveolar fibroblasts and alveolar macrophages. High STAT3 expression in these compartments correlates with higher mortality in patients suffering from IPF, whereas low STAT3 correlates with a higher survival probability.



STAT3 is Activated in Major Compartments of IPF-Affected Mouse and Human Lung Tissue

Images on the right hand side were derived from Pedroza, M., Le, T.T., Lewis, K., Karmouty-Quintana, H., To, S., George, A.T., Blackburn, M.R., Tweardy, D.J. and Agarwal, S.K. (2016), *STAT-3 contributes to pulmonary fibrosis through epithelial injury and fibroblast-myofibroblast differentiation*. The FASEB Journal, 30: 129 – 140. Western blot analysis of phospho-STAT-3 expression in human patients with mild and severe IPF. STAT-3 and GAPDH were used as controls ($n \ge 4$). Phospho-STAT-3 band intensity was quantified using ImageJ analysis. Values are presented as the percentages of Glyceraldehyde 3-phosphate dehydrogenase (GAPDH), \pm sem ($n \ge 4$). *P ≤ 0.05 control vs. IPF. Western blot analysis using an antibody against phospho-STAT-3 in whole-lung lysates. STAT-3 and α -actin were used as controls. Phospho-STAT-3 band intensity was quantified using ImageJ analysis. Values are presented as the percentages of α -actin \pm sem ($n \ge 4$). *P ≤ 0.05 PBS vs. bleomycin (BLM).

Market Opportunity in IPF and Limitations of Existing Treatments

In the United States, approximately 150,000 individuals have IPF, while globally the number is estimated to be three million. Currently, there are two approved anti-fibrotic therapies for IPF, nintedanib (Ofev, marketed by Boehringer Ingelheim Pharma GmbH & Co. KG) and pirfenidone (Esbriet, marketed by Roche Holding AG).

The currently approved anti-fibrotic therapies target single mechanisms of IPF. Nintedanib is a tyrosine kinase inhibitor (TKI), that non-specifically targets kinases implicated in the pathogenesis of fibrotic tissue, while pirfenidone's mechanism of action has not been established. Only approximately 25% of patients suffering from IPF are treated with nintedanib or pirfenidone. In addition, approximately 50% of patients treated with SoC required dose adjustment due to adverse events. Nintedanib and pirfenidone have been shown to slow disease progression, however neither treatment reverses or prevents clinical decline in FVC lung function. Despite the significant unmet need for better treatment options and the notable side effects of both approved agents, the peak sales of nintedanib and pirfenidone were \$3.8 billion and \$1.1 billion, respectively, which Tvardi believes represents a significant commercial opportunity for a disease-modifying and well-tolerated treatment for patients suffering with IPF.

Tvardi's Solution: TTI-101 for IPF

TTI-101's differentiated mechanism of action is designed to directly inhibit STAT3 to address the unmet need in IPF without interfering with its other essential biological functions. As a central mediator across critical fibrotic signaling pathways, pY-STAT3 intrinsically increases myofibroblast proliferation and ECM deposition and extrinsically plays a major role in immune suppression, resulting in the dual cascades associated with IPF. Preclinical studies have shown that TTI-101 not only halts further development of lung

fibrosis, but also has the potential to reverse established fibrosis. Through validated functional animal models of fibrosis-driven diseases, TTI-101 has been shown to inhibit STAT3 activation, both intrinsically and extrinsically. Tvardi also has demonstrated preclinically that TTI-101 impacts both key components of IPF pathology: downregulation of deposition and upregulation of degradation. In addition, clinically, Tvardi has demonstrated oral dosing with TTI-101 lowered levels of pY-STAT3 and was generally well-tolerated. In its Phase 1 clinical trial, eight patients out of ten evaluable patients had elevated baseline pY-STAT3, measured by immunohistochemistry using H-scores, defined as greater than 30 (out of a total score of 300). All eight patients demonstrated a decrease in H-score at the follow-up biopsy (approximately six weeks after initiating treatment), with a median decrease of 55%. Among the three patients who demonstrated a clinical benefit, the median decrease in the H-score was 79%. Tvardi therefore believes TTI-101 is a novel therapeutic candidate that could offer a much-needed treatment option in IPF. Unblinded results from the ongoing Phase 2 REVERT_{IPF} clinical trial are expected in the second half of 2025.

Preclinical Fibrosis Studies Supporting the Development of TTI-101 for IPF

In animal models, TTI-101 downregulated key pro-fibrotic mediators across fibrosis-driven diseases. Specifically, TTI-101 demonstrated dose-dependent decreases in validated targets associated with intrinsic deposition as well as extrinsic degradation. Dr. Tweardy and his collaborators at BCM have evaluated TTI-101 across various established mouse models of fibrosis and observed biologically relevant changes supporting the clinical development of TTI-101.

	Observations of TTI-101 Administration
BLM-induced IPF	• Observed histologic reduction in lung fibrosis, quantified using Ashcroft score and Masson's trichrome from murine lung tissues, and increased BLM-induced decline in lung function, measured by percent or SO_2
	• Targeted multiple pathogenic steps as evidenced by decreased BLM-induced expression levels of validated biomarkers for deposition; increased BLM-reduced expression levels validated biomarkers for degradation as measured by transcripts from isolated RNA and relative real time polymerase reaction (RT-PCR)
	 Observed accumulation of TTI-101 concentration in lung in comparison to plasma concentration measured by LC/MS/MS
	• Reduced levels of pY-STAT3 in lung tissue
GEM (Tsk-1) and BLM- induced skin fibrosis	• Observed a reduction in BLM-induced expression of validated biomarkers for fibrosis, including Col1, TGF- β and IL-6 as measured as measured by transcripts from isolated RNA and relative RT-PCR
	 Reduced levels of pY-STAT3 in skin tissue as measured by Western blot bands quantified by Image J analysis
	• Decreased skin thickness, a measure of fibrosis (p≤0.05 Tks-1 vs. TTI-101), measured by histological examination of skin sections stained with H&E and Masson's trichome
NASH-induced HCC	• Reduced elevated hepatic enzymes and microsteatosis, or abnormal liver fat accumulation, reduced hepatic fibrosis, measured by Masson's trichrome staining and reduced tumor growth by comparing the average tumor volume determined by MRI
	GEM (Tsk-1) and BLM- induced skin fibrosis

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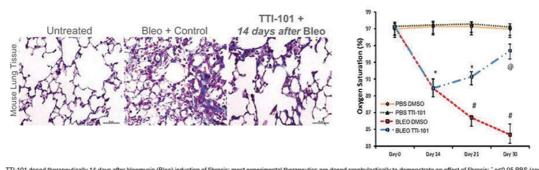
driven Disease	Mouse Models	Observations of TTI-101 Administration		
	Humanized mice + patient derived HCC xenografts	• Reduced tumor size with monotherapy, as measured by tumor weight		
		• Observed additive effect in reducing tumor size, as measured by tumor weight, with TTI-101 in combination with HCC standard of care therapies		

GEM: genetically engineered mouse

Observed Reduction of Fibrotic Lung Tissue and Improved Lung Function with TTI-101 in a Bleomycin-Induced IPF Mouse Model

Dr. Tweardy and his collaborators at BCM demonstrated that administration of TTI-101 resulted in downregulation of targets associated with fibrosis, attenuation of fibrosis and recovery of lung function as measured by arterial oxygen saturation levels (SO₂). In this preclinical study, TTI-101 was dosed 14 days after induction of fibrosis with BLM. Wild-type mice exposed to BLM displayed characteristic increases in ECM deposition and subsequent administration of TTI-101 significantly decreased all established fibrotic endpoints assessed in the model, including COL1A1, α -smooth muscle actin (α -SMA), hypoxia-inducible factor-1 α (HIF-1 α), and plasminogen activator inhibitor-1 (PAI-1) (p \leq 0.05). Administration of TTI-101 in mice also resulted in statistically significant increases in SO₂ levels (p \leq 0.05), which returned to near normal levels, as compared to vehicle, where SO₂ levels continued to decline in untreated mice. p = "p-value," the conventional method for determining the statistical significance of a result, which represents the probability that random chance caused the result (e.g., a p-value = 0.01 means that there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant.

Reduction of Lung Fibrosis and Statistically Significant Improvement of Oxygen Saturation Observed with TTI-101



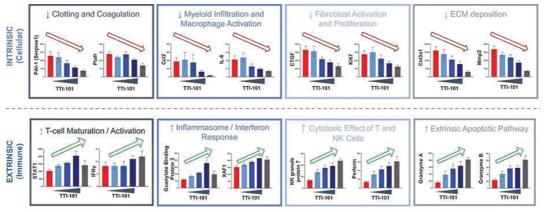
TTI-101 dosed therapeutically 14 days after bleomycin (Bleo) induction of fibrosis; most experimental therapeutics are dosed prophylactically to demonstrate an effect of fibrosis; "p<0.05 PBS (control) DMSO (vehicle) or TTI-101 vs BLEO DMSO or TTI-101; "p<0.05 BLEO TTI-101 and PBS BLEO or TTI-101; "p<0.05 BLEO TTI-101; "p<0.05 BLEO DMSO or TTI-101;" p>0.05 BLEO DMSO or TTI-101; "p<0.05 BLEO TTI-101;" p>0.05 BLEO DMSO or TTI-101;" p>0.05 BLEO DMSO or TTI-101;" p>0.05 BLEO TTI-101;" p>0.05 BLEO TTI-101 vs BLEO DMSO or TTI-101;" p>0.05 BLEO TTI-10

TTI-101 Targeted Multiple Pathogenic Steps of IPF in a BLM-Induced IPF Mouse Model

Tvardi conducted a dose-range-finding, PK and PD preclinical study of TTI-101 in the BLM-induced IPF model to understand the therapeutic impact on reducing the severity of fibrosis and inflammation in relationship to TTI-101's PK and PD profile in the United States. TTI-101 was administered nine days after induction of BLM-induced fibrosis, in human equivalent doses (HED), of 200, 400 and 800 mg/day. Biomarkers to identify the mechanism of action, drug exposure, pY-STAT3 levels and clinical outcomes (fibrosis and SO₂) were evaluated.

Tvardi observed dose-dependent decreases in validated biomarkers associated with myofibroblast proliferation and ECM deposition downstream of intrinsic STAT3 signaling, as measured in florescence units of gene expression by RT-PCR, BLM + placebo vs BLM + either 12.5, 25 or 50mg/kg TTI-101. Specifically,

Tvardi demonstrated significant decreases in biomarkers associated with clotting and coagulation (PAI1 and Ptafr), myeloid infiltration and macrophage activation (Ccl2 and IL-6), fibroblast activation and proliferation (Ccl2 and IL-6) and ECM deposition (Ccl2 and IL-6) with increased doses of TTI-101 (p<0.05 for trend). In addition, Tvardi demonstrated dose-dependent increases in validated biomarkers associated with increased degradation downstream of extrinsic STAT3 signaling. Specifically, Tvardi demonstrated significant increases in biomarkers associated with T-cell activation (STAT1 and IFN γ), interferon responses (GBP3 and XAF1), cytotoxic T- and NK cells (NK GP7 and Perforin) and apoptosis-inducing factors (Granzyme A and B) with increased doses of TTI-101 (p<0.05 for trend).



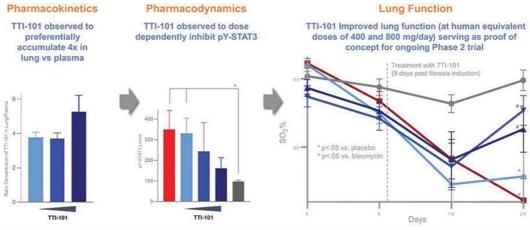
TTI-101's Impact on Both Extrinsic and Intrinsic STAT3 Canonical Functions Associated with IPF

Bleomycin-induced IPF mouse model — No Bleomycin + Bleomycin + Placebo 🛥 Bleomycin + 50 mg/kg TTI-101 — Bleomycin + 25 mg/kg TTI-101 — Bleomycin + 12.5 mg/kg TTI-101 p<0.05

These findings translated into a dose-dependent relationship between TTI-101 dose and observed effects:

- Pharmacokinetics Tvardi observed TTI-101 concentration in mouse lungs accumulated in the lung four times as much as compared to its accumulation in the plasma as measured by LC/MS/MS (50mg/kg: 8868 vs 1672; 25mg/kg: 8927 vs 2348; 12.5mg/kg: 7407 vs 1995). Administration of TTI-101 in a non-disease mouse model did not accumulate in the lung.
- Pharmacodynamics Dose-dependent decrease of pY-STAT3 observed: the higher the dose of TTI-101 administered, the lower the levels of activated STAT3.
- Biological activity At the higher two doses of 25 mg/kg and 50 mg/kg, TTI-101 demonstrated statistically significant improvement in lung function as compared to treatment with placebo (50mg/kg: 91.3; 25mg/kg: 92.7; 12.5mg/kg: 87.9 versus 94.9) (p<0.05) or with BLM alone (86.1) (p<0.05) as measured by SO₂, where mice continued to experience loss of lung function.





TTI-101's Demonstrated Dose-Dependent PK exposure, PD and Improved Lung Function

Sleomycin-induced IPF mouse model — No Bleomycin - Bleomycin + Placebo 🖚 Bleomycin + 50 mg/kg TTI-101 — Bleomycin + 25 mg/kg TTI-101 — Bleomycin + 12.5 mg/kg TTI-101 N=10 per arm

Tvardi believes its findings further support TTI-101 as a therapeutic product candidate for IPF as it was able to impact multiple mechanisms associated with the critical components of deposition and degradation in the pathogenesis of IPF.

Clinical Development of TTI-101 for IPF

Phase 1 TTI-101 Healthy Volunteer Drug-Drug Interaction Clinical Trial

Prior to the initiation of Tvardi's ongoing Phase 2 clinical trial of TTI-101 in IPF, Tvardi completed a Phase 1 healthy volunteer clinical trial in the United States to determine the safety, tolerability and PK potential of a drug-drug interaction with IPF standard of care therapies (nintedanib and pirfenidone). The clinical trial enrolled 41 healthy volunteers, all of whom received 1,200 mg/day of TTI-101 in addition to nintedanib or pirfenidone.

No severe adverse events (SAEs), were reported in this clinical trial. The most frequent treatmentemergent adverse events (TEAEs), were predominantly mild in severity and resolved on study with no change in therapy. One subject withdrew early due to a severe non-serious adverse event of pneumonia, which was deemed by the clinical trial investigator to be possibly related to TTI-101.

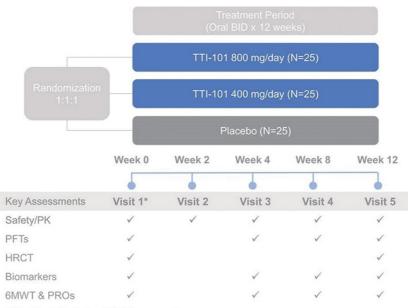
When comparing the drug-drug interactions between the two evaluated standard of care therapies when concurrently administered with TTI-101, optimal exposures were observed with nintedanib. Based on the findings of this healthy volunteer DDI clinical trial, Tvardi chose nintedanib as the standard of care in its ongoing Phase 2 clinical trial.

Tvardi's Ongoing REVERT_{IPF} Phase 2 Clinical Trial of TTI-101 in Patients suffering from IPF

Tvardi is currently enrolling a Phase 2, multicenter, randomized, double-blind, placebo-controlled clinical trial of TTI-101 to evaluate its safety, tolerability, PK and preliminary efficacy in patients suffering from IPF. Approximately 75 patients are randomly assigned (1:1:1) to receive oral TTI-101 400 mg/ day, TTI-101 800 mg/day or placebo for 12 weeks as monotherapy or in addition to SoC, nintedanib. In addition to safety and PK endpoints, Tvardi plans to evaluate established Phase 3 efficacy endpoints including pulmonary function tests (PFTs), providing measurements for FVC and diffusing capacity of the lung for carbon monoxide (DLCO), six-minute walk test (6MWT), and imaging, including Quantitative Lung Fibrosis High Resolution CT (HRCT). Additionally, Tvardi will be evaluating validated biomarkers and patient reported outcomes (PROs). The clinical trial is being conducted in 26 sites across the United States and is enrolling patients with mild and moderate IPF who have been on a stable dose of nintedanib or are not on anti-fibrotic therapy.



REVERT_{IPF} Phase 2 Clinical Trial of TTI-101 Evaluating Safety, PK, Biomarkers and Preliminary Efficacy including FVC in Patients suffering from IPF



BID: twice daily dosing; *Visit 1 or screening

The dosing regimen of this clinical trial was informed by Tvardi's learnings from its concurrently enrolling Phase 1b/2 clinical trial in HCC, where Tvardi explored escalating dosages of TTI-101 up to 1200 mg/day and determined 800 mg/day as the recommended monotherapy Phase 2 dose (RP2D). Based upon the HCC RP2D determination as well as other early data, Tvardi requested that the Safety Monitoring Committee of the Phase 2 clinical trial in IPF convene to consider discontinuation of enrollment to 1200 mg/day arm. In July 2024, an independent safety monitoring committee (SMC), after reviewing unblinded data, agreed with Tvardi's recommendation to discontinue enrollment to the 1200 mg/day arm. In addition, the SMC conducted an unblinded risk-benefit analysis of the remaining arms of the clinical trial, and recommended that Tvardi continue enrolling to the 400 mg/day, 800 mg/day and placebo arms of the clinical trial.

Blinded, Preliminary Interim Data from Ongoing Phase 2 Clinical Trial

On September 30, 2024, the SMC completed a follow-up unblinded assessment of AEs, discontinuations, and pulmonary function test data and noted that it did not see any significant safety concerns and recommended continuation of the clinical trial without modification. Tvardi conducted a preliminary review of blinded data assessed by the SMC, which includes preliminary safety data of 45 patients and preliminary data for 38 efficacy evaluable patients defined as patients with acceptable baseline and at least one on-treatment pulmonary function test. At the time of analysis, the absolute FVCs comparing percent change from baseline to last visit on treatment were available for the following timepoints: 12 weeks (n=19); 8 weeks (n=9); 4 weeks (n=10). The purpose of this blinded data review was to enable an assessment of the overall management and conduct of the clinical trial, without unblinding any individual patient data.

The preliminary blinded data indicated all TEAEs were grade 3 or below, and the most commonly reported TEAE reported to date was diarrhea.

Tvardi reviewed the absolute percentage change in FVC from baseline to last on-treatment acceptable pulmonary function test across all patients on a blinded and pooled basis. Decline in FVC, used to measure percentage of preserved lung function, is the main indicator of disease progression in IPF. Tvardi observed that approximately 39% of patients administered with 400 mg/day dose of TTI-101, 800 mg/day dose of TTI-101 or placebo showed a drop in FVC levels from baseline, defined as <-1% change from

baseline FVC, while 34% showed positive change in FVC levels from baseline, defined as >1% change from baseline FVC and 26% showed stable FVC levels from baseline, defined as -1% to 1% change from baseline FVC. Due to the blinded nature of the TTI-101 Phase 2 clinical trial, Tvardi currently does not know if participants receiving TTI-101 experienced any change in FVC levels from baseline, or if the changes, if any, differed from participants receiving placebo. In addition, the clinical trial is ongoing, and Tvardi will not know whether treatment with TTI-101 will result in a change in FVC levels in a clinically meaningful manner until all clinical trials Tvardi intends to complete have been conducted. The final unblinded analysis for TTI-101 dose levels versus the matching placebo will be conducted using a mixed effect model repeated measure model with mean change from baseline as the response variable. Due to the preliminary and blinded nature of the data, this interim data set was not subject to the standard quality control measures typically associated with final clinical trial results. For example, the data that is available at the conclusion of a clinical trial would be unblinded following a data cleansing review, source verification of data using documents from the local clinical trial sites and other quality control measures to ensure the highest level of accuracy and fidelity possible. In contrast, the blinded data used for its preliminary reviews did not undergo this process and is therefore highly preliminary and not yet validated.

Hepatocellular Carcinoma

Background on HCC

Hepatocellular carcinoma (HCC), is the third-leading cause of cancer-related mortality globally and in the United States. Furthermore, HCC incidence and mortality rates have been increasing for decades. According to the World Health Organization, mortality in the United States was approximately 31,000 in 2022. There remains a high unmet need in HCC given a two-year survival rate less than 50% and a five-year survival rate of only 10% in the U.S. The majority of patients diagnosed with HCC present with advanced disease and have an estimated survival time of six to 20 months following diagnosis.

More than 90% of HCC cases arise in the setting of hepatic injury and inflammation, which involve production of several cytokines, notably hepatocyte growth factor and IL-6, which activate STAT3 to drive further injury, inflammation, fibrosis and proliferation. In addition, pY-STAT3 is a major contributor to immune resistance in HCC through its actions that promote the development and function of several immunosuppressive cells found within the tumor microenvironment, including myeloid-derived suppressor cells (MDSC). MDSCs have been demonstrated to impair the anticancer activity of immune-checkpoint inhibitor (ICI), therapies, and therefore, Tvardi believes that a drug inhibiting STAT3 has the potential to improve responsiveness to ICI therapy.

Market Opportunity in HCC and Limitations of Existing Treatments

Tvardi believes that HCC represents a large commercial opportunity. In 2024, an estimated 42,000 new cases of liver cancer will be diagnosed in the United States. In 2022, the incidence was 850,000 cases worldwide, approximately a third of whom are treated with systemic therapies. The first-line standard of care treatment for HCC are ICI combination therapies and second-line treatments primarily consist of anti-angiogenic therapies. Currently there are no approved third-line treatments. None of the existing approved therapies for HCC target STAT3.

Despite the recent approval and use of ICIs, current standard of care therapies remain suboptimal for the treatment of HCC. In Roche's IMBrave150 clinical trial, the combination of atezolizumab, an anti-PD-L1 antibody, and bevacizumab, an anti-vascular endothelial growth factor (anti-VEGF), antibody, the current first-line standard of care, resulted in an overall response rate (ORR), of 27% with a median duration of 18.1 months. Second-line therapies consist of anti-angiogenic therapies, such as tyrosine kinase inhibitors and anti-VEGF therapies, for patients who progress on first-line combination ICI therapy, with modest expected clinical benefit.

Approved treatments for advanced HCC can prolong survival in some patients, but most patients do not respond to treatment. Furthermore, as a result of the significant toxicities associated with atezolizumab + bevacizumab standard of care therapy, over 40% of patients experienced treatment interruptions in registrational studies. Similarly, second-line therapies have high rates of discontinuations due to associated

severe adverse events. The limited efficacy across a broad patient population, coupled with the advanced stage of disease upon diagnosis, emphasizes the ongoing high medical need for more effective therapies in HCC.

Tvardi's Solution: TTI-101 for HCC

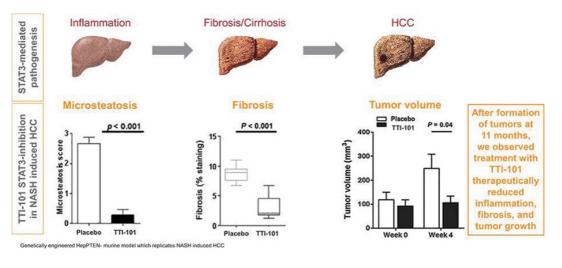
TTI-101 is designed to deliver therapeutic benefit as monotherapy and in combination with existing approved agents for the treatment of HCC. STAT3 has been shown to be activated in 89% to 100% of patients with HCC samples and correlate closely with tumor vascularity and aggressiveness, and its expression is significantly associated with poor overall survival. The pathogenesis of HCC is mediated by pY-STAT3 through intrinsically increasing tumor cells proliferation and extrinsically playing a major role in immune suppression. Tvardi believes TTI-101 is a novel therapeutic candidate that could offer a much-needed treatment option in HCC.

Preclinical Studies in HCC

Preclinical studies in genetically engineered mouse models replicating NASH-induced HCC demonstrated TTI-101's potential to reverse inflammation and fibrosis and inhibit tumor growth. In addition, as further described below, HCC models demonstrated the synergistic effect of double and triple combination therapy with inhibition of multiple pathways in HCC, ultimately leading to reduced tumor size, supporting further exploration of TTI-101 in combination with ICIs and anti-VEGF therapies.

TTI-101 Reversed Multiple Pathogenic Steps of Liver Cancer in NASH-induced Mouse Model

Dr. Tweardy and his collaborators at the University of Texas MD Anderson Cancer Center, conducted a preclinical study where TTI-101 was tested in a NASH-induced HCC mouse model. The model replicated the human pathogenesis over a 11-month period, where the livers in mice over that time period developed inflammation and fibrosis and formed tumors. Thereafter, mice were administered TTI-101 or placebo once a day for four weeks. TTI-101 statistically significantly impacted critical STAT3-mediated steps of pathogenesis; specifically, TTI-101 demonstrated statistically significant changes in (1) microsteatosis score (abnormal liver fat accumulation) that was 89% lower in animals treated with TTI-101 versus placebo treated animals (p<0.001), (2) fibrosis, measured by histologic staining, that was 65% lower in animals treated with TTI-101 versus placebo treated animals (p<0.001) and (3) tumor growth, measured by comparing the average tumor volume determined by MRI, that was 57% lower in animals treated with TTI-101 versus placebo treated animals (p=0.04).



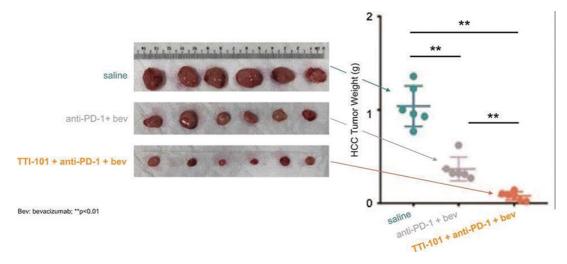
TTI-101 in NASH-induced HCC Mouse Model

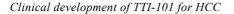
TTI-101 Showed Activity that was Enhanced in Combination with Standard of Care HCC Therapies in Humanized Mouse Models

An independent academic lab in Singapore conducted a preclinical study to evaluate the activity of TTI-101 where mice with humanized immune systems were implanted with human-derived HCC cells, a HCC-PDX model. HCC-PDX mice were randomized into different groups, including TTI-101 monotherapy and in combination therapy with a PD-1 inhibitor and/or anti-VEGF.

TTI-101 showed enhanced activity in combination with bevacizumab and/or an anti-PD-1, an ICI, therapy for HCC. In the HCC-PDX model, TTI-101 showed clinically meaningful benefit as monotherapy compared to placebo as measured by tumor weight (p<0.01), which was further enhanced when combined with either anti-PD-1 or bevacizumab. After four weeks of treatment, the triple combination of TTI-101 with anti-PD-1 and bevacizumab (n=6) demonstrated markedly larger reduction in tumor weight compared to treatment with saline (n=6), TTI-101 with bevacizumab (n=6), anti-PD-1 with bevacizumab (n=6) or TTI-101 with anti-PD-1 (n=6) (p<0.01). In addition, the results showed the anti-tumor effect of triple combination therapy was inhibited in the absence of human CD8+ or CD14+ immune cells confirming that these two immune cell types were critical in the triple combination. Taken together, the results showed that triple combination therapy using TTI-101, anti-PD-1 and bevacizumab significantly increased the anti-tumor response in vivo compared with monotherapy or dual therapy.







Phase 1 Clinical Trial Demonstrated Clinical Benefit with TTI-101 Monotherapy in Advanced Solid Tumors

Tvardi completed a Phase 1, multicenter, open-label, dose-escalation/dose-expansion clinical trial in the United States in patients with advanced solid tumors (n=64), enriched for patients with HCC (n=17) to determine the maximum tolerated dose (MTD), safety, PK, PD and clinical outcomes of TTI-101. TTI-101 was observed to be generally well tolerated. Over the conduct of the trial, multiple formulations were investigated per protocol, which decreased pill burden. The last formulation was observed to be better tolerated than the previous two and was therefore selected for further development. The results summarized below represent pooled data from all evaluated formulations. No dose limiting toxicities or fatal treatment-related adverse events (fatal TRAEs), were observed. The most common TRAE was diarrhea, mostly grade 1 or 2.

TTI-101 showed linear PK from dose level 1-3 plateauing at dose level 3 which was selected as the RP2D. The exposures of patients treated with TTI-101 at its trough exceeded the expected concentration

required for 90% inhibition of STAT3-dependent growth, or the IC90. PD values were available from ten patients who agreed to pre- and on-treatment paired tumor biopsies. Eight of these patients had elevated pre-treatment pY-STAT3. Each of these patients demonstrated a decrease in their pY-STAT3 levels at the follow-up biopsy (approximately six weeks after initiating treatment), with a median decrease of 55% in pY-STAT3 levels. Among the three patients who demonstrated a clinical benefit, the median decrease was 79% in pY-STAT3 levels.

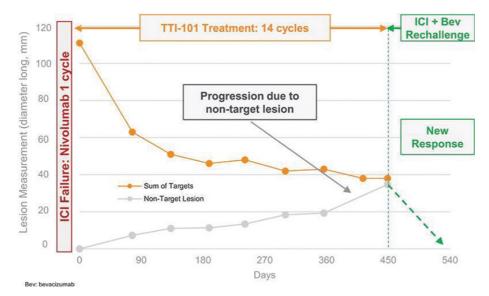
The biologic effect of TTI-101 monotherapy in patients with advanced diseases, who had previously been treated with a median of over three prior systemic therapies and evaluable for tumor response is outlined in the table below. Overall, 41 patients were evaluable for response, and Tvardi observed a disease control rate of 54%, as measured by RECIST v1.1, among all tumor types, including confirmed partial responses in HCC, ovarian and gastric tumor types. Among the 17 patients with HCC, Tvardi observed a disease control rate of 53%, as measured by RECIST v1.1.

	Patients with HCC (N=17) n (%)	All Patients with Advanced Solid Tumors (N=41) n (%)
Confirmed partial response ⁽¹⁾	3 (18)	5 (12)*
Stable disease ⁽²⁾	6 (35)	17 (41)
Progressive disease ⁽³⁾	8 (47)	19 (46)
Disease Control Rate ⁽⁴⁾	53%	54%
Median Number of Therapies	2	3.5

Evaluable patients included patients with a follow-up on-study tumor assessment at least 42 days following cycle 1, day 1. *Two non-HCC patients demonstrated a confirmed partial response: one had ovarian cancer, the second had gastric cancer.

- (1) Confirmed partial response (cPR), means at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- (2) Stable disease means neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease, taking as reference the smallest sum diameters while on study.
- (3) Progressive disease means at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. Note that the appearance of one or more new lesions is also considered progression.
- (4) The disease control rate was calculated as the proportion of participants with a complete response, cPR, or SD, as the best overall response, per RECIST v1.1.

All patients with HCC who demonstrated partial responses were refractory to prior immunotherapy and anti-angiogenic agents. In addition to observing biologic effect of TTI-101 monotherapy in advanced HCC tumors, Tvardi observed clinical proof of concept, in a single patient, supporting the potential of TTI-101 monotherapy to overcome ICI resistance. The patient previously failed treatment with lenvatinib, and subsequently nivolumab, before initiating treatment with TTI-101. Their best response was a 66% reduction in the sum of overall RECIST targets. They sustained the partial response for 14 months, after which time they demonstrated disease progression and discontinued treatment with TTI-101. They were subsequently treated with atezolizumab + bevacizumab within 30 days of discontinuation of TTI-101, and after two months of treatment demonstrated a new response, with decreases in target and nontarget lesions, suggesting a potential role for TTI-101 in resensitizing the tumor to ICI therapy. Tvardi believes resensitizing patients to ICI therapy has the potential to further improve survival and quality of life for patients with HCC.



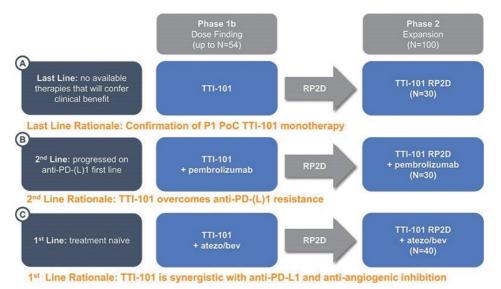
Tumor Trajectories for Participant on TTI-101 Treatment Demonstrated Potential Resensitization to ICI Therapy

Based on Tvardi's data from the Phase 1 clinical trial in advanced solid tumors, it initiated a Phase 1b/2 clinical trial designed to evaluate TTI-101 across multiple lines of therapy as monotherapy and combination therapy.

Tvardi's Ongoing REVERT_{LIVER CANCER} Phase 1b/2 Clinical Trial of TTI-101 as Monotherapy and in Combination in Patients with HCC

The completed Phase 1 clinical trial was a first in human clinical trial with the primary objectives of evaluating safety and efficacy of TTI-101 as monotherapy in a variety of advanced, or metastatic cancers (including HCC). Tvardi has initiated a multicenter, open-label Phase 1b/2 clinical trial to further investigate the safety and efficacy of TTI-101 in patients with locally advanced or metastatic, and unresectable HCC, both as monotherapy and in combination with standard of care therapy. Eligible patients are treated in one of three preselected treatment arms:

- Cohort A: TTI-101 as a single agent in participants who have recently demonstrated objective progression on up to three prior lines of systemic drug therapy.
- Cohort B: TTI-101 in combination with pembrolizumab in participants who have recently demonstrated objective progression following at least three months of first-line anti-PD-1 or anti-PD-L1 monotherapy or combination therapy.
- Cohort C: TTI-101 in combination with atezolizumab and bevacizumab in participants who are treatment-naïve.



REVERT_{LIVER CANCER} Phase 1b/2 Clinical Trial Design

NCT05440708

Overall, a total of up to 154 participants in all cohorts and phases of the clinical trial will be enrolled across 21 Tvardi sites. For Phase 1b, a 3+3 dose-escalation design will be used. The primary objectives for the Phase 1b portion are to evaluate the safety and tolerability of TTI-101 as a single agent (Cohort A) and in combination with pembrolizumab (Cohort B) and in combination with atezolizumab + bevacizumab (Cohort C) and to determine the MTD and/or RP2D of TTI-101 as a single agent or in combination with pembrolizumab or atezolizumab + bevacizumab. The secondary objectives are to assess the preliminary efficacy of TTI-101 (ORR using RECIST) as a single agent or in combination with pembrolizumab therapy (Cohort B) and in combination with atezolizumab + bevacizumab therapy (Cohort C) in participants with locally advanced or metastatic, and unresectable HCC, to assess additional efficacy endpoints, to characterize the plasma PK of TTI-101 following oral administration.

For Phase 2, a single-stage design will be used. The co-primary objectives for the Phase 2 portion are to evaluate the safety and tolerability of TTI-101 at the RP2D as a single agent (Cohort A) and in combination with pembrolizumab (Cohort B) and in combination with atezolizumab + bevacizumab (Cohort C) and to assess the preliminary efficacy of TTI-101 at the RP2D as a single agent (Cohort A) and in combination with pembrolizumab (Cohort B) and in combination with atezolizumab + bevacizumab (Cohort C). The secondary objectives are to assess additional efficacy endpoints, to characterize the plasma PK of TTI-101 following oral administration and to determine the PD of TTI-101 following oral administration.

The data from each of the cohorts will be used to inform future clinical development of TTI-101 in patients with locally advanced or metastatic, and unresectable HCC.

As of August 2024, Tvardi has completed enrollment in the Phase 1b portion of the clinical trial for Cohorts A and B, determined the RP2D and are currently enrolling patients in the Phase 2 portion of the clinical trial. It continues to enroll in Cohort C of the Phase 1b portion of the clinical trial. In preliminary safety data, Tvardi has observed similar incidence, grade and TEAEs in Cohort A treated with TTI-101 monotherapy as observed in the Phase 1 clinical trial, with diarrhea being the most commonly reported TEAE, mostly grade 1 or 2. Early safety data from the combination arms (TTI-101 + pembrolizumab (Cohort B) or TTI-101 + atezolizumab + bevacizumab (Cohort C)) of the Phase 1b portion of the clinical trial in HCC revealed a higher than expected incidence of pulmonary-related TEAEs, which are known side effects when treated with SoC. Based upon this information, and after consultations with thought leaders and investigators, the protocol was modified to explore lower dosages and intermittent schedules of TTI-101 in combination with pembrolizumab (Cohort B) or atezolizumab + bevacizumab + bevacizumab (Cohort C).

Preliminary efficacy is available for all three cohorts. In Cohort A, of 21 efficacy evaluable patients, 14 patients achieved a best response of SD. This disease control rate of 67% is comparable to the disease control rate (53%) observed in the HCC cohort of the Phase 1 trial of TTI-101 monotherapy. In Cohort B, four of eight patients achieved SD. Lastly, in Cohort C, out of 12 enrolled patients, four achieved a cPR with an overall disease control rate of 93%.

Based on Tvardi's Phase 1 data and this clinical trial design, TTI-101 received Fast Track designation from the FDA. Fast Track designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TTI-101 will receive marketing approval.

Tvardi's TTI-109 Product Candidate

Tvardi's second product candidate, TTI-109, is an oral, small-molecule, prodrug of, and mechanistically identical to, TTI-101. TTI-109 itself does not inhibit STAT3, but rapidly converts to TTI-101 in the blood. TTI-109 is designed to enhance Tvardi's ability to target STAT3 as a more efficient delivery vehicle for TTI-101 with the potential to improve tolerability.

Prodrugs generated by attaching a phosphate moiety are relatively common and several have been approved by the FDA. The addition of a phosphate group improves the druggability of the active compounds, and the mechanism of action of the prodrugs remains identical to that of their parent drugs. Similarly, for TTI-109, the prodrug approach allows Tvardi to improve the drug product formulation with improved drug solubility.

In Tvardi's completed in vitro preclinical studies conducted in France, China and the United States, Tvardi has observed no unexpected results compared to TTI-101. In the completed 28-day IND-enabling toxicology studies conducted in China, in rats and monkeys, TTI-109 has been observed to result in equivalent drug exposure as compared to TTI-101, with no toxicity observed.

In recent discussions with the FDA in a pre-IND filing, which included the preclinical data with TTI-109 and available clinical safety data with the active moiety, TTI-101, the package was sufficient to support proceeding with a clinical trial of TTI-109 in oncology. To maximize the potential of TTI-109 in fibrosisdriven diseases, Tvardi is planning additional preclinical studies to be conducted in China and a first-inhuman IND submission for TTI-109 in the first half of 2025.

Other Potential Development Plans for Tvardi's STAT3 Platform

Tvardi believes its STAT3 inhibitors have broad applicability across multiple fibrosis-driven diseases including systemic sclerosis (SSc). SSc is a chronic autoimmune disease characterized by widespread progressive fibrosis of the skin and internal organs including the lung, heart and kidneys. The prevalence of SSc in the United States is approximately 100,000 and globally is 2.5 million. SSc is associated with life-threatening complications and a poor prognosis, with no FDA-approved disease modifying treatment. Similar to other fibrosis-driven diseases, pY-STAT3 plays a critical role in the intrinsic and extrinsic pro-fibrotic cascades. STAT3 inhibition in SSc has strong therapeutic rationale due to its central role in fibrosis, immune dysregulation and vascular dysfunction. In multiple SSc mouse models, Tvardi's founder demonstrated that Tvardi's STAT3 inhibitor, TTI-101, downregulated validated biomarkers of fibrosis, inhibited levels of pY-STAT3 in skin tissue and reduced skin fibrosis. Inhibiting STAT3 could potentially reduce fibrosis, control immune-mediated damage and improve vascular health, offering a promising approach for treating this complex and multifaceted disease. Tvardi is dedicated to improving the quality of life for patients with fibrosis-driven diseases by advancing its oral small molecule STAT3 inhibitors to address unmet medical needs, extend life expectancy and enhance overall patient well-being.

License Agreements

First License Agreement with Baylor College of Medicine

In July 2012, Stem Med entered into the BCM First Agreement. StemMed assigned the BCM First Agreement to Tvardi in connection with the transfer of all or substantially all of the assets and businesses to which the BCM First Agreement relates in January 2018. Under the BCM First Agreement, Tvardi obtained

an exclusive, worldwide, sublicensable license under BCM's rights to certain patents in oncology and certain non-oncology indications, which are referred to herein as the BCM Patent Rights, together with certain cell lines, biological materials, compounds, know-how and technologies, collectively referred to as the BCM Technology. Under the license, Tvardi is permitted to make, have made, use, market, sell, offer to sell, lease and import products, processes or services that incorporate, utilize or are made with the use of the BCM Patent Rights or BCM Technology, referred to as BCM1 Licensed Products, in all fields of use.

Tvardi's license is subject to specified retained rights, consisting of: BCM's rights to grant a nonexclusive license under the BCM Patent Rights and BCM Technology to other academic or research institutions for non-commercial research purposes, and, if required by law, to grant a non-exclusive license to the United States government or to a foreign state pursuant to a treaty with the United States; BCM's rights to make or use the BCM Patent Rights and BCM Technology for non-commercial research, patient care and educational purposes; the rights of academic institutions, research institutions and certain BCM employees, if at academic or research institutions, to make or use the BCM Patent Rights and BCM Technology for non-commercial research purposes; and additional rights reserved by the government of the United States.

Tvardi is obligated to use reasonable efforts to introduce BCM1 Licensed Products to the commercial market as soon as practicable. Tvardi is obligated to achieve specified development milestones by specified timelines or to make payments to BCM if Tvardi does not achieve certain diligence milestones, and to produce, market and support the BCM1 Licensed Products with at least the same diligence Tvardi employs for comparable products and services. In consideration for the license rights, Tvardi paid BCM a license fee of \$75,000. Tvardi paid an annual maintenance fee of \$30,000 each year on the anniversary of the agreement until a specified anniversary before it increased to \$50,000 each year on the anniversary of the agreement and are required to pay such annual maintenance fee until the introduction of a BCM1 Licensed Product. Tvardi is obligated to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM1 Licensed Products during the term, which expire, on a country-by-country basis, on the later of the date of expiration of the last-to-expire of the BCM Patent Rights, or, if no BCM Patent Rights issued in such country, the tenth anniversary of the date of first commercial sale of the BCM1 Licensed Product in such country. Tvardi currently expects the BCM Patent Rights to expire April 18, 2039. Upon the initiation of the Phase 2 clinical trials for two BCM1 Licensed Products, Tvardi paid BCM development milestone payments of \$250,000 in the aggregate. Upon the achievement of additional specified development and regulatory milestones, Tvardi is obligated to pay BCM one-time milestone payments of up to \$2,200,000 in the aggregate for the first BCM1 Licensed Product in an oncology indication and the first BCM1 Licensed Product in a non-oncology indication to achieve such milestones. Furthermore, in connection with the initiation of the Phase 3 clinical trial, Tvardi would expect to incur approximately \$400,000 of oncologyrelated costs and approximately \$300,000 of non-oncology-related costs. Tvardi is additionally obligated to pay BCM a tiered low-double-digit percentage of sublicensing revenue obtained in connection with any sublicense granted by Tvardi under the BCM Patent Rights or BCM Technology.

Tvardi may terminate the BCM First Agreement at its convenience following a specified notice period upon advance written notice to BCM. The BCM First Agreement may also be terminated by BCM for Tvardi's default or failure to perform any of terms of the BCM First Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM First Agreement if Tvardi undergoes specified bankruptcy or insolvency events, following the expiration of a specified period. Upon expiration of the term of the BCM First Agreement in a given country, the license grant from BCM to Tvardi will be fully paid and perpetual in such country.

In April 2015, Tvardi entered into a first amendment with BCM to update the schedule of BCM Patent Rights and description of BCM Technology covered by the license and Tvardi paid an additional \$5,000 as consideration. In August 2019, Tvardi entered into a second amendment with BCM which amended its diligence and insurance obligations and further updated the schedule of BCM Patent Rights.

Second License Agreement with Baylor College of Medicine

In June 2015, StemMed entered into a license agreement with BCM, and such agreement, as amended, the BCM Second Agreement. StemMed assigned the BCM Second Agreement to Tvardi in connection with the transfer of all or substantially all of the assets and business to which the BCM Second Agreement relates in February 2018. Under the BCM Second Agreement, Tvardi obtained an exclusive, worldwide,

sublicensable license under certain patents and patent applications co-owned by BCM and the National Institutes of Health (NIH), related to methods and compositions for the use of STAT3 inhibitors in certain conditions like anaphylaxis, which rights it refers to as the Licensed Patent Rights. Under the license, Tvardi is permitted to make, to have made, use, market, sell, offer to sell, lease and import products, processes or services that incorporate, utilize or are made with the use of the Licensed Patent Rights (BCM2 Licensed Products) in all fields of use.

Tvardi's license is subject to specified retained rights, consisting of: BCM's rights to grant a nonexclusive license under the Licensed Patent Rights to other academic or research institutions for noncommercial research purposes, and, if required by law, to grant a non-exclusive license to the United States government or to a foreign state pursuant to a treaty with the United States; BCM's rights to grant a research license to a third party as required by the NIH; BCM's rights to make or use the Licensed Patent Rights for non-commercial research, patient care and educational purposes; the rights of academic institutions, research institutions and the inventors of the Licensed Patent Rights at BCM and NIH, to make or use the Licensed Patent Rights for non-commercial research purposes; and additional rights reserved by the government of the United States.

Tvardi is obligated to use reasonable efforts to introduce BCM2 Licensed Products to the commercial market as soon as practicable. Tvardi is obligated to achieve specified development milestones by specified timelines or to make payments to BCM if it does not achieve certain diligence milestones, and to produce, market and support the BCM2 Licensed Products with at least the same diligence Tvardi employs for comparable products and services.

In consideration for the license rights, Tvardi paid BCM a license execution fee of \$5,000. Tvardi initially paid an annual maintenance fee of \$30,000 each year on the anniversary of the agreement until a specified anniversary before it increased to \$50,000 each year on the anniversary of the agreement. Tvardi is obligated to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM2 Licensed Products during the term, which expires, on a country-by-country basis, on the later of the date of expiration of the last to expire of the Licensed Patent Rights, or, if no Licensed Patent Rights issued in such country, the tenth anniversary of the date of first commercial sale of the BCM2 Licensed Product in such country. Tvardi currently expects the License Patent Rights to expire July 18, 2034. Upon the achievement of specified development and regulatory milestones, Tvardi is obligated to pay BCM one-time milestone payments of up to \$1,225,000 in the aggregate for the first BCM2 Licensed Product to achieve such milestone. Furthermore, in connection with the initiation of the Phase 3 clinical trial, Tvardi would expect to incur approximately \$300,000 in costs. Additionally, Tvardi is obligated to pay BCM a tiered low-double-digit percentage of sublicensing revenue obtained in connection with any sublicense granted by Tvardi under the Licensed Patent Rights.

Tvardi may terminate the BCM Second Agreement at its convenience following a specified notice period upon advance written notice to BCM. The BCM Second Agreement may also be terminated by BCM for Tvardi's default or failure to perform any of terms of the BCM Second Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM Second Agreement if Tvardi undergoes specified bankruptcy or insolvency events, following the expiration of a specified period. The NIH may terminate its license to BCM under specified limited circumstances, including Tvardi's failure to fulfill certain obligations. Upon expiration of the term of the BCM Second Agreement in a given country, the license grant from BCM to Tvardi will be fully paid and perpetual in such country.

The BCM Second Agreement was amended in June 2019 to amend Tvardi's diligence and insurance obligations. Tvardi entered into a second amendment April 2023 to further amend its diligence obligations and to terminate the obligation to pay annual maintenance fees until the first anniversary of the achievement of certain patent milestones and annually thereafter.

Intellectual Property

Tvardi's success depends in large part upon its ability to obtain and maintain its technology and intellectual property. To protect its intellectual property rights, Tvardi primarily relies on patents, trade secret laws, confidentiality procedures and employee disclosure and invention assignment agreements. Tvardi's intellectual property is critical to its business, and it strives to protect it through a variety of

approaches, including by obtaining and maintaining patent protection in various countries for Tvardi's product candidates and other inventions that are important to its business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The time required for development, testing and regulatory review of Tvardi's product candidates limits the commercially useful lifespan of its patents.

The patent positions of companies like Tvardi's are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of patentable claims in the field of pharmaceuticals has emerged, for example, in the United States and in Europe. Changes in the patent laws and rules, either by legislation, judicial decisions or regulatory interpretation may diminish Tvardi's ability to protect its inventions and enforce its intellectual property rights. These changes could affect the scope and value of Tvardi's intellectual property.

Filing, prosecuting, enforcing and defending patents protecting its product candidates in all countries throughout the world would be prohibitively expensive. Tvardi cannot seek patent protection for its product candidates throughout the world. Furthermore, the intellectual property rights it obtains in some countries outside the United States can be less extensive than those obtained in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where Tvardi pursues patent protection, there can be no assurance that any patents will issue with claims that cover Tvardi's product candidates.

Tvardi's ability to stop third parties from infringing any of its patented inventions, either directly or indirectly, will depend in part on its success in obtaining, defending and enforcing patent claims that cover its product candidates. Tvardi cannot be sure that any patents will be granted with respect to any of its pending patent applications or with respect to any patent applications filed by Tvardi in the future. Tvardi cannot be sure that any of its existing patents or any patents that may be granted to Tvardi in the future will be found by a court to be enforceable. Protecting Tvardi's competitive position around its product candidates may involve lawsuits to enforce its patents or other intellectual property, which is expensive and time-consuming, and may ultimately be unsuccessful. Furthermore, Tvardi's issued patents and those that may issue in the future may be challenged, narrowed, circumvented or invalidated, which could limit Tvardi's ability to stop competitors from marketing related product candidates or limit the length of the term of patent protection that Tvardi may have for its product candidates and future product candidates. Tvardi cannot be sure that any of its existing patents or any patents that may be granted to Tvardi in the future will be useful in protecting its commercialized product candidates. The rights granted under any issued patents may not provide Tvardi with complete protection or competitive advantages against competitors with similar but not identical technology or technologies that achieve similar outcomes but with different approaches. For these reasons, Tvardi may have competition for its product candidates.

Tvardi's issued patents and those that may issue in the future do not guarantee Tvardi the right to practice its product candidates. Third parties may have issued patents or be granted patents in the future that could block Tvardi's ability to commercialize its product candidates.

Tvardi relies on trade secrets to protect certain aspects of its product candidates. If Tvardi is unable to protect the confidentiality of its trade secrets, its competitive position could be harmed. Furthermore, reliance on trade secrets does not prevent third parties from independently inventing those aspects of Tvardi's product candidates. While Tvardi takes commercially reasonable steps to ensure that its employees do not use the trade secrets of third parties, third parties may file claims asserting that Tvardi or its employees have misappropriated their trade secret.

For this and other risks related to Tvardi's inventions, please see the section titled "*Risk Factors* — *Risks Related to Tvardi's Intellectual Property.*"

Patent Portfolio

As of September 30, 2024, Tvardi has in-licensed four issued U.S. patents, one pending U.S. nonprovisional patent application and 62 issued foreign patents, including patents issued in Australia, Canada, France, Italy, Germany, Spain and the United Kingdom, all in-licensed from BCM and all related to TTI-101. Tvardi co-owns two issued U.S. patents, two pending U.S. non-provisional patent applications, 29 issued

foreign patents, including patents issued in China, Japan, France, Italy, Germany, Spain and the United Kingdom, and 13 pending foreign patent applications, including patent applications pending in Australia, Canada, China, Europe and Japan, all co-owned with BCM. Tvardi owns four issued U.S. patents, four pending U.S. non-provisional patent applications, two pending U.S. provisional applications, one issued Eurasia patent, 32 foreign patent applications, including patent applications pending in Australia, Canada, China, Europe and Japan, and four pending PCT applications.

The patent portfolios of Tvardi's product candidates as of September 30, 2024, are summarized below.

TTI-101 is protected by twelve patent families.

Four patent families are in-licensed from BCM.

The first patent family in-licensed from BCM relates to methods of using TTI-101 to treat certain specific cancers and pulmonary fibrosis. The first patent family includes one issued U.S. patent expiring on November 13, 2030, and 11 issued foreign patents in Australia, Canada, Denmark, France, Germany, Italy, Netherlands, Norway, Spain, Switzerland and the United Kingdom, all expiring on June 3, 2029.

The second patent family in-licensed from BCM relates to methods of using TTI-101 to treat cachexia, muscle wasting and muscle weakness. This family includes two issued U.S. patents and 15 issued foreign patents in Australia, Canada, France, Germany, Italy, Spain, the United Kingdom and Hong Kong, all expiring on July 18, 2034.

The third patent family in-licensed from BCM relates to methods of using TTI-101 to treat fibrosis, excluding pulmonary fibrosis and myelofibrosis. This family includes one issued U.S. patent and 22 issued foreign patents in Australia, Canada, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and Hong Kong, all expiring on July 18, 2034.

The fourth patent family in-licensed from BCM relates to methods of using TTI-101 to reduce the risk or severity of or prevent allergic reaction. This family includes one pending U.S. patent application and 14 issued foreign patents in Australia, Canada, Belgium, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland, Turkey, United Kingdom and Hong Kong, all expiring on July 18, 2034.

Tvardi co-owns one patent family with BCM. This family is directed to methods of using TTI-101 to treat insulin resistance. This patent family includes one pending U.S. patent application and four pending foreign patent application in Canada, China, Europe and Japan. If issued, the patent applications in this patent family are expected to expire on December 3, 2040.

In addition to the above, TTI-101 is protected by seven patent families owned by Tvardi.

The first patent family Tvardi owns relates to self-emulsifying drug dispersion formulation of TTI-101 and includes three issued U.S. patents and one issued foreign patent in Eurasia, all expiring on January 22, 2041, and three pending foreign patent applications in China, Europe and Hong Kong.

The second patent family Tvardi owns relates to spray-dried dispersion tablets of TTI-101 and includes one pending U.S. patent application and 15 pending patent applications in Argentina, Pakistan, Taiwan, Australia, Brazil, Canada, Eurasia, Europe, India, Israel, Japan, Korea, Mexico, New Zealand and Singapore. If issued, patents in this family are expected to expire on March 1, 2043.

The third patent family Tvardi owns relates to highly pure compositions of TTI-101 and includes one pending U.S. patent application, three pending foreign patent applications in Argentina, Pakistan and Taiwan, and one pending PCT application. If issued, patents in this family are expected to expire on July 18, 2043.

The fourth patent family Tvardi owns relates to methods of treating cancer using a combination of TTI-101 and an immune checkpoint inhibitor such as anti-PD-1 antibody and anti-PD-L1 antibody and includes one pending U.S. patent application and 8 pending foreign patent applications in Australia, Canada, Eurasia, Europe, Japan, Mexico, New Zealand and Singapore. If issued, patents in this family are expected to expire on March 3, 2043.

The fifth patent family Tvardi owns relates to methods of treating non-viral liver cancer with TTI-101 and includes one pending PCT application. If issued, patents in this family are expected to expire on December 11, 2043.

The sixth patent family Tvardi owns relates to methods of treating cancer with certain doses of TTI-101 and includes one pending PCT application. If issued, patents in this family are expected to expire on September 5, 2044.

The seventh patent family Tvardi owns relates to methods of treating cancer with TTI-101 in certain patient populations and includes one pending U.S. provisional patent application. If issued, patents in this family are expected to expire on February 29, 2045.

TTI-109 is protected by three patent families owned by Tvardi.

The first patent family claims the TTI-109 compound and includes one issued U.S. patent expiring on June 9, 2043, one pending U.S. patent application, three pending foreign patent applications in Argentina, Pakistan and Taiwan and one pending PCT application. If issued, patents in this family are expected to expire on June 9, 2043.

The second patent family relates to methods of treating cancer with TTI-109 in certain patient populations and includes one pending U.S. provisional patent application. If issued, patents in this family are expected to expire on February 29, 2045.

The third patent family relates to solid forms of TTI-109 and includes one pending U.S. provisional patent application. If issued, patents in this family are expected to expire on December 2, 2044.

Tvardi cannot predict whether the patent applications it pursues or may license in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide any protection from competitors. Even if its pending patent applications are granted as issued patents, those patents, as well as any patents Tvardi may license in the future from third parties now or in the future, may be challenged, circumvented or invalidated by third parties. Consequently, Tvardi may not obtain or maintain adequate patent protection for any of its programs and product candidates.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which Tvardi files, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. In the United States, the patent term of a patent may be extended by patent term adjustment, which compensates the patent owner for patent office delays. Additionally, in the United States, patents that cover an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug or biologic may be extended and only those claims covering the approved drug or biologic, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in European Member States and other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. In the future, if Tvardi's product candidates receive FDA approval, it expects to apply for patent term extensions where applicable on patents covering those products. Tvardi plans to seek patent term extensions to any of its issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the U.S. Patent and Trademark Office in the United States, will agree with Tvardi's assessment of whether these extensions should be granted, and if granted, the length of these extensions.

Tvardi's intellectual property is critical to its business, and it strives to protect it through a variety of approaches, including by obtaining and maintaining patent protection in various countries for its product candidates and other inventions that are important to its business.

Trademarks

As of September 30, 2024, Tvardi owns the trademark registrations for the company. Trademarks include "TVARDI," which is registered in Australia, China, European Union, Japan, the United Kingdom and the United States, and pending in Canada and Korea.

Trade Secrets and Proprietary Information

In addition to Tvardi's reliance on patent protection for its inventions, it also relies on trade secrets, know-how, confidentiality agreements and continuing technological innovation to develop and maintain Tvardi's competitive position. Although Tvardi takes steps to protect its proprietary information and trade secrets, including through contractual means with its employees, advisors and consultants, these agreements may be breached, and Tvardi may not have adequate remedies for any breach. In addition, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to Tvardi's trade secrets or disclose its technology. As a result, Tvardi may not be able to meaningfully protect its trade secrets. It is Tvardi's policy to require its employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with Tvardi. These agreements provide that all confidential information concerning its business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with Tvardi is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived of by the individual during the course of employment, and which relate to or are reasonably capable or being used in its current or planned business or research and development are Tvardi's exclusive property. In addition, Tvardi takes other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of its technology by third parties. However, such agreements and policies may be breached, and Tvardi may not have adequate remedies for such breaches. For more information regarding the risks related to Tvardi's intellectual property, see the section titled "Risk Factors — Risks Related to Tvardi's Intellectual Property."

Sales and Marketing

Tvardi currently has no sales, marketing or commercialization capabilities and has no experience as a company performing such activities. However, it intends to build the necessary capabilities and infrastructure over time following the advancement of its product candidates through clinical development. Clinical data, the size of the opportunity and the size of the commercial infrastructure required will influence its commercialization plans and decision making.

Commercialization

None of Tvardi's product candidates have been approved for sale. If and when its product candidates receive marketing approval, it intends to commercialize them on its own, or jointly with a partner, in the United States and potentially in other geographies. Tvardi will continually evaluate the economics of commercializing its product candidates versus other strategic commercialization arrangements.

Manufacturing

Tvardi does not own or operate, and currently has no plans to establish, any manufacturing facilities. Tvardi has engaged, and expects to continue to rely on, well-established third-party Contract Development and Manufacturing Organizations (CDMOs), to supply its product candidates for use in its preclinical studies and clinical trials. Should any of these CDMOs become unavailable to Tvardi for any reason, it believes that there are a number of potential replacements, although Tvardi may incur some delay in identifying and qualifying such replacements.

Additionally, it intends to rely on third-party CDMOs for commercial manufacturing, if its product candidates receive marketing approval. As its lead product candidates advance through development, it expects to enter into longer-term commercial supply agreements to fulfill and secure its production needs. Additionally, to adequately meet its projected commercial manufacturing needs, its CDMOs will need to scale-up production, or it will need to secure additional suppliers. Processes for producing drug substances

and drug product for commercial supply are currently being developed, with the goal of achieving reliable, reproducible and cost-effective production.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical and diagnostic products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of drug products.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the FDCA), and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve a pending new drug application (NDA), withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, debarment, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on Tvardi. FDA approval is required before a drug may be marketed in the United States and drug candidates are also subject to other federal, state and local statutes and regulations.

The process required by the FDA before drug candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory and animal tests, which must be conducted in accordance with applicable regulations, including good laboratory practices and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin and must be updated annually;
- approval by an independent institutional review board (IRB) or ethics committee for each clinical site or centrally before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy
 of the proposed drug candidate for its intended use, performed in accordance with Good Clinical
 Practices (GCPs) requirements to establish the safety and efficacy of the product candidate for each
 proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical studies that include substantial evidence of safety and efficacy of the drug from analytical studies and from results of nonclinical testing and clinical trials and payment of user fees;
- satisfactory completion of an FDA advisory committee review, if applicable;
- determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of a pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with current Good Manufacturing Practices (cGMPs) and GCPs;
- satisfactory completion of FDA audits of clinical trial sites to ensure compliance with GCPs and the integrity of the clinical data;
- FDA review and approval of an NDA to permit commercial marketing for particular indications for use in the United States; and



- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS), and the potential requirement to conduct postapproval studies.
- The testing and approval process requires substantial time, effort and financial resources.

Preclinical Studies

Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a drug candidate, a sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other required information, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug or biological product to humans. Some preclinical studies may continue even after the IND is submitted. The central focus of an initial IND submission is on the general investigational plan and the protocol or protocols for clinical trials. The IND submission also includes results of animal and *in vitro* preclinical studies assessing the toxicology, PK, PD and pharmacology characteristics of the product, chemistry, manufacturing and controls (CMC), information, and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30day time period, raises safety concerns or questions about the conduct of the clinical trial and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose a partial clinical hold that would limit a clinical trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each institution participating in the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to clinical trial subjects before the clinical trial commences at that site. An IRB is charged with protecting the welfare and rights of clinical trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the clinical trial plans. While the IND is active, and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected AEs, findings from other clinical trials suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* preclinical testing suggesting a significant risk to humans and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, or if the drug has been associated with unexpected serious harm to subjects. Some clinical trials also include a DSMB, which receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

Phase 1. Clinical trials are initially conducted to test the drug candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. Phase 1a trials are typically single ascending dose escalation of the investigational drug alone, while Phase 1b trials, or the Phase 1b portion of a combined phase trial (Phase 1b/2) may have multiple ascending doses to expand and identify optimal dosing, including in combination with other drugs. If possible, Phase 1 clinical trials may also be used to gain early evidence of product effectiveness.

Phase 2. Controlled clinical trials are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expansive Phase 3 clinical trials.

Phase 3. These clinical trials are generally undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These clinical trials may be done at clinical trial sites outside the United States as long as the global sites are also representative of the U.S. population and the conduct of the clinical trial at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 post-marketing studies may be made a condition to be satisfied after approval. The results of Phase 4 post-marketing studies can confirm the effectiveness of a drug candidate and can provide important safety information.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the clinical trial by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the clinical trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Information about some clinical trials, including a description of the clinical trial and clinical trial results, must be submitted within specific time frames to the National Institutes of Health for public dissemination on their *clinicaltrials.gov* website. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if SAEs occur.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and

clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA may refer drugs to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has set the review goal of 10 months from the 60-day filing date to complete its initial review of a standard NDA for a new molecular entity (NME), and make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal, and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding the submission during the review period that amends the original application.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter (CRL) or an approval letter. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information or analyses in order for the FDA to reconsider the application in the future. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product, or impose other conditions, including distribution restrictions or other

risk management mechanisms. For example, the FDA may require a REMS as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product, or impose additional post-marketing requirements, based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, which has resulted in a boxed warning. A boxed warning is the strictest warning put in the labeling of prescription drugs or drug products by the FDA when there is reasonable evidence of an association of a serious hazard with the drug. The FDA also may not approve the inclusion of all labeling claims sought by an applicant. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat patients with a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more than individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA. After the FDA grants Orphan Drug Designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on the website *www.clinicaltrials.gov*. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the clinical trial. Competitors may

use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

U.S. Post-Approval Requirements

Any products manufactured or distributed by Tvardi pursuant to FDA approvals are subject to continuing regulation by the FDA, including periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program fee requirements for approved products, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are consistent with the FDA approved labeling. Physicians, in their independent professional medical judgment, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by Tvardi and approved by the FDA. However, manufacturers and third parties acting on their behalf are prohibited from marketing or promoting drugs in a manner inconsistent with the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials and/or post-approval clinical studies, refusal to approve pending applications or supplements to approved applications, warning letters, untitled letters, mandated modification of promotional materials or labeling, required issuance of corrective information, issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. It is also possible that failure to comply with the FDA's requirements relating to the promotion of prescription drugs may lead to investigations alleging

violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Any of these sanctions could result in adverse publicity, among other adverse consequences.

U.S. Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of some marketing applications. The FDA provides periods of non-patent regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. For example, five years of exclusivity are available to new chemical entities (NCEs). A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an Abbreviated New Drug Application (ANDA) or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of approval for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of patent or non-patent exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in some circumstances.

Regulation Outside the United States

In order to market any product outside of the United States, Tvardi would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of Tvardi products. Whether or not it obtains FDA approval for a product, it would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Other Healthcare Laws and Compliance Requirements

Tvardi's business activities, including but not limited to, research, sales, promotion, distribution, medical education and other activities are subject to regulation by numerous regulatory and law enforcement

authorities in the United States in addition to the FDA, including the Department of Justice, the Department of Health and Human Services (HHS), and its various divisions, including the Centers for Medicare & Medicaid Services and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense and state and local governments. Tvardi's business activities must comply with numerous healthcare laws and regulations, including those described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, a person or entity no longer does not need to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it, to have violated the statute.

The federal civil and criminal false claims laws, including the False Claims Act (FCA) prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the U.S. federal government, including Medicare and Medicaid programs, or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program. Moreover, a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the FCA.

Health Insurance Portability and Accountability Act (HIPAA), created additional federal criminal statutes that prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Additionally, a person or entity does not need to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

The federal Open Payments program pursuant to the Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians, as defined by such law, certain other healthcare providers (such as physician assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties.

In addition, Tvardi may be subject to data privacy and security regulation by both the federal government and the states in which Tvardi conducts its business. HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates and their covered subcontractors. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Tvardi may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

Ensuring that Tvardi's internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that Tvardi's business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Tvardi's operations were found to be in violation of any of these laws or any other governmental regulations that may apply to Tvardi, Tvardi may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if it becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment of its operations, any of which could substantially disrupt Tvardi's operations. If the physicians or other providers or entities with whom Tvardi expects to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Coverage and Reimbursement

Tvardi's ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for the procedures utilizing its drug candidates, performed by health care providers, once approved, will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which procedures, and the products utilized in such procedures, they will cover and establish reimbursement levels. Assuming coverage is obtained for procedures utilizing a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients

who undergo procedures for the treatment of their conditions, and their treating physicians, generally rely on third-party payors to reimburse all or part of the costs associated with the procedures which utilize Tvardi's products. Treating physicians are unlikely to use and order Tvardi's products unless coverage is provided and the reimbursement is adequate to cover all or a significant portion of the cost of the procedures which utilize Tvardi's products. Therefore, coverage and adequate reimbursement for procedures which utilize new products is critical to the acceptance of such new products. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of cost containment, such as including price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products and procedures. Government and other third-party payors are increasingly challenging the prices charged for health care products and procedures, examining the cost effectiveness of procedures, and the products used in such procedures, in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement. Further, no uniform policy requirement for coverage and reimbursement exists among third-party payors in the United States, which causes significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and the procedures which may utilize such newly approved products. Therefore, coverage and reimbursement can differ significantly from payor to payor and health care provider to health care provider. As a result, the coverage determination process is often a time-consuming and costly process that requires the provision of scientific and clinical support for the use of new products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may also be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product, or the procedures which utilize such product, will be paid for in all cases or at a rate which the health care providers who purchase those products will find cost effective. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. Additionally, there may be pricing pressures in connection with the sale of any of Tvardi's drug candidates, once approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes.

Coverage and reimbursement may impact the demand for, the price of, or Tvardi's ability to successfully commercialize, any drug candidate for which it obtains marketing approval.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect Tvardi's ability to sell its products profitably. By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Moreover, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the

"donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers, which went into effect in April 2013 and will remain in effect until 2032 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

The heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics, also has resulted in executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the IRA (1) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to 15 additional drugs covered under Part D for price negotiation in 2025. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Patent and Trademark Law Amendments Act (the Bayh-Dole Act). On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies.

Tvardi expects that these initiatives, as well as other healthcare reform measures that may be adopted in the future, as well as the trend toward managed healthcare and increasing influence of managed care organizations, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that Tvardi receives for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect Tvardi's operations and prevent Tvardi from being able to generate revenue, attain profitability or commercialize its drug candidates.

Data Privacy and Security

In the ordinary course of Tvardi's business, it collects, processes and stores confidential and sensitive information, including personal information, intellectual property, trade secrets and proprietary information owned or controlled by Tvardi or other third parties. Tvardi, and third parties upon whom it relies, use sophisticated information technology, software and services to process, store, use, generate, transfer and disclose information, as well as other sensitive information controlled by Tvardi or other third parties.

Tvardi may be subject to federal, state, and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure and protection of health-related and other personal information and could apply to its operations or the operations of Tvardi's partners, vendors or other third parties on whom Tvardi relies. The legislative and regulatory framework related to the collection, use, retention, safeguarding, disclosure, sharing, transfer, security and other processing of personal data worldwide is rapidly evolving. The number and scope of data protection laws and regulations is changing, subject to differing applications and interpretations and may be inconsistent among jurisdictions, or in conflict with other rules, laws or other data processing obligations. Efforts to ensure that Tvardi's current and future business arrangements, including its relationship with its third-party contract research organizations (CROs) or other vendors who process data on its behalf, comply with applicable data privacy and data security laws and regulations will involve substantial costs.

For example, HIPAA, as amended by HITECH, imposes requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health plans and health care clearinghouses, known as covered entities, as well as their business associates and covered subcontractors that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to civil and criminal penalties. Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Tvardi expects that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union (EU) and other jurisdictions, such as the California Consumer Privacy Act (CCPA). Although the CCPA exempts certain data processed in the context of clinical trials, the CCPA, to the extent applicable to Tvardi's business and operations, may increase its compliance costs and potential liability with respect to the personal information Tvardi maintains about California residents. The CCPA creates individual privacy rights for California consumers (as defined in the law), places increased privacy and security obligations on entities handling certain personal information of consumers or households, requires covered companies to provide disclosures to consumers regarding data collection, use and sharing practices, requires covered companies to allow users to opt-out of certain sales or transfers of personal information, and provides consumers with a private right of action for certain data breaches. The CCPA became effective on January 1, 2020, and the California Attorney General's authority to begin bringing enforcement actions began July 1, 2020. The CCPA may impact Tvardi's business activities and exemplifies the vulnerability of its business to the evolving regulatory environment related to personal information and protected health information. Further, the California Privacy Rights Act (CPRA), went into effect on January 1, 2023, and became enforceable on July 1, 2023. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on covered companies

doing business in California, including additional consumer rights processes and opt-outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States.

Tvardi also are or may become subject to privacy laws in the jurisdictions in which it is established, sell or market its products or run clinical trials. For example, in the EU, Regulation (EU) 2016/679 (the GDPR), governs the collection, control, processing, and other use of personal data (i.e., data relating to an identified or identifiable living individual). The GDPR is directly applicable in each EU and European Economic Area (EEA), Member State; however, it provides that EU and EEA Member States may introduce further conditions, including limitations which could limit Tvardi's ability to collect, use and share personal data (including health and medical information), or could cause its compliance costs to increase, ultimately having an adverse impact on its business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and to disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used; imposes limitations on retention of personal data; imposes requirements with respect to pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities.

Tvardi also may become subject to EEA rules with respect to cross-border transfers of personal data out of the EEA. As noted above, recent legal developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union (the CJEU) states that reliance on the standard contractual clauses — a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism — alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for U.S. Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework (the DPF) as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. The DPF also introduced a new redress mechanism for EU citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in future. Additionally, on September 8, 2020, the Swiss Data Protection Authority (the Federal Data Protection and Information Commissioner) concluded that the Swiss-U.S. Privacy Shield does not provide an adequate level of protection for personal data transfer from Switzerland to the U.S. pursuant to the Swiss Federal Act on Data Protection. Tvardi expects the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, Tvardi expects the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, to the extent Tvardi begins transferring personal data out of the EEA, it may have to make certain operational changes and will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

Fines for certain breaches of the GDPR are significant: up to the greater of $\notin 20.0$ million or 4% of total global annual turnover. Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and the EU, Tvardi will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of $\notin 20$ million / £17 million or 4% of global turnover. Following December 31, 2020, and the expiry of the post-Brexit transitional arrangements between the United Kingdom and EU, although it is likely that the data protection obligations of the GDPR will continue to apply to UK-related processing of personal data in substantially unvaried form and

fashion, for at least the short term thereafter, the relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear.

Moreover, Tvardi uses third-party service providers and subprocessors to help operate its business and engage in processing on its behalf. If Tvardi, its service providers, partners or other relevant third-parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure or disclosure of sensitive information, or compromise related to the security, confidentiality, integrity of Tvardi's (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation or an inability to process data in some jurisdictions. Applicable data protection laws, privacy policies and data protection obligations may require Tvardi to notify relevant stakeholders of security breaches, including affected individuals, customers and regulators. Such disclosures are costly, and the disclosure or the failure to comply with such requirements, could result in a material adverse impact, including without limitation, regulatory investigations.

For more information on the potential impact of data protection laws on Tvardi's business, see the section titled "Risk Factors — General Risk Factors — Tvardi is subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security. Tvardi's actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of its business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences."

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect Tvardi's business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If Tvardi's operations result in contamination of the environment or expose individuals to hazardous substances, it could be liable for damages and governmental fines. Equivalent laws have been adopted in other countries that impose similar obligations.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies and understanding of disease etiology, intense development, strong competition and an emphasis on intellectual property. While Tvardi believes that its approach, strategy, scientific capabilities, know-how and experience, particularly in the field of STAT3 biology and product development provide Tvardi with competitive advantages, it faces substantial competition from many different sources, including larger pharmaceutical companies with greater resources. Smaller specialty biotechnology and biopharmaceutical companies, academic research institutions and governmental agencies, as well as public and private institutions, are also potential sources of competitive products and technologies, including through collaborative arrangements with large and established biopharmaceutical companies. It also faces competition in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling patients for clinical trials and acquiring technologies complementary to, or necessary for, its programs. Tvardi believes that the key competitive factors affecting the success of any of its product

candidates will include efficacy, safety profile, convenience, method of administration, cost, level of promotional activity and intellectual property protection.

There are a number of large biopharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of fibrosis. Companies that Tvardi is aware of that are actively developing STAT3 inhibitors preclinically and clinically to treat fibrosis-driven diseases include Bayer, Flamingo Therapeutics, Kymera Therapeutics, Moleculin Biotech, Purple Biotech, Recludix Pharma and Scopus BioPharma.

Although Tvardi's novel approach is differentiated from most other existing or investigational therapies across the disease areas where Tvardi is focusing its development, it will need to compete with currently approved therapies, and potentially those in currently in development if they are approved. Tvardi is aware of several marketed and investigational products in its leading disease areas, including but not limited to:

- *IPF*: There are currently two approved products for the treatment of IPF, including nintedanib (Ofev, Boehringer Ingelheim Pharma GmbH & Co. KG) and pirfenidone (Esbriet, marketed by Roche Holding AG), with generics marketed by Sandoz Group AG, Teva Pharmaceutical Industries Ltd. and others. Companies currently developing product candidates in IPF include, but are not limited to, AbbVie, Amgen, Avalyn Pharma, Boehringer Ingelheim, BridgeBio, Bristol Myers Squibb, Contineum Therapeutics, CSL Behring, Endeavor BioMedicines, Horizon Therapeutics, Liminal BioSciences, Pliant Therapeutics, PureTech Health, Redx Pharma, Roche, Structure Therapeutics, Syndax Pharmaceuticals, United Therapeutics and Vicore Pharma.
- HCC: There are currently eight available treatments for HCC, including sorafenib (Nexavar, marketed by Bayer HealthCare Pharmaceuticals), atezolizumab in combination with bevacizumab (Tecentriq and Avastin, respectively, marketed by Genentech), lenvatinib (Lenvima, marketed by Eisai R&D Management Co., Ltd.), durvalumab in combination with tremelimumab (Imfinzi and Imjudo, respectively, marketed by AstraZeneca), regorafenib (Stivarga, marketed by Bayer HealthCare Pharmaceuticals), ramucirumab (Cyramza, marketed by Eli Lilly and Company), cabozantinib (Cabometyx, marketed by Exelixis Inc.), pembrolizumab (Keytruda, marketed by Merck & Co., Inc.), and nivolumab in combination with ipilimumab (Opdivo and Yervoy, marketed by Bristol-Myers Squibb Company). Companies currently developing product candidates in HCC include, but are not limited to, AstraZeneca, Beigene, Bristol Myers Squibb, Elevar Therapeutics, Eli Lilly, Immune-Onc, Iterion Therapeutics, Omega Therapeutics and Tempest Therapeutics. Based on Tvardi's review of published research, the current SoC in second-line patients with HCC is estimated to have an ORR of ≤ 5%.

The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of Tvardi's product candidates, if approved for marketing. Tvardi's competitors also may obtain FDA or other regulatory approval for their products more rapidly than it does, which could result in its competitors establishing a strong market position before Tvardi is able to enter the market.

Employees and Human Capital Resources

As of September 30, 2024, Tvardi had 12 full-time employees, 10 of whom are involved in research and development activities. Five of Tvardi's employees hold Ph.D. or M.D. degrees. None of its employees are subject to a collective bargaining agreement. Tvardi considers its relationship with its employees to be good.

Tvardi recognizes that its continued ability to attract, retain and motivate exceptional employees is vital to ensuring its long-term competitive advantage. Tvardi's employees are critical to its long-term success and are essential to helping Tvardi meet its goals. Among other things, it supports and incentivizes its employees in the following ways:

• Talent development, compensation and retention: Tvardi's human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating its existing and additional employees. The principal purposes of Tvardi's equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

- Health and safety: Tvardi supports the health and safety of its employees by providing comprehensive insurance benefits, an employee assistance program, company-paid holidays, a personal time-off program and other additional benefits which are intended to assist employees to manage their well-being.
- Inclusion and diversity: Tvardi is committed to efforts to increase diversity and foster an inclusive work environment that supports its workforce.

Facilities

Tvardi's corporate headquarters is located in Sugar Land, Texas, where it leases approximately 5,900 square feet of space. Tvardi's lease expires in August 2027. Tvardi believes its facilities are adequate and suitable for its current needs and that should it be needed, suitable additional or alternative space will be available to accommodate its operations.

Legal Proceedings

From time to time, Tvardi may become involved in material legal proceedings or be subject to claims arising in the ordinary course of its business. Tvardi is currently not party to any legal proceedings material to its operations or of which any of its property is the subject, nor is it aware of any such proceedings that are contemplated by a government authority. Regardless of outcome, such proceedings or claims can have an adverse impact on Tvardi because of defense and settlement costs, diversion of resources, and other factors, and there can be no assurances that favorable outcomes will be obtained.

TVARDI MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of Tvardi's financial condition and results of operations in conjunction with Tvardi's financial statements and the related notes included elsewhere in this proxy statement/prospectus. In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Tvardi's actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this proxy statement/prospectus, particularly in the section titled "Risk Factors."

Overview

Tvardi is a clinical-stage biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting STAT3 to treat fibrosis-driven diseases with significant unmet need. Based upon Tvardi's founder's seminal work and deep understanding of the transcription factor, STAT3, Tvardi designed an innovative approach to directly inhibit STAT3, a highly validated, yet historically undruggable target. Leveraging this expertise, Tvardi is developing a pipeline of STAT3 inhibitors with a differentiated mechanism of action and convenient oral dosing. Tvardi's lead product candidate, TTI-101, is currently in Phase 2 clinical development for the treatment of fibrosis-driven diseases, with an initial focus on IPF and HCC. Tvardi expects to report unblinded data from its Phase 2 IPF clinical trial in the second half of 2025 and anticipate preliminary topline data from its HCC Phase 1b/2 HCC clinical trial in the second half of 2025. Tvardi's second product candidate, TTI-109, is also an oral, small molecule STAT3 inhibitor that is structurally related to, yet chemically distinct from, TTI-101 and is designed to enhance Tvardi's ability to target STAT3. Tvardi expects to submit an IND application for TTI-109 in the first half of 2025.

Since commencing operations in 2017, Tvardi has devoted substantially all of its efforts and financial resources to developing its product candidates, organizing and staffing its company, business planning, raising capital, establishing its intellectual property portfolio and performing research and development of its product candidates, signaling and biology, medicinal chemistry and clinical insights to discover and develop novel therapies for the treatment of fibrosis-driven diseases. Through the date of this filing, Tvardi has historically financed its operations principally through the issuance and sale of its preferred stock and convertible debt. As of September 30, 2024, it has received total gross proceeds of \$83.4 million from the issuance and sale of its Preferred Stock and convertible debt, which was converted into Preferred Stock in 2018 and 2021. As of September 30, 2024, Tvardi had \$9.4 million in cash and cash equivalents. Management has determined that Tvardi's cash and cash equivalents as of September 30, 2024 will not be sufficient to fund its planned operations beyond one year from the issuance of its financial statements included elsewhere in this proxy statement/prospectus, which raises substantial doubt as to Tvardi's ability to continue as a going concern. Tvardi has based this estimate on assumptions that may prove to be wrong, and it could exhaust its capital resources sooner than it expects. See the subsection titled "- Liquidity and Capital Resources" below for further discussion. Even if this Merger is successful, Tvardi will require additional funding in order to finance operations and complete its ongoing and planned clinical trials. Access to such funding on acceptable terms cannot be assured.

Tvardi has incurred net losses since inception. As of September 30, 2024 and December 31, 2023, its accumulated deficit was \$79.5 million and \$62.8 million, respectively. For the nine months ended September 30, 2024 and 2023, Tvardi reported net losses of \$16.7 million and \$13.0 million, respectively, and for the years ended December 31, 2023 and 2022, Tvardi reported net losses of \$17.3 million and \$20.5 million, respectively. Tvardi's net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of its clinical development activities and other research and development activities. Tvardi expects that its expense and capital requirements will increase substantially in connection with its ongoing activities and for the foreseeable future, particularly if Tvardi, among other things:

- advances TTI-101, TTI-109 and its other product candidates through clinical development and, if successful, later-stage clinical trials;
- · discovers and develops additional product candidates;
- · advances its preclinical development programs into clinical development;

- experiences delays or interruptions to preclinical studies, clinical trials, receipt of services from its third-party service providers on whom it relies, or its supply chain;
- seeks and maintains regulatory approvals for any product candidates that successfully complete clinical trials;
- commercializes TTI-101, TTI-109, its other product candidates and any future product candidates, if approved;
- hires additional clinical development, quality control, scientific and management personnel;
- expands its operational, financial and management systems and increase personnel, including
 personnel to support its clinical development and manufacturing efforts and operations as a public
 company;
- establishes a sales, marketing, medical affairs and distribution infrastructure to commercialize any
 products for which Tvardi may obtain marketing approval and intend to commercialize on its own or
 jointly with third parties;
- · maintains, expands and protects its intellectual property portfolio;
- invests in or in-licenses other technologies or product candidates;
- · continues to build out its organization to engage in such activities; and
- incurs additional legal, accounting, investor relations and other general and administrative expenses associated with operating as a public company.

Given Tvardi's stage of development, to date it has not had any products approved for sale and has not generated any revenue. Tvardi does not expect to generate any revenues from product sales unless and until it successfully completes development and obtains regulatory approval for one or more of its product candidates, which may not be for several years, if ever. If Tvardi obtains regulatory approval for any of its product candidates, it expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that Tvardi can generate substantial product revenue, it expects to finance its cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, Tvardi may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. If Tvardi does raise additional capital through public or private equity offerings, the ownership interest of its existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. If Tvardi raises additional capital through debt financing, it may be subject to covenants or other restrictions limiting its ability to engage in specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on its financial condition and on its ability to pursue its business plans and strategies, including its research and development activities. If Tvardi is unable to raise capital, Tvardi will need to delay, reduce or terminate planned activities, including its ongoing and planned clinical trials, to reduce costs.

Economic uncertainty in various global markets, including the United States and Europe, caused by political instability and conflict, such as the ongoing conflict in Ukraine and in the Middle East and Africa, have led to market disruptions, including significant volatility in commodity prices, credit and capital market instability and supply chain interruptions, which have caused record inflation globally. Tvardi's business, financial condition and results of operations could be materially and adversely affected by further negative impact on the global economy and capital markets resulting from these global economic conditions, particularly if such conditions are prolonged or worsen.

Although, to date, Tvardi's business has not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which its operations will be impacted in the short and long term, or the ways in which such instability could impact its business and results of operations. The extent and duration of these market disruptions, other geopolitical tensions, record inflation or otherwise, are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this proxy statement/prospectus.

License Agreements

In July 2012 and June 2015, Stem Med Limited Partnership (StemMed) entered into license agreements with Baylor College of Medicine (BCM) referred to herein as the BCM First Agreement and BCM Second Agreement, respectively. StemMed assigned the BCM First Agreement and BCM Second Agreement to Tvardi in connection with the transfer of all or substantially all of the assets and businesses to which BCM First Agreement and BCM Second Agreement relate in January 2018 and February 2018, respectively. Under both the BCM First Agreement and BCM Second Agreement, Tvardi obtained exclusive, worldwide, sublicense licenses under certain of BCM's patents and patent applications and additionally in the case of the BCM First Agreement, certain BCM technology. Under these licenses, Tvardi is permitted to make, have made, use, market, sell, offer to sell, lease and import products, processes or services that incorporate, utilize or are made with the use such patents and patent applications or technologies (respectively, the BCM1 Licensed Products and BCM2 Licensed Products) in all fields of use. The licenses, patents and patent applications and technologies applicable to the BCM First Agreement and BCM Second Agreement are further discussed below.

First License Agreement with Baylor College of Medicine

Under the BCM First Agreement, Tvardi obtained an exclusive, worldwide, sublicensable license under BCM's rights to certain patents and patent applications related to STAT3 inhibitors in oncology and certain non-oncology indications, which Tvardi refers to as the BCM Patent Rights, together with certain cell lines, biological materials, compounds, know-how and technologies, which Tvardi collectively refers to as the BCM Technology, to make, have made, use, market, sell, offer to sell, lease and import BCM1 Licensed Products, in all fields of use.

Pursuant to the terms of the BCM First Agreement, StemMed owed an initial license fee of \$75,000 as consideration for the license rights. Upon the assignment of the agreement to Tvardi, Tvardi became responsible for the payment of annual maintenance fees on the anniversary of the agreement, which range from \$30,000 to \$50,000. Tvardi is also required to pay BCM royalties in the amount of a low-singledigit percent of net sales of BCM1 Licensed Products during the term, which expires, on a country-bycountry basis, on the later of (i) the date of expiration of the last-to-expire of the BCM Patent Rights, or, (ii) if no BCM Patent Rights issued in such country, the tenth anniversary of the first commercial sale of the BCM1 Licensed Product in such country. Tvardi currently expects the BCM Patent Rights to expire April 18, 2039. Upon the initiation of the Phase 2 clinical trials for two BCM1 Licensed Products, Tvardi paid BCM development milestone payments of \$250,000 in the aggregate. Upon the achievement of additional specified development and regulatory milestones. Tvardi is required to pay BCM one-time milestone payments of up to \$2,200,000 in the aggregate for the first BCM1 Licensed Product in an oncology indication and for the first BCM1 Licensed Product in a non-oncology indication to achieve such milestones. Further, in connection with the initiation of the Phase 3 clinical trial, Tvardi would expect to incur approximately \$400,000 of oncology-related costs and approximately \$300,000 of non-oncologyrelated costs. Tvardi is additionally required to pay BCM a tiered low-double-digit percentage of sublicensing revenue obtained in connection with any sublicense granted by Tvardi under the BCM Patent Rights or BCM Technology.

Tvardi may terminate the BCM First Agreement at its convenience following a specified notice period upon advance written notice to BCM. The BCM First Agreement may also be terminated by BCM for Tvardi's default or failure to perform any of terms of the BCM First Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM First Agreement if Tvardi undergoes specified bankruptcy or insolvency events, following the expiration of a specified period. Upon expiration of the term of the BCM First Agreement in a given country, the license grant from BCM to Tvardi will be fully-paid and perpetual in such country.

The BCM First Agreement was amended in April 2015 to update the schedule of BCM Patent Rights and description of description of BCM Technology covered by the license for immaterial consideration. The BCM First Agreement was further amended in August 2019 to amend Tvardi's diligence and insurance obligations as well as to further update the schedule of BCM Patent Rights.

Under the BCM First Agreement, Tvardi recorded \$50,000 of annual maintenance fees during the nine months ended September 30, 2024 and \$50,000 of annual maintenance fees during each of the years



ended December 31, 2023 and 2022. Tvardi incurred \$125,000 for milestones in connection with the initiation of a Phase 2 clinical trial during each of the years ended December 31, 2023 and 2022. No milestone fees were incurred during the nine months ended September 30, 2024 and 2023. No royalty fees have been incurred to date.

Second License Agreement with Baylor College of Medicine

Under the BCM Second Agreement, Tvardi obtained an exclusive, worldwide, sublicensable license under certain patents and patent applications co-owned by BCM and the National Institutes of Health (NIH), related to methods and compositions for the use of STAT3 inhibitors in certain conditions like anaphylaxis, which rights Tvardi refers to as the Licensed Patent Rights, to make, have made, use, market, sell, offer to sell, lease and import the BCM2 Licensed Products, in all fields of use.

Pursuant to the terms of the BCM Second Agreement, StemMed owed an initial license fee of \$5,000 in consideration for the license rights. Upon the assignment of the agreement to Tvardi, it became responsible for the payment of maintenance fees on the anniversary of the agreement, which range from \$30,000 to \$50,000. Tvardi is also required to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM2 Licensed Products during the term, which expires, on a country-by-country basis, on the later (i) of the date of expiration of the last to expire of the Licensed Patent Rights, or, (ii) if no Licensed Patent Rights issued in such country, the tenth anniversary of the first commercial sale of the BCM2 Licensed Product in such country. Tvardi currently expects the Licensed Patent Rights to expire July 18, 2034. Upon the achievement of additional specified development and regulatory milestones, Tvardi is required to pay BCM one-time milestone payments of up to \$1,225,000 in the aggregate for the first BCM2 Licensed Product to achieve such milestones. Further, in connection with the initiation of the Phase 3 clinical trial, Tvardi would expect to incur approximately \$300,000 in costs. Tvardi is additionally required to pay BCM a tiered low-double-digit percentage of sublicensing revenue obtained in connection with any sublicense granted by Tvardi under the Licensed Patent Rights.

Tvardi may terminate the BCM Second Agreement at its convenience following a specified notice period upon advance written notice to BCM. The BCM Second Agreement may also be terminated by BCM for Tvardi's default or failure to perform any of terms of the BCM Second Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM Second Agreement if Tvardi undergoes specified bankruptcy or insolvency events, following the expiration of a specified period. The NIH may terminate its license to BCM if Tvardi fails to fulfill certain obligations. Upon expiration of the term of the BCM Second Agreement in a given country, the license grant from BCM to Tvardi will be fully-paid and perpetual in such country.

The BCM Second Agreement was amended in June 2019 to amend Tvardi's diligence and insurance obligations. Tvardi entered into a second amendment April 2023 to further amend its diligence obligations and to terminate the obligation to pay annual maintenance fees until the first anniversary of the achievement of certain patent milestones and annually thereafter.

Under the BCM Second Agreement, no payments were made or incurred during nine months ended September 30, 2024 and 2023 or during the years ended December 31, 2023 and 2022. No royalty fees have been incurred to date.

Components of Operating Results

Revenue

Tvardi has not generated any revenue since its inception and does not expect to generate any revenue from the sale of products in the near future, if at all. If Tvardi's development efforts for TTI-101, TTI-109 or additional product candidates that it may develop in the future are successful and result in marketing approval, or if Tvardi enters into collaboration or license agreements with third parties, it may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Tvardi's operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs.

Research and Development Expenses

Tvardi's research and development expenses consist primarily of direct and indirect costs incurred in performing clinical and preclinical development activities.

Direct costs include:

- expenses incurred under agreements with consultants and third-party CROs that conduct research and development activities on Tvardi's behalf;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers; and
- · costs associated with license agreements.

Indirect costs include:

- personnel costs, which includes salaries, benefits, stock-based compensation expense and travel expenses, for personnel engaged in research and development functions;
- facilities, amortization and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs related to compliance with quality and regulatory requirements.

Pursuant to U.S. GAAP and Tvardi's internal policies, including its clinical trial accrual policy, Tvardi expenses all research and development costs in the periods in which they are incurred, including the costs of treatment center start-up activities, patient enrollment, and study reporting. Tvardi tracks research and development expenses on an aggregate basis, but not on an indication-by-indication basis. Costs for certain other research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to Tvardi by its vendors and third-party service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in Tvardi's financial statements as prepaid or accrued research and development expenses.

The majority of Tvardi's clinical spending in the years ended December 31, 2023 and 2022 was on TTI-101, for which certain direct research and development costs are tracked by clinical trial. Spending for the development of TTI-109 primarily began in 2023.

Tvardi expects its research and development expenses to increase substantially for the foreseeable future as it continues to invest in the development of TTI-101 and TTI-109, support its ongoing preclinical programs and discover any new product candidates, as well as increase its headcount. In particular, clinical development, as opposed to preclinical development, generally has higher development costs, primarily due to the increased size and duration of later-stage clinical trials. Moreover, the costs associated with Tvardi's clinical activities, which are managed by its CROs, and Contract Development and Manufacturing Organizations (CDMOs), to manufacture materials for Tvardi's product candidates and future commercial products, are much more costly as compared to early-stage preclinical development. Tvardi cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of its current and future candidates due to the inherently unpredictable nature of preclinical and clinical development. Preclinical and clinical development timelines, the probability of success and development costs can differ materially from expectations. Tvardi anticipates that it will make determinations as to which therapeutic candidates to pursue and how much funding to direct to each therapeutic candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and Tvardi's ongoing assessments as to each therapeutic candidate's commercial potential. Tvardi will need substantial additional capital in the future to support these efforts. In addition, Tvardi cannot forecast which therapeutic candidates may be subject to future



collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect its development plans and capital requirements.

At this time, Tvardi cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any of its product candidates. Tvardi is also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of its product candidates. This is due to the numerous risks and uncertainties associated with drug development, including:

- negative or inconclusive results from Tvardi's preclinical studies or clinical trials or the clinical trials of others for product candidates similar to Tvardi's, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- undesirable product-related side effects experienced by subjects in Tvardi's clinical trials or by individuals using drugs or therapeutics similar to its product candidates;
- poor efficacy of Tvardi's product candidates during clinical trials;
- delays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from FDA or other comparable foreign regulatory authorities to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of Tvardi's clinical trials;
- delays in enrolling subjects in clinical trials, including due to operational challenges or competition with other clinical trials;
- high drop-out rates or screening failures of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of Tvardi's clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- failure to secure or maintain orphan designation in some jurisdictions;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of Tvardi's third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to Tvardi's technology in particular; or
- varying interpretations of data by the FDA and other comparable foreign regulatory authorities.

A change in the outcome of any of these variables with respect to the development of any of Tvardi's product candidates or potential future product candidates could mean a significant change in the costs and timing associated with the development of that product candidate or potential future product candidate. For example, if the FDA or another regulatory authority were to require Tvardi to conduct clinical trials beyond those that we anticipate would be required for the completion of clinical development of a product candidate or potential future product candidate, or if Tvardi experiences significant delays in its clinical trials due to slower than expected patient enrollment or other reasons, it would be required to expend significant additional financial resources and time on the completion of clinical development. Tvardi may never obtain regulatory approval for any of its product candidates, and, even if Tvardi does, drug commercialization takes several years and millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, for personnel in Tvardi's executive, finance, corporate and business

development and administrative functions. General and administrative expenses also include outside professional services, such as legal, audit and accounting services, insurance costs and facility-related expenses, which includes direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Tvardi expects its general and administrative expenses to increase over the next several years as it continues its research and development activities, prepares for potential commercialization of its current and future product candidates, as well as expands its operations and begins operating as a public company. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory and other fees and services associated with maintaining compliance with listing rules and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Interest Income

Interest income for the nine months ended September 30, 2024 consists of interest earned on Tvardi's cash equivalents and interest income for the nine months ended September 30, 2023 consists of interest earned on its cash equivalents, previously outstanding short-term investments, as well as accretion of the discount on its short-term investments.

Other Income (Expense)

Other income (expense) for the years ended December 31, 2023 and 2022 primarily consists of interest earned on Tvardi's cash, cash equivalents, and short-term investments as well as accretion of the discount on its short-term investments.

Income Taxes

Tvardi recorded a full valuation allowance of its deferred tax asset position as of December 31, 2023 and 2022 as it believes it was more likely than not that Tvardi would not be able to utilize its deferred tax assets.

As of December 31, 2023, Tvardi had a federal NOL carryforward of \$34.5 million. Of the federal NOL carryforwards, \$0.4 million expires in 2037 and \$34.1 million may be carried forward indefinitely. As of December 31, 2023, Tvardi had federal research and development credits of \$0.4 million, which will begin to expire in 2039.

Results of Operations

Comparison of the nine months ended September 30, 2024 and 2023

The following table sets forth Tvardi's results of operations for the nine months ended September 30, 2024 and 2023 (in thousands, except percentages):

	Nine Mont Septem		Change	
	2024 2023		Amount	Percent
Operating expenses:				
Research and development	\$ 15,047	\$ 11,884	\$ 3,163	26.6%
General and administrative	2,258	2,117	141	6.7%
Total operating expenses	17,305	14,001	3,304	23.6%
Loss from operations	(17,305)	(14,001)	(3,304)	23.6%
Interest income	615	1,005	(390)	(38.8)%
Net loss	\$(16,690)	\$(12,996)	\$(3,694)	28.4%

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2024 and 2023 were comprised of the following (in thousands, except percentages):

	Nine Months Ended September 30,		Change	
	2024	2023	Amount	Percent
Direct research and development expenses by program:				
TTI-101:				
НСС	\$ 4,996	\$ 1,239	\$ 3,757	303.2 <mark>%</mark>
IPF	2,991	2,828	163	5.8%
mBC	2,771	456	2,315	507.7 <mark>%</mark>
Pre-clinical, CMC, and other (unallocated)	715	3,340	(2,625)	(78.6)%
TTI-109	697	870	(173)	(19.9)%
Unallocated research and development expense:				
Personnel costs (including stock-based compensation)	2,273	2,199	74	3.4%
Consultant fees and other costs	604	952	(348)	(36.6)%
Total research and development expenses	\$15,047	\$11,884	\$ 3,163	26.6%

Research and development expenses were \$15.0 million for the nine months ended September 30, 2024, compared to \$11.9 million for the nine months ended September 30, 2023. The increase of \$3.2 million was primarily driven by costs associated with Tvardi's product candidate TTI-101, including a \$3.8 million increase related to Tvardi's hepatocellular carcinoma, or HCC, trial due to increased enrollment and a \$2.3 million increase related to the closeout of Tvardi's metastatic breast cancer (mBC) trial, which we decided to discontinue in January 2024. These increases in costs are partially offset by a \$2.6 million decrease in pre-clinical, chemistry, manufacturing and control (CMC) costs, and other unallocated direct costs attributable to (i) reductions in the production of API and tablets for use in TTI-101 clinical trials and (ii) reduced spend on preclinical testing as we moved forward in clinical trials.

The decrease of \$0.2 million related to Tvardi's product candidate TTI-109 was primarily related to decreased expenditures related to the manufacturing of the TTI-109 drug product.

The increase of personnel costs of \$0.1 million was primarily related to increases in compensation across the research and development functions. The \$0.3 million decrease in consultant fees and other costs was primarily related to reduced usage of consultants due to the usage of internal resources.

General and Administrative Expenses

General and administrative expenses were \$2.2 million for the nine months ended September 30, 2024, compared to \$2.1 million for the nine months ended September 30, 2023. The increase of \$0.1 million was primarily driven by increases in compensation and consulting and legal fees, totaling \$0.2 million, partially offset by a decrease in other office and administrative costs of \$0.1 million.

Interest Income

Interest income was \$0.6 million for the nine months ended September 30, 2024, compared to \$1.0 million for the nine months ended September 30, 2023. The \$0.6 million of interest income for the nine months ended was driven by interest income earned on Tvardi's cash equivalents. The \$1.0 million of interest income for the nine months ended September 30, 2023 includes interest earned on Tvardi's cash, cash equivalents, previously outstanding short-term investments, as well as the accretion of the discount on its short-term investments, which fully matured during fiscal 2023.

Comparison of the years ended December 31, 2023 and 2022

The following table sets forth Tvardi's results of operations for the years ended December 31, 2023 and 2022 (in thousands, except percentages):

	Year Ended I	December 31,	, Change		
	2023	2022	Amount	Percent	
Operating expenses:					
Research and development	\$ 15,866	\$ 18,466	\$(2,600)	(14.1)%	
General and administrative	2,799	2,727	72	2.6%	
Total operating expenses	18,665	21,193	(2,528)	(11.9)%	
Loss from operations	(18,665)	(21,193)	2,528	(11.9)%	
Other income (expense):					
Interest income	1,318	654	664	101.5%	
Interest expense		(2)	2	(100.0)%	
Total other income, net	1,318	652	666	102.1%	
Net loss	\$(17,347)	\$(20,541)	\$ 3,194	(15.5)%	

Research and Development Expenses

Research and development expenses for the years ended December 31, 2023 and 2022 were comprised of the following (in thousands, except percentages):

	Year Ended December 31,		Change	
	2023	2022	Amount	Percent
Direct research and development expenses by program:				
TTI-101:				
НСС	\$ 2,127	\$ 1,481	\$ 646	43.6 <mark>%</mark>
IPF	3,210	2,378	832	_%
mBC	646	770	(124)	(16.1)%
Pre-clinical, CMC, and other (unallocated)	4,373	10,354	(5,981)	(57.8%
TTI-109	1,466	79	1,387	1755.7%
Unallocated research and development expense:				
Personnel costs (including stock-based compensation)	2,900	1,709	1,191	69.7 <mark>%</mark>
Consultant fees and other costs	1,144	1,695	(551)	(32.5)%
Total research and development expenses	\$15,866	\$18,466	\$(2,600)	(14.1)%

Research and development expenses were \$15.9 million for the year ended December 31, 2023, compared to \$18.5 million for the year ended December 31, 2022. The decrease of \$2.6 million was primarily driven by a decrease of \$3.2 million in direct costs related to Tvardi's research and development programs, offset by a \$0.6 million increase of unallocated research and development expenses.

The decrease of \$4.6 million related to Tvardi's product candidate TTI-101 was partially driven by a decrease of \$6.0 million in pre-clinical, CMC and other unallocated direct costs primarily attributable to (i) reductions in the production of API and tablets for use in TTI-101 clinical trials and (ii) reduced spend on preclinical testing as Tvardi moved forward in clinical trials. This decrease was partially offset by increased costs for Tvardi's Phase 1b/2 clinical trials for idiopathic pulmonary fibrosis, or IPF, and hepatocellular carcinoma, or HCC, for which there were an increased number of patient enrollments.

While costs for Tvardi's clinical trial in mBC decreased by \$0.1 million for the year ended December 31, 2023 as compared to the year ended December 31, 2022, Tvardi expects closeout costs to be incurred in 2024, as Tvardi decided to discontinue this trial in January 2024.

The increase in direct costs of \$1.4 million related to Tvardi's product candidate TTI-109 was primarily driven by CMC costs, as development of TTI-109 primarily began in fiscal 2023.

The increase of personnel costs of \$1.2 million increase was primarily related to the hiring of new fulltime employees as Tvardi advances its product candidates, including a new chief medical officer in February 2023. The \$0.6 million decrease in consultant fees and other costs was related to the reduction of certain consultants due to the hiring of full-time employees.

General and Administrative Expenses

General and administrative expenses were \$2.8 million for the year ended December 31, 2023, compared to \$2.7 million for the year ended December 31, 2022. The increase of \$0.1 million was primarily driven by an increase of \$0.2 million related to a full year of common area maintenance expense for Tvardi's lease entered into in April 2022, a full year of compensation for its chief financial officer, hired in January 2022, as well as general increases in compensation across its general and administrative functions. This increase was offset by a \$0.1 million decrease in consulting and legal fees.

Other Income (Expense)

Total other income, net was \$1.3 million for the year ended December 31, 2023, compared to \$0.7 million for the year ended December 31, 2022, primarily attributable to (i) interest earned on its cash equivalents and short-term investments and (ii) the accretion of the discount on its short-term investments for both periods.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, Tvardi has not generated any revenue from product sales or any other sources and has incurred significant operating losses. Tvardi has not yet commercialized any products and does not expect to generate revenue from sales of any product candidates for several years, if ever. To date, Tvardi has financed its operations primarily through the issuance and sale of its preferred stock and convertible debt, for total gross proceeds of \$83.4 million. Any previously outstanding convertible debt was converted into preferred stock in 2018 and 2021. To date Tvardi has devoted substantially all of its efforts and financial resources to developing its product candidates and establishing its corporate infrastructure. As of September 30, 2024, Tvardi had \$9.4 million in cash and cash equivalents.

Funding Requirements

Tvardi's primary uses of cash are to fund its operations, which consist primarily of research and development costs related to the development of its product candidates, and, to a lesser extent, general and administrative costs. Tvardi has incurred significant operating losses since its inception, and as of September 30, 2024, had an accumulated deficit of \$79.5 million. Management has determined that its present capital resources will not be sufficient to fund its planned operations for at least one year from the issuance date of the financial statements included elsewhere in this proxy statement/prospectus, which raises substantial doubt as to Tvardi's ability to continue as a going concern.

Tvardi anticipates that it will continue to incur significant and increasing expenses for the foreseeable future as it continues to advance its product candidates, expand its corporate infrastructure, including the costs associated with being a public company, further Tvardi's research and development initiatives for its product candidates and incur costs associated with the potential commercialization of its product candidates, if approved. Tvardi is subject to all of the risks typically related to the development of new drug candidates, and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. Tvardi anticipates that it will need substantial additional funding in connection with its continuing operations. However, Tvardi may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If Tvardi raises additional capital through public or private equity offerings, the ownership interest of its existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. If Tvardi raises additional capital through debt financing, it may be subject to covenants or other restrictions limiting its ability to engage in specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could

have a negative impact on Tvardi's financial condition and on its ability to pursue its business plans and strategies. If Tvardi is unable to raise capital, it will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, Tvardi is unable to estimate the exact amount of its operating capital requirements.

Tvardi's future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for its potential future product candidates;
- the clinical development plans Tvardi establishes for its product candidates;
- the timelines of its clinical trials and the overall costs to conduct and complete the clinical trials, including any increased costs due to disruptions caused by marketplace conditions, including the effects of health epidemics, or other geopolitical and macroeconomic conditions;
- the cost and capital commitments required for manufacturing its product candidates at clinical and if, approved, commercial scales;
- the number and characteristics of product candidates that Tvardi develops;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- whether Tvardi is able to enter into future collaboration agreements and the terms of any such agreements;
- the ability to achieve and timing of achieving a favorable pricing and reimbursement decision by the pricing authorities in the markets of interest;
- the cost of filing, prosecuting, defending and enforcing its patent claims and other intellectual property rights, including patent infringement actions brought by third parties against Tvardi or its product candidates;
- the effect of competing technological and market developments;
- · the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which Tvardi may receive regulatory approval in regions where it chooses to commercialize its products on its own.

A change in the outcome of any of these or other variables with respect to the development of any of Tvardi's current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. See the section titled "Risk Factors" for additional risks associated with Tvardi's substantial capital requirements.

Cash Flows

The following table summarizes Tvardi's cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,		Year Ended Decembe	
	2024	2023	2023	2022
Net cash used in operating activities	\$(13,472)	\$(15,291)	\$(21,040)	\$(17,866)
Net cash provided by (used in) investing activities	_	22,468	22,468	(22,000)
Net cash (used in) provided by financing activities	(9)	2	2	4
Net (decrease) increase in cash	\$(13,481)	\$ 7,179	\$ 1,430	\$(39,862)

Operating Activities

Net cash used in operating activities was \$13.5 million for the nine months ended September 30, 2024, reflecting a net loss of \$16.7 million and net changes in operating assets and liabilities of \$2.8 million, partially offset by non-cash charges for depreciation and amortization, stock-based compensation expense, and non-cash lease expense of \$0.4 million. The net changes in operating assets and liabilities of \$2.8 million was primarily driven by (i) a \$2.0 million decrease in prepaid expenses and other current assets, attributable to the timing of patient enrollments, and (ii) a \$0.9 million increase in accounts payable and accrued expenses, driven by the timing of invoices and payments.

Net cash used in operating activities was \$15.3 million for the nine months ended September 30, 2023, reflecting a net loss of \$13.0 million and net changes in operating assets and liabilities of \$2.4 million, partially offset by non-cash charges for depreciation and amortization, stock-based compensation expense, non-cash lease expense and accretion of discounts on short-term investments of \$0.1 million. The net changes in operating assets and liabilities of \$2.4 million was primarily driven by (i) a \$3.3 million increase in prepaid expenses and other current assets, attributable to the timing of patient enrollments, partially offset by (ii) a \$0.9 million decrease in accounts payable and accrued expenses, driven by the timing of invoices and payments.

Net cash used in operating activities was \$21.0 million for the year ended December 31, 2023, reflecting a net loss of \$17.3 million and net changes in operating assets and liabilities of \$4.0 million, partially offset by non-cash charges for depreciation and amortization, stock-based compensation expense, non-cash lease expense and accretion of discounts on short-term investments of \$0.3 million. The net changes in operating assets and liabilities of \$4.0 million was primarily driven by (i) a \$2.9 million increase in prepaid expenses and other current assets, attributable to the timing of patient enrollments, and (ii) a \$1.0 million decrease in accounts payable and accrued expenses, driven by the timing of invoices and payments.

Net cash used in operating activities was \$17.9 million for year ended December 31, 2022, reflecting a net loss of \$20.5 million, partially offset by (i) net changes in operating assets and liabilities of \$2.7 million and (ii) a net impact of non-cash charges for depreciation and amortization, stock-based compensation expense, non-cash lease expense and accretion of discounts on short-term investments of that was relatively flat. The net changes in operating assets and liabilities of \$2.7 million increase in accounts payable and accrued expenses and a decrease in prepaid and other current assets of \$0.5 million, both primarily attributable to the timing of research and development costs.

While Tvardi's net cash used in operating activities increased by \$3.2 million for the year ended December 31, 2023 as compared to the year ended December 31, 2022, net loss decreased by \$3.2 million for the year ended December 31, 2023 as compared to the year ended December 31, 2022. The decrease in net loss as compared to the increase in Tvardi's net cash used in operating activities is directly attributable to the increase in net operating assets, and more specifically, the adjusted timing of patient enrollments.

Investing Activities

Net cash provided by investing activities was \$22.5 million for the year ended December 31, 2023 and nine months ended September 30, 2023, attributable to the maturities of short-term investments.

Net cash used in investing activities was \$22.0 million for the year ended December 31, 2022, primarily due to \$44.0 million from the purchase of short-term investments, mostly offset by \$22.0 million from the maturities of short-term investments.

Financing Activities

The net cash used in financing activities for the nine months ended September 30, 2024 was due to the payments of deferred offering costs, partially offset by proceeds from the exercise of stock options.



The immaterial net cash provided by financing activities for the years ended December 31, 2023 and 2022 and for the nine months ended September 30, 2023 was due to proceeds from the exercise of stock options.

Contractual Obligations and Commitments

Lease Obligations

Tvardi leases space under one operating lease agreement for corporate office space in Sugar Land, Texas, which expires in August 2027. As of September 30, 2024, Tvardi had future operating lease liabilities of \$0.3 million.

License Agreements

As discussed above, Tvardi has license agreements with BCM for exclusive use of patent rights of TTI-101. The license agreements contain terms for annual maintenance fees, milestone payments and net revenue royalties. Annual maintenance fees range from \$30,000 to \$50,000 per year, per license. Potential milestone payments are up to \$1,225,000 in the aggregate per license. Milestones include new drug filings, clinical trial stages, and New Drug Application approval by the FDA. Tvardi is obligated to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM1 Licensed Products or BCM2 Licensed Products during the term, which expire, on a country-by-country basis, on the later of (i) the date of expiration of BCM Patent Rights or Licensed Patent Rights, whichever is the last to expire, or, (ii) if no BCM Patent Rights or Licensed Patent Rights are issued in such country, the tenth anniversary the first commercial sale of the BCM1 Licensed Products or BCM2 Licensed Products in such country. License fees are expensed as incurred within research and development within Tvardi's statements of operations. Tvardi recorded \$50,000 of annual maintenance fees during the nine months ended September 30, 2024 and \$50,000 of annual maintenance fees during each of the years ended December 31, 2023 and 2022. Tvardi incurred \$125,000 for milestones connected with the initiation of Phase 2 clinical trials in each of the years ended December 31, 2023 and 2022. No milestone fees were incurred during the nine months ended September 30, 2024 and 2023. No royalty fees have been incurred to date.

Other Capital Requirements and Additional Royalty Obligations

Tvardi enters into agreements in the normal course of business with various third-party providers for the provision of research and development services, which include preclinical studies and clinical trial services with CROs and the manufacturing of product candidates for use in its preclinical studies and clinical trials with CDMOs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not presented separately.

In addition to Tvardi's obligation to make potential royalty payments under the BCM First Agreement and BCM Second Agreement discussed above, pursuant to Tvardi's founder restricted stock purchase agreements with each of its founders, David J. Tweardy, M.D. and Ron DePinho, M.D., Tvardi is also obligated to pay royalties to each such founder in an amount equal to 1% each on the worldwide net sales of TTI-101 and any derivative formulations, or Royalty Bearing Product. These royalty obligations last, on a country-by-country basis, for the later of (i) the date on which the sale of Royalty Bearing Product is no longer covered by a Covered Patent (as defined below) in such country, or (ii) 15 years after the first commercial sale of Royalty Bearing Product in such country. The timing of when Tvardi's royalty payments will actually be made is uncertain as the payments are contingent upon future activities, including the successful development, regulatory approval and commercialization of Royalty Bearing Product. A Covered Patent means, subject to certain customary exceptions, an issued patent that is owned by us or an affiliate, or for which all rights to develop and commercialize pharmaceutical products for the treatment of any human disorder, are exclusively licensed to Tvardi or an affiliate by the owner of such patent, with Tvardi's right or Tvardi's affiliate's right to grant sublicenses.

Critical Accounting Estimates

Tvardi's financial statements are prepared in accordance with U.S. GAAP. The preparation of the financial statements and related disclosures requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses in Tvardi's financial statements. Tvardi bases its estimates on historical experience, known trends and events and various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management evaluates estimates and assumptions on a periodic basis. Tvardi's actual results may differ from these estimates.

While Tvardi's significant accounting policies are described in more detail in Note 2 to the unaudited condensed financial statements for the nine months ended September 30, 2024 and 2023 and in Note 2 to the financial statements for the years ended December 31, 2023 and 2022, appearing elsewhere in this proxy statement/prospectus, management believes that the following accounting policies are critical to understanding Tvardi's historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of the financial statements.

Prepaid and Accrued Research and Development Costs

Accounting for preclinical studies and clinical trials relating to activities performed by CROs and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. Tvardi estimates costs of research and development activities conducted by service providers, which include costs to properly initiate and manage ongoing preclinical studies and clinical trials. The diverse nature of services being provided under contracts with Tvardi's CROs, CDMOs and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain pre-clinical and clinical activities complicates the estimation of accruals for services rendered by the CROs, CDMOs and other vendors in connection with preclinical studies and clinical trials.

Examples of estimated accrued research and development expenses include:

- expenses incurred under agreements with third parties, including Tvardi's CROs that conducts research, preclinical studies and clinical trials on its behalf;
- expenses incurred under agreements with third parties, including its CDMOs, that develop and manufacture its product candidate for use in Tvardi's preclinical studies and clinical trials; and;
- · other providers and vendors in connection with research and development activities.

Tvardi bases its expenses related to preclinical studies and clinical trials on its estimates of the services received and efforts expended pursuant to quotes and contracts with its CROs, CDMOs and other third-party vendors that conduct research, preclinical studies and clinical trials on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to Tvardi's vendors will exceed the level of services provided and result in a prepayment of the expense.

Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing fees, Tvardi estimates the time period over which services will be performed, the enrollment of patients and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from Tvardi's estimate, it adjusts the accrual or amount of prepaid expense accordingly. Although Tvardi does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in Tvardi reporting amounts that are too high or too low in any particular period. To date, Tvardi has not made any material adjustments to its prior estimates of accrued research and development expenses.

Tvardi also record advance payments to service providers as prepaid expenses and other current assets, which are expensed when the contracted services are performed. If the actual timing of the performance of services varies from the estimate, then Tvardi adjusts the amount of the accrued expense or the prepaid expense accordingly.

Stock-Based Compensation Expense and Fair Value of Stock-Based Awards

Stock-Based Compensation Expense

Tvardi measures and records the expense related to stock-based awards granted to employees, directors, consultants and advisors based upon their respective fair value at the date of grant. Generally, Tvardi issues stock option awards with service-based vesting conditions and record the expense for these awards using the straight-line method such that the aggregate amount of expense recognized is at least the fair value of what has legally vested. Tvardi estimates the grant date fair value of each common stock option using the Black-Scholes option-pricing model, which requires the input of highly subjective assumptions and management's best estimates. These estimates involve inherent uncertainties and management's judgement. If factors change and different assumptions are used, Tvardi's stock-based compensation could be materially different in the future.

These assumptions are estimated as follows:

- *Fair value* Because Tvardi's common stock is not yet publicly traded, it must estimate the fair value of common stock. Tvardi's board of directors considers numerous objective and subjective factors to determine the fair value of its common stock at each meeting in which awards are approved.
- *Expected Volatility* Because Tvardi does not have any trading history for its common stock, the expected volatility is estimated using averages of the historical volatility of its peer group of companies for a period equal to the expected term of the stock options granted. Tvardi's peer group of publicly traded companies was chosen based on their similar size, stage in the life cycle or area of specialty. Tvardi intends to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of its own common stock price becomes available.
- *Expected Term* Derived from the life of the options granted under the option plan and is based on the simplified method which is essentially the weighted average of the vesting period and contractual term.
- *Risk-Free Interest Rate* The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a term that is equal to the options' expected term at the grant date.
- *Dividend Yield* Tvardi has not declared or paid dividends to date and does not anticipate declaring dividends. As such, the dividend yield has been estimated to be zero.

Changes in the foregoing assumptions can materially affect the estimate of fair value and ultimately how much share-based compensation expense is recognized; and the resulting change in fair value, if any, is recognized in Tvardi's statements of operations during the period the related services are rendered. These inputs are subjective and generally require significant analysis and judgment to develop.

Fair Value of Stock-Based Awards

As a privately held company, there has been no public market for Tvardi's common stock to date. The estimated fair value of Tvardi's common stock has been determined by its board of directors as of the date of each option grant, with input from management, considering the most recently available third-party valuations of its common stock and its board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

Tvardi's third-party valuations of common stock were prepared using the option-pricing method (OPM), which used a market approach to estimate Tvardi's enterprise value. The OPM treats common stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method,

the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger.

These third-party valuations resulted in a valuation of Tvardi's common stock of \$0.92 and \$0.82 as of June 30, 2023 and June 30, 2022, respectively. In addition to considering the results of these third-party valuations, Tvardi's board of directors considered various objective and subjective factors to determine the fair value of its common stock as of each grant date, including:

- the prices at which Tvardi sold shares of its preferred stock and the superior rights and preferences of the preferred stock relative to its common stock at the time of each grant;
- the lack of an active public market, for Tvardi's common stock and preferred stock;
- the progress of Tvardi's research and development programs, including the status and results of preclinical studies and clinical trials for its product candidates;
- Tvardi's stage of development and commercialization and its business strategy, and material risks to its business;
- external market conditions affecting the pharmaceutical and biopharmaceutical industry and trends within each industry;
- Tvardi's financial position, including cash on hand, and its historical and forecasted performance and operating results;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of Tvardi in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if Tvardi had used significantly different assumptions or estimates, the fair value of its common stock and its stock-based compensation expense could have been materially different. For the nine months ended September 30, 2024 and year ended December 31, 2023, if there was a 10% increase in the valuation of its common stock at each of the valuation dates listed above and to the underlying exercise price of stock options granted during the year assuming that such options were granted with an exercise price equal to the fair value of common stock, the impact to its stock-based compensation expense would not be material. If there was a 10% decrease in the valuation of its common stock at each of the valuation dates listed above and to the underlying exercise price of stock options were granted with an exercise price and to the underlying exercise price of stock options were granted with an exercise price and to the underlying exercise price of stock options granted during the year assuming that such options were granted during the year assuming that such options were granted with an exercise price of stock options granted during the year assuming that such options were granted with an exercise price equal to the fair value of common stock, the impact to its stock-based compensation expense would not be material for the nine months ended September 30, 2024 and year ended December 31, 2023. Tvardi's estimate of fair value is reviewed and approved by its board of directors.

Once a public trading market for Tvardi's common stock has been established in connection with the completion of this Merger, it will no longer be necessary for Tvardi's board of directors to estimate the fair value of its common stock in connection with its accounting for stock options and other such awards Tvardi may grant, as the fair value of its common stock will be determined based on the quoted market price of its common stock.

Options Granted

The following table summarizes by grant date the number of shares subject to options granted from January 1, 2023 through the date of this proxy statement/prospectus, the per share exercise price of the

options, the per share fair value of common stock underlying the options on each grant date and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject to Options Granted	Per Share Exercise Price of Options	Per Share Fair Value of Common Stock	Per Share Estimated Fair Value of Options
January 12, 2023	607,129	\$0.82	\$0.82	\$0.52
June 27, 2023	60,000	\$0.82	$0.82^{(1)}$	\$0.52
June 27, 2023	20,000	\$0.82	$0.82^{(1)}$	\$0.53
January 31, 2024	25,000	\$0.92	\$0.92	\$0.62

(1) At the time of the options grants on June 27, 2023, Tvardi's board of directors determined that the fair value of its common stock of \$0.82 per share, calculated by its third-party valuation as of June 30, 2022, reasonably reflected the per share fair value of its common stock as of the grant date. Tvardi applied the fair value of common stock from its retrospective fair value assessment to determine the fair value of the June 27, 2023 awards, noting an immaterial incremental stock-based compensation expense to be recorded for accounting purposes of approximately \$2,000.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact Tvardi's financial position and results of operations is disclosed in Note 2 to the unaudited condensed financial statements for the nine months ended September 30, 2024 and 2023 and in Note 2 to the financial statements for the years ended December 31, 2023 and 2022, included elsewhere in this proxy statement/prospectus.

Quantitative and Qualitative Disclosures About Market Risks

Interest Rate Risk

As of September 30, 2024 and December 31, 2023, Tvardi had \$9.4 million and \$22.9 million in cash and cash equivalents, respectively, which are primarily maintained in accounts with multiple financial institutions in the United States. Tvardi may maintain cash and cash equivalent balances in excess of Federal Deposit Insurance Corporation limits. Tvardi does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Tvardi's primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration and low risk profile of Tvardi's cash equivalents, it believes an immediate 10% change in interest rates would not have a material effect on their fair market value.

Effects of Inflation

Inflation generally affects Tvardi by increasing the cost of labor and research and development contract costs. Tvardi does not believe inflation has had a material effect on its results of operations during the periods presented in its financial statements included elsewhere in this proxy statement/prospectus.

Foreign Currency Exchange Risk

All of Tvardi's employees and its operations are currently located in the United States, and expenses are generally denominated in U.S. dollars. As such, Tvardi is not exposed to financial risks from exchange rate fluctuations between U.S. dollars and other currencies.

MANAGEMENT FOLLOWING THE MERGER

The following table provides information regarding the expected directors and executive officers of the combined company following the closing of the Merger:

Name Age	Position
Imran Alibhai, Ph.D. 48	Chief Executive Officer and Director
Dan Conn, J.D., M.B.A. 57	Chief Financial Officer
John Kauh, M.D. 51	Chief Medical Officer
Jeffrey Larson, Ph.D., DABT 63	Senior Vice President, Research & Development
Yixin "Joseph" Chen, Ph.D. 64	Vice President, Chemistry, Manufacturing and Controls
Sujal Shah 51	Chairman of the Board
Wallace Hall 62	Director
Shaheen Wirk, M.D. 47	Director
Michael Wygza 69	Director

Executive Officers

Imran Alibhai, Ph.D. has served as Tvardi's Chief Executive Officer and a member of its board of directors since December 2018. Since 2018, Dr. Alibhai has also served on the Scientific Advisory Board for NASA's Translational Research Institute for Space Health. Prior to serving as Tvardi's Chief Executive Officer, Dr. Alibhai was a Senior Vice President and Managing Director of DNAtrix, a clinical stage biotechnology company developing oncolytic viruses for cancer from 2014 to 2018. From 2010 to 2013, Dr. Alibhai was an investment banker in Peter J. Solomon's Healthcare Advisory Group, focused on M&A transactions in science-based markets including biopharmaceuticals, medical devices/diagnostics and life science tools. From 2007 to 2010, Dr. Alibhai served as the Senior Director at Alexandria Venture Investments, where he was responsible for investments in emerging companies and funds in the healthcare sector. From 2006 to 2007, he directed investments for PIPE's and long/short positions in MPM Capital's BioEquities hedge fund. Dr. Alibhai received a Ph.D. in Molecular Neuroscience from the University of Texas Southwestern Medical School and a B.S. in Biology from Duke University. We believe that Dr. Alibhai's scientific and medical expertise, as well as his industry, academic and leadership roles, and his knowledge of the Company as Chief Executive Officer, makes him well qualified to serve on the combined company board of directors.

Dan Conn, J.D., M.B.A. has served as Tvardi's Chief Financial Officer since January 2022. Previously, Mr. Conn held multiple positions at Christie's International Real Estate, including Chief Operating Officer from January 2014 to October 2014 and Chief Executive Officer and a member of the board of directors from October 2014 to November 2021. In these roles, Mr. Conn managed Christie's global real estate brand licensing and brokerage business and focused on expanding the business into new areas and strategic development. From January 2012 to January 2014, Mr. Conn served as Senior Vice President of Asset Management at Brookfield Asset Management. Prior to that, he served as a Director in the Restructuring Advisory Group of Peter J. Solomon Company from June 2010 to March 2012. Mr. Conn received an M.B.A. from the Anderson School of Business at the University of California, Los Angeles and a J.D. and B.A. in Philosophy from the University of Toronto.

John Kauh, M.D. has served as Tvardi's Chief Medical Officer since January 2023. Prior to that, Dr. Kauh held multiple positions at HUTCHMED, including serving as Vice President of Clinical Development from September 2020 to February 2023 and Executive Director, Clinical Development from September 2018 to September 2020. In these roles, he oversaw clinical development of agents ranging from Phase 1 to Phase 3 and provided medical oversight to various global clinical trials evaluating smallmolecule inhibitors in oncology and personally led the NDA and MAA regulatory submissions for surufatinib. From May 2017 to September 2018, Dr. Kauh served as the Executive Director of Clinical Science — Oncology at Glenmark Pharmaceuticals. From November 2013 to May 2017, he served as the Senior Medical Director at ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company. Dr. Kauh received an M.D. from Kimmel College of Medicine (formerly known as Jefferson Medical College) and a B.S. in Science from Penn State University.

Jeffrey Larson, Ph.D., DABT has served as Tvardi's Senior Vice President, Research & Development, since November 2020. Since November 2016, he has also served a member of the Houston Methodist Academic Institute, Translational Research Initiative External Advisory Board. From June 2018 to November 2020, Dr. Larson served as Vice President of Product Development at Iterion Therapeutics, where he oversaw chemistry manufacturing and controls, regulatory affairs, and quality and nonclinical research and development. From December 2015 to June 2018, Dr. Larson served as Vice President, Nonclinical Development at Beta Cat Pharmaceutical, which is now Iterion Therapeutics. From December 2015 to February 2019, Dr. Larson also served as Vice President, Nonclinical Development at Salarius Pharmaceuticals. Dr. Larson received a Ph.D. in Toxicology/Pharmacology from Washington State University and a B.A. in Environmental Science from Minot State University.

Yixin "Joseph" Chen, Ph.D. has served as Tvardi's Vice President, Chemistry, Manufacturing and Controls, since October 2021. From March 2015 to October 2021, Dr. Chen served as the Owner and President of Cheminopti LLC, a consulting firm, where he provided strategic guidance and technical leadership for all aspects of CMC development. From September 2019 to October 2021, Dr. Chen served as the Director of Pharmaceutical Development and Manufacturing at SIGA Technology, Inc., a commercialstage pharmaceutical company, where he oversaw both drug substance and drug product CMC activities for early-stage development and commercialization in the United States and European Union. Dr. Chen received a Ph.D. in analytical chemistry from the University of Memphis, Tennessee and B.S. and M.S degrees in Chemical Engineering from Tianjin University, China.Non-Employee Directors

Non-Employee Directors

Sujal Shah has served as a member of Tvardi's board of directors since January 2021 and as Chairman of the board of directors since March 2024. Mr. Shah served as President and Chief Executive Officer at CymaBay Therapeutics from April 2017 until the sale of the company to Gilead Sciences for \$4.3 billion in March 2024. Mr. Shah joined CymaBay as Chief Financial Officer in 2012, taking the company public in 2013. Prior to CymaBay, Mr. Shah was a healthcare investment banker for Citigroup from 2010 to 2012 and Credit Suisse First Boston from 2004 to 2010, where he was responsible for managing client relationships and executing strategic and financing related transactions for clients focused on life sciences. Mr. Shah also serves as a director at Opthea Limited, an Australia based clinical-stage biopharmaceutical company. Mr. Shah received an M.B.A. from the Carnegie Mellon University Tepper School of Business, where he currently serves on the Business Board of Advisors, and M.S. and B.S. degrees in Biomedical Engineering from Northwestern University. We believe Mr. Shah's extensive executive experience managing the operational and financial issues of biopharmaceutical companies provide him with the qualifications and skills to serve on the combined company board of directors.

Wallace Hall has served as a member of Tvardi's board of directors since June 2018. Mr. Hall cofounded and has served as the President of Wetland Partners, LP, which is primarily engaged in wetland mitigation banking and oil & gas investment from February 1999 to present. Mr. Hall also co-founded BioMatrix Partners, an investment partnership focused on public and private biotechnology companies, where he has served as Limited Partner from October 2013 to present. From February 2011 to February 2017, Mr. Hall served on the University of Texas System Board of Regents. Mr. Hall also serves as a director at Vooks, Inc., a private company. Mr. Hall received a B.A. in Economics from the University of Texas at Austin. We believe Mr. Wallace is qualified to serve on the combined company board of directors because of his business expertise and experience serving as an investment partner to both public and private biotechnology companies.

Shaheen Wirk, M.D. has served as a member of Tvardi's board of directors since March 2024 and as a special advisor to management and the board since January 2021. Dr. Wirk is the founder of Palkon Capital Management, a health-care dedicated investment firm, where he has served as the Chief Investment Officer since August 2013. From May 2001 to 2012, Dr. Wirk served as a Healthcare Analyst at Bridger Capital LLC. Dr. Wirk received his M.D., M.B.A., and B.S. in Biology from Duke University. We believe Dr. Wirk is qualified to serve on the combined company board of directors due to his educational background and extensive experience in the life science industry as an analyst and investor.

Michael S. Wyzga has been a member Tvardi's board of directors since March 2021. Since November 2013, Mr. Wyzga has served as the President of MSW Consulting Inc., a strategic consulting group focused in the life sciences area. From December 2011 until November 2013, Mr. Wyzga served as President and Chief Executive Officer and a member of the board of directors of Radius Health, Inc., a publicly traded biopharmaceutical company. Prior to that, Mr. Wyzga served in various senior management positions at Genzyme Corporation, a publicly traded global biotechnology company. Mr. Wyzga joined Genzyme in February 1998 and most recently served as Executive Vice President, Finance from May 2003 until November 2011 and as Chief Financial Officer from July 1999 until November 2011.Mr. Wyzga is also the Chairman of the board of directors of X4 Pharmaceuticals, Inc., a public company since July 2018, Chairman of the board of directors of GenSight Biologics S.A., a Euronext traded biopharmaceutical company, where he has served since July 2015, and Chairman of the board of directors of Mereo BioPharma Group plc (formerly Oncomed Pharmaceuticals, Inc.), where he served from October 2013 through the business combination in April 2019. He received an M.B.A. from Providence College and a B.S. from Suffolk University. We believe that Mr. Wyzga's senior management experience at biopharmaceutical and biotechnology companies, his current and past experience on boards of directors of public companies, and his financial expertise qualifies him to serve as a member of the combined company board of directors.

Family Relationships

There are no family relationships among any of Cara's current directors and executive officers, and there are no family relationships among any of the combined company's proposed directors and executive officers.

Composition of the Board of Directors Following the Merger

Cara's Board is divided into three classes. Each class has a three-year term. Vacancies on the Cara Board shall remain open unless the Cara Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders, except as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum or by the sole remaining director. A director elected by the Cara Board to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified.

Pursuant to the Merger Agreement, each of the directors and officers of Cara who will not continue as directors or officers of the combined company following the completion of the Merger shall resign immediately prior to the Effective Time. Following the completion of the Merger, the Combined Company Board anticipates that it will consist of seven directors and will be comprised of five members designated by Tvardi (Sujal Shah, Michael Wyzga, Wallace Hall, Shaheen Wirk and Imran Alibhai), one member to be designated by Cara prior to Closing and one vacancy, to be designated by Tvardi if prior to the closing of the Merger or by the combined company if following the consummation of the Merger.

Independence of the Board of Directors

Nasdaq Rule 5605 requires a majority of a listed company's board of directors to be comprised of independent directors. In addition, Nasdaq requires that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of the Combined Company Board, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

It is anticipated that each individual expected to serve on the Combined Company Board upon the completion of the Merger, other than Imran Alibhai will qualify as an independent director under the Nasdaq listing standards.

Board Leadership Structure

The Combined Company Board shall be chaired by Sujal Shah. Mr. Shah is an independent director. The Chairperson has authority, among other things, to establish the agenda for meetings of the independent directors of the Board and to preside over meetings of the independent directors and any portions of the meetings of the Board evaluating the performance of the Board. Our management believes that this governance structure creates an environment that is conducive to objective evaluation and independent oversight, thereby improving the effectiveness of the Board as a whole.

Role of Board in Risk Oversight

One of the key functions of the Combined Company Board will be to oversee the combined company's risk management process. The Combined Company Board is not anticipated to have a standing risk management committee, but rather expects to administer this oversight function directly through the Combined Company Board as a whole, as well as through various standing committees of the Combined Company Board that address risks inherent in their respective areas of oversight. In particular, Combined Company Board will be responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for the combined company, The Combined Company Board is also expected to focus on emerging risks, as well as risk mitigation strategies. The audit committee of the Combined Company Board (Audit Committee) will have the responsibility to consider and discuss, with management and the combined company's independent auditors, the major financial risk exposures and the steps its management should take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management will be undertaken. The Audit Committee is also expected to monitor compliance with legal and regulatory requirements, as well as cyber-security risk, in addition to oversight of the combined company's internal control over financial reporting and disclosure controls and procedures. The Compensation Committee will also assess and monitor whether any of the combined company's compensation policies and programs has the potential to encourage excessive risk taking.

Committees of the Combined Company Board

The Combined Company Board will have an Audit Committee, a Compensation Committee and a nominating and corporate governance committee (Nominating and Corporate Governance Committee, and together with the Audit Committee and the Compensation Committee, the Committees), each of which will have the composition and the responsibilities described below. It is anticipated that each member of the Committees will be an independent director as that term is defined by the SEC and Nasdaq. Each of the Committees has the authority, as its members deem appropriate, to engage legal counsel or other experts or consultants in order to assist the Committee in carrying out its responsibilities.

Audit Committee

The Audit Committee assists the Combined Company Board by providing oversight of financial management, independent auditor and financial reporting procedures, as well as such other matters as directed by the Combined Company Board or the Audit Committee Charter. Among other things, the Audit Committee's responsibilities include:

- evaluating the performance of and assesses the qualifications of the independent auditors;
- determining and approving the engagement of the independent auditors;
- determining whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors;
- reviewing and approving the retention of the independent auditors to perform any proposed permissible non-audit services;
- monitoring the rotation of partners of the independent auditors on the combined company's audit engagement team as required by law;
- reviewing and approving or reject transactions between the combined company and any related persons;



- conferring with management and the independent auditors regarding the effectiveness of internal controls over financial reporting, the objectivity of the combined company's financial reporting and the combined company's accounting policies and practices;
- establishing procedures, as required under applicable law, for the receipt, retention and treatment of
 complaints received by the combined company regarding accounting, internal accounting controls or
 auditing matters and the confidential and anonymous submission by employees of concerns
 regarding questionable accounting or auditing matters; and
- meeting to review the combined company's annual audited financial statements and quarterly
 financial statements with management and the independent auditor, including a review of the
 combined company's disclosures under "Management's Discussion and Analysis of Financial
 Condition and Results of Operations."

The Audit Committee of the combined company is expected to retain these duties and responsibilities following the completion of the Merger.

Following the completion of the Merger, the members of the combined company's Audit Committee are expected to be , who is expected to be the Chair, and . All members of the Audit Committee will meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq and will qualify as an audit committee financial expert as defined under the applicable rules of the SEC and have the requisite financial sophistication as defined under the applicable rules and regulations of Nasdaq. Under the rules of the SEC, members of the Audit Committee must also meet heightened independence standards. Cara and Tvardi believe that, following the completion of the Merger, each member of the Audit Committee will be independent under the applicable rules of the SEC and Nasdaq. The Audit Committee will operate under a written charter that will satisfy the applicable standards of the SEC and Nasdaq.

Compensation Committee

The Compensation Committee reviews the performance and development of management in achieving corporate goals and objectives and assures that the combined company's executive officers (including the chief executive officer) are compensated effectively in a manner consistent with the combined company's strategy, competitive practice and stockholder interests, as well as such other matters as directed by the Combined Company Board or the Compensation Committee Charter. Among other things, the Compensation Committee's responsibilities include:

- establishment of corporate and individual performance objectives relevant to the compensation, including incentive-based and equity-based compensation, of the combined company's Chief Executive Officer and evaluation of performance in light of these stated objectives;
- review and approval of the corporate and individual performance objectives of the combined company's other executive officers;
- review and approval of the compensation and other terms of employment or service, including severance and change-in-control arrangements, of the combined 's Chief Executive Officer;
- setting the compensation of the Company's other executive officers and directors based in part on recommendations of the Chief Executive Officer;
- administration of the Company's equity compensation plans, 401(k) plan, and other similar plans and programs;
- preparing a compensation committee report on executive compensation as may be required from time to time to be included in the Company's annual proxy statements or annual reports on Form 10-K filed with the SEC;
- reviewing and discussing with management the Company's Compensation Discussion and Analysis that the Company may be required from time to time to include in proxy statements and other SEC filings and considers whether to recommend that it be included in such filings; and



• overseeing risk management of our compensation programs, policies and practices, including an annual review of our programs to ensure that they are not reasonably likely to incentivize employee behavior that would result in any material adverse risk to the Company.

The Compensation Committee has the authority to form and delegate authority to one or more subcommittees as it deems appropriate from time to time under the circumstances. The Compensation Committee annually reviews the performance of each of the executive officers, including the chief executive officer. In accordance with the authority granted to it, the Committee then either determines the compensation of each executive officer or makes recommendations regarding such compensation to the Combined Company Board for approval.

The Compensation Committee of the combined company is expected to retain these duties and responsibilities following the completion of the Merger.

Following the completion of the Merger, the members of the Compensation Committee are expected to be , who is expected to be the Chair, and . To qualify as independent to serve on the combined company's Compensation Committee, the Nasdaq listing standards require a director not to accept any consulting, advisory, or other compensatory fee from the combined company, other than for service on the Combined Company Board, and that the Combined Company Board consider whether a director is affiliated with the combined company and, if so, whether such affiliation would impair the director's judgment as a member of the combined company's Compensation Committee. Cara and Tvardi believe that, after the completion of the Merger, the composition of the Compensation Committee will meet the requirements for independence under, and the functioning of such Compensation Committee will comply with any applicable requirements of the rules and regulations of Nasdaq and the SEC.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee identifies qualified individuals for membership on the Combined Company Board, recommends to the Combined Company Board the director nominees to fill vacancies on the Combined Company Board and to stand for election at the next annual meeting of stockholders, develops and recommends to the Combined Company Board a set of corporate governance guidelines for the Combined Company Board and provides oversight of the corporate governance affairs of the Combined Company Board, as well as such other matters as directed by the Combined Company Board or the Nominating and Corporate Governance Charter. Among other things, the Nominating and Corporate Governance Committee's responsibilities include:

- assessing the need for new directors;
- identifying, reviewing and evaluating candidates to serve as directors of the combined company (consistent with criteria approved by the Combined Company Board);
- reviewing and evaluating incumbent directors' performance, participation and qualifications;
- recommending to the Combined Company Board candidates for selection to the Combined Company Board;
- making recommendations to the Combined Company Board regarding the membership of the committees of the Combined Company Board;
- monitoring the quality of the relationship between management and the Combined Company Board;
- · annually assessing the performance of the Combined Company Board; and
- developing and monitoring a set of corporate governance principles for the combined company.

The Nominating and Corporate Governance Committee is responsible for identifying individuals that the Nominating and Corporate Governance Committee believes are qualified to become members of the Combined Company Board.

Following the completion of the Merger, the members of the Nominating and Corporate Governance Committee are expected to be , who will serve as Chair, and . Each of the



members of the combined company's Nominating and Corporate Governance Committee will be independent under the applicable rules and regulations of Nasdaq relating to nominating and corporate governance committee independence. Cara's Board has adopted a written Nominating and Corporate Governance Committee charter available to stockholders.

The Nominating and Corporate Governance Committee regularly reviews director competencies, qualities and experiences, with the goal of ensuring that the Combined Company Board is comprised of an effective team of directors who function collegially and who are able to apply their experience toward meaningful contributions to our business strategy and oversight of our performance, risk management, organizational development and succession planning.

The Nominating and Corporate Governance Committee of the combined company is expected to retain these responsibilities following completion of the Merger.

Compensation Committee Interlocks and Insider Participation

In connection with the completion of the Merger, the Combined Company Board is expected to select members of the Compensation Committee. Each member of the Compensation Committee is expected to be a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. None of the proposed members of the of the Compensation Committee was or is one of the combined company's officers or employees, and none of the combined company's executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers who is proposed to serve on the combined company's Board of Directors or Compensation Committee following the completion of the Merger.

Corporate Governance Guidelines

Following the completion of the Merger, the Combined Company Board expects to retain the Corporate Governance Guidelines adopted by Cara, which are designed to ensure effective corporate governance of the combined company. The guidelines cover topics including, but not limited to, board composition and selection, board meetings and involvement of senior management, chief executive officer performance evaluation and succession planning, and board committees and compensation. The Corporate Governance Guidelines will be reviewed periodically by the Nominating and Corporate Governance Committee and amended by the Combined Company Board when appropriate.

Code of Business Conduct and Ethics

The Combined Company Board will maintain a Code of Business Conduct and Ethics that applies to all directors, officers and employees, including the combined company's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Code of Business Conduct and Ethics will cover fundamental ethical and compliance-related principles and practices such as conflicts of interest, compliance with laws, use of our assets and business ethics. The Code of Business Conduct and Ethics, and any applicable waivers or amendments, will be made available on the combined company's website.

TVARDI'S EXECUTIVE AND DIRECTOR COMPENSATION

Executive Compensation

This section provides an overview of Tvardi's executive compensation programs as they relate to the executive officers named below (named executive officers), including a narrative description of the material factors necessary to understand the information disclosed in the summary compensation table below. For the year ended December 31, 2023, Tvardi's named executive officers were:

- Imran Alibhai, Ph.D., Tvardi Chief Executive Officer and Director;
- John Kauh, M.D., Tvardi Chief Medical Officer; and
- Dan Conn, J.D., M.B.A., Tvardi Chief Financial Officer.

2023 Summary Compensation Table

The following table presents all of the compensation awarded to or earned by or paid to Tvardi's named executive officers during the fiscal year ended December 31, 2023.

Name and Principal Position	Fiscal Year	Salary (\$)	Bonus (\$)	Option Awards (\$) ⁽¹⁾	All Other Compensation (\$) ⁽³⁾	Total (\$)
Imran Alibhai, Ph.D.	2023	535,000	_	_	28,757	563,757
Chief Executive Officer and Director						
John Kauh, M.D.	2023	369,445 ⁽⁴⁾	135,466 ⁽²⁾	288,455	25,989	819,355
Chief Medical Officer						
Dan Conn, J.D., M.B.A.	2023	370,000	—			370,000
Chief Financial Officer						

(1) Amounts reflect the full grant-date fair value of options awards granted during 2023 computed in accordance with Financial Accounting Standards Board (FASB), Accounting Standard Codification (ASC), Topic 718, rather than the amounts paid to or realized by the named executive officer. See Note 10 to Tvardi's financial statements included elsewhere in this proxy statement/prospectus for a discussion of the assumption used in the calculation. All of the option awards were granted under the 2018 Plan, the terms of which plan are described below under "— Equity Benefit Plans — 2018 Stock Incentive Plan."

- (2) The amount stated reflects (i) a one-time sign-on advance in an amount of \$25,000 paid to Dr. Kauh in connection with his commencement of employment with Tvardi and (ii) a discretionary bonus in an amount of \$110,466 earned for 2023 performance and paid in 2024, as further described below under "— Narrative to the Summary Compensation Table Annual Performance Bonus Opportunity."
- (3) Amounts shown represent (i) premium payments that Tvardi made in 2023 on behalf of Drs. Alibhai and Kauh for certain health plan benefits coverage in the amounts of \$28,232 and \$25,989, respectively, and (ii) airline club fees Tvardi paid in 2023 on behalf of Dr. Alibhai in the amount of \$525.
- (4) The amount stated reflects the prorated portion of Dr. Kauh's annual base salary from the commencement of his employment as Tvardi Chief Medical Officer on January 30, 2023.

Narrative to the Summary Compensation Table

Tvardi's board of directors reviews compensation annually for all employees, including its named executive officers. In making compensation determinations, Tvardi considers compensation for comparable positions in the market, individual performance as compared to its expectations and objectives, its desire to motivate its employees to achieve short- and long-term results that are in the best interests of its stockholders and a long-term commitment to its company.

Tvardi's board of directors has historically determined its executive officers' compensation and has typically reviewed and discussed management's proposed compensation with its chief executive officer for

all executives other than its chief executive officer. Based on those discussions and its discretion, its board of directors then approved the compensation of each executive officer. Following the completion of this Merger, the compensation committee will determine its executive officers' compensation in accordance with the terms of its written charter.

Annual Base Salary

Base salaries for Tvardi executive officers are initially established through arm's-length negotiations at the time of the executive officer's hiring, taking into account such executive officer's qualifications, experience, the scope of such executive officer's responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, typically in connection with Tvardi's annual review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, experience and adjustments to reflect cost of living increases. In making decisions regarding salary increases, Tvardi may also draw upon the experience of members of its board of directors with executives at other companies.

The 2023 annual base salaries for its named executive officers are set forth in the table below:

Name	Base Salary (\$)
Imran Alibhai, Ph.D.	535,000
John Kauh, M.D. ⁽¹⁾	400,000
Dan Conn, J.D., M.B.A.	370,000

 The amount stated in the Summary Compensation Table above reflects the prorated portion of Dr. Kauh's annual base salary from the commencement of his employment as Tvardi's Chief Medical Officer on January 30, 2023.

Annual Performance Bonus Opportunity

In 2023, Tvardi named executive officers were eligible to receive discretionary annual performance bonuses based on individual performance, company performance or as otherwise determined appropriate, as determined by its board of directors. For 2023, each of Drs. Alibhai and Kauh and Mr. Conn were eligible to receive a target bonus equal to 50%, 30% and 30% of his base salary, respectively. In January 2024, Tvardi board of directors approved and paid an annual performance bonus for Dr. Kauh in the amount of \$110,466, as reflected in the "Bonus" column of the Summary Compensation Table above. Dr. Alibhai and Mr. Conn elected not to participate in the bonus pool for 2023.

Equity-Based Incentive Awards

Tvardi's equity award program is the primary vehicle for offering long-term incentives to its executive officers. Tvardi believes that equity awards provide its executives with a strong link to its long-term performance, creates an ownership culture and helps to align the interests of its executives and its stockholders. To date, Tvardi has used stock option grants for this purpose because believes they are an effective means by which to align the long-term interests of its executive officers with those of its stockholders. Tvardi believes that its equity awards are an important retention tool for its executive officers, as well as for its other employees. Grants to its executive officers and other employees have historically been made at the discretion of its board of directors and are not made at any specific time period during a year.

In January 2023, in connection with his commencement of employment with Tvardi, Tvardi granted Dr. Kauh a stock option to purchase 552,129 shares of its common stock. The option has an exercise price of \$0.82 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting on the first anniversary of the vesting commencement date and the balance vesting monthly over 36 months thereafter, subject to Dr. Kauh's continued service with Tvardi.

Outstanding Equity Awards as of December 31, 2023

The following table provides information regarding outstanding equity awards held by Tvardi's named executive officers as of December 31, 2023.

			Option Awards ⁽¹⁾⁽²⁾			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share (\$)	Option Expiration Date
Imran Alibhai, Ph.D.	01/16/2019	12/01/2018	1,550,000	—	0.09	01/15/2029
	01/30/2021	01/01/2020	14,687	313	0.09	01/29/2031
	12/16/2021	06/04/2021	750,000	450,000	0.63	12/15/2031
John Kauh, M.D.	01/12/2023	01/30/2023	_	552,129	0.82	01/11/2033
Dan Conn, J.D., M.B.A	02/04/2022	01/12/2022	318,166	345,834	0.82	02/03/2032

(1) All of the option awards were granted under the 2018 Plan, the terms of which plan are described below under "— Equity Benefit Plans — 2018 Stock Incentive Plan."

(2) Stock option awards vest over a period of four years with 25% of the shares underlying the option vesting on the one-year anniversary of the vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

Awards held by certain of Tvardi named executive officers are eligible for accelerated vesting under specified circumstances. Please see the subsection titled "— *Potential Payments and Benefits Upon Termination or Change in Control*" below for a description of such potential acceleration.

Pension Benefits

Tvardi's named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by Tvardi during the fiscal year ended December 31, 2023.

Nonqualified Deferred Compensation

Tvardi's named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by Tvardi during the fiscal year ended December 31, 2023.

Employment Agreements

Below are descriptions of Tvardi employment arrangements with its named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with its named executive officers, see the subsection titled "— Potential Payments and Benefits upon Termination or Change in Control" below.

Imran Alibhai, Ph.D. Tvardi entered into an offer letter agreement with Dr. Alibhai in November 2018, which governs the current terms of his employment with Tvardi. The agreement has no specific term and provides for at-will employment. Pursuant to the agreement, Dr. Alibhai is entitled to an annual base salary and is eligible to receive an annual performance bonus with a target equal to a pre-determined percentage of his annual base salary, based on the achievement of individual performance and company performance as determined by its board of directors. Dr. Alibhai's agreement also provides for certain severance benefits, as described below under the subsection titled "*Potential Payments and Benefits upon Termination or Change in Control.*"

John Kauh, M.D. Tvardi entered into an offer letter agreement with Dr. Kauh in December 2022, which governs the current terms of his employment with Tvardi. The agreement has no specific term and provides for at-will employment. Pursuant to the agreement, Dr. Kauh is entitled to an annual base salary and is eligible to receive an annual performance bonus with a target equal to a pre-determined percentage of his annual base salary, based on the achievement of individual performance and company performance as determined by its board of directors. Dr, Kauh's agreement provided for an initial option grant, which was



awarded in January 2023, and a sign-on advance, which was paid in 2023 and subject to repayment for one year following Dr. Kauh's commencement of services. Dr. Kauh's agreement also provides for certain severance benefits, as described below under the subsection titled "— *Potential Payments and Benefits upon Termination or Change in Control.*"

Dan Conn, J.D., M.B.A. Tvardi entered into an offer letter agreement with Mr. Conn in January 2022, which governs the current terms of his employment with Tvardi. The agreement has no specific term and provides for at-will employment. Pursuant to the agreement, Mr. Conn is entitled to an annual base salary and is eligible to receive an annual performance bonus with a target equal to a pre-determined percentage of his annual base salary, based on the achievement of individual performance and company performance as determined by its board of directors. Mr. Conn's agreement also provides for certain severance benefits, as described below under the subsection titled "— Potential Payments and Benefits upon Termination or Change in Control."

Potential Payments and Benefits upon Termination or Change in Control

Regardless of the manner in which a named executive officer's service terminates, each named executive officer is entitled to receive amounts earned during his term of service, including unpaid salary.

Pursuant to the terms of Dr. Alibhai's offer letter agreement, if Tvardi terminates his employment without "cause" or if he resigns for "good reason" (each as defined in his offer letter agreement), Dr. Alibhai will be entitled to receive, subject to his execution and non-revocation of a severance and release of claims agreement in a form prescribed by Tvardi, (i) continued payment of his then-current base salary for a "severance period" of six months, plus one additional month for each full year of employment with Tvardi (not to exceed a total severance period of 10 months), (ii) premiums for COBRA continuation coverage for such severance period and (iii) 24 months of accelerated vesting of all of his outstanding and unvested equity awards as of the date of his termination of employment. Furthermore, if within three months prior to, or within 12 months following, a "change of control" (as defined in his offer letter agreement), Dr. Alibhai's employment is terminated without cause or if he resigns for good reason, Dr. Alibhai will instead be entitled to receive, subject to his execution and non-revocation of a severance and release of claims agreement in a form prescribed by Tvardi, (i) continued payment of his then-current base salary for a severance period of 12 months, (ii) premiums for COBRA continuation coverage for such severance period of 12 months, (ii) premiums for COBRA continuation coverage for such severance period of 12 months, (ii) premiums for COBRA continuation coverage for such severance period of 12 months, (ii) premiums for COBRA continuation coverage for such severance period of 12 months, (ii) premiums for COBRA continuation coverage for such severance period and (iii) full accelerated vesting of all of his outstanding and unvested equity awards.

Pursuant to the terms of Dr. Kauh's offer letter agreement, if Tvardi terminates his employment without "cause" or if he resigns for "good reason" (each as defined in his offer letter agreement), Dr. Kauh will be entitled to receive, subject to his execution and non-revocation of a severance and release of claims agreement in a form prescribed by Tvardi, (i) continued payment of his then-current base salary for a "severance period" of six months, (ii) premiums for COBRA continuation coverage for such severance period, and (iii) vesting of 12.5% of his outstanding and unvested equity awards as of the separation date. Furthermore, if within three months prior to, or within 12 months following, a "change of control" (as defined in his offer letter agreement), Dr. Kauh's employment is terminated without cause or if he resigns for good reason, Dr. Kauh will instead be entitled to receive, subject to his execution and non-revocation of a severance and release of claims agreement in a form prescribed by Tvardi, (i) continued payment of his then-current base salary for a severance period of 12 months, (ii) premiums for COBRA continuation coverage for such severance period, and (iii) full accelerated vesting of all of his outstanding and unvested equity awards.

Pursuant to the terms of Mr. Conn's offer letter agreement, if Tvardi terminates his employment without "cause" or if he resigns for "good reason" (each as defined in his offer letter agreement), Mr. Conn will be entitled to receive, subject to his execution and non-revocation of a severance and release of claims agreement in a form prescribed by Tvardi, (i) continued payment of his then-current base salary for a "severance period" of six months, plus one additional month for each full year of employment with Tvardi (not to exceed a total severance period of 10 months), plus any pay in lieu of any unused accrued vacation, (ii) premiums for COBRA continuation coverage for a period of six months, plus one additional month for each full year of employment with Tvardi, and (iii) vesting of all outstanding and unvested equity awards that would have vested in accordance with the vesting schedule set forth in his offer letter agreement as if he had remained employed by Tvardi until the end of his relevant severance period. Furthermore, if within

three months prior to, or within 12 months following, a "change of control" (as defined in his offer letter agreement), Mr. Conn's employment is terminated without cause or if he resigns for good reason, Mr. Conn will instead be entitled to receive, subject to his execution and non-revocation of a severance and release of claims agreement in a form prescribed by Tvardi, (i) continued payment of his then-current base salary for a severance period of 12 months, (ii) premiums for COBRA continuation coverage for a period of six months, plus one additional month for each full year of employment with Tvardi, and (iii) full accelerated vesting of all of his outstanding and unvested equity awards.

Tvardi's named executive officers' stock awards granted prior to this Merger are subject to the terms of the 2018 Plan; a description of the termination and change in control provisions in the 2018 Plan and options granted thereunder is provided below under "*— Equity Benefit Plans — 2018 Stock Incentive Plan.*"

Other Compensation and Benefits

All of Tvardi's current named executive officers are eligible to participate in its employee benefit plans, in each case on the same basis as all of its other employees. These employee benefit plans include medical, dental, vision, short- and long-term disability and life and accidental dismemberment insurance plans. Tvardi pays the premiums for the medical, dental and vision insurance plans for certain of its named executive officers. Tvardi otherwise generally does not provide perquisites or personal benefits to its named executive officers.

Equity Benefit Plans

Tvardi believes that its ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of Tvardi's employees, consultants and directors with the financial interests of its stockholders. In addition, it believes that its ability to grant equity-based awards helps Tvardi to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to its business and financial success. The principal features of its equity incentive plan is summarized below. The summary is qualified in its entirety by reference to the actual text of the plan, which is filed as an exhibit to the Registration Statement of which this proxy statement/prospectus forms a part.

2018 Stock Incentive Plan

Tvardi's board of directors adopted, and its stockholders approved, the 2018 Plan in March 2018. The 2018 Plan was most recently amended in June 2021. Tvardi will not grant any additional awards under the 2018 Plan after the 2025 Plan becomes effective. However, any outstanding stock awards granted under the 2018 Plan will remain outstanding, subject to the terms of Tvardi's 2018 Plan and award agreements, until such outstanding options are exercised or until any stock awards terminate or expire by their terms. For a further discussion of the treatment of Tvardi stock awards in connection with the Merger, please see the section titled "*The Merger Agreement* — *Treatment of Tvardi Stock Options*" beginning on page <u>144</u> of this proxy statement/prospectus.

Types of Awards. The 2018 Plan allows for the grant of ISOs to Tvardi's employees and any of its subsidiary corporations' employees, and for the grant of nonqualified stock options, restricted stock, stock appreciation rights, restricted stock unit awards and other stock-based awards to its employees, officers, directors, consultants and advisors and those of Tvardi's subsidiary corporations.

Authorized Shares. Subject to certain capitalization adjustments, the aggregate number of shares of Tvardi's common stock that may be issued pursuant to stock awards under the 2018 Plan will not exceed 6,657,329 shares, all of which may be issued as ISOs. No shares will be available for future issuance under the 2018 Plan following the effectiveness of the Registration Statement of which this proxy statement/ prospectus forms a part. However, the 2018 Plan will continue to govern outstanding awards granted thereunder.

Plan Administration. The 2018 Plan is administered by Tvardi's board of directors or a committee appointed by it (referred to herein as the plan administrator). The plan administrator has authority to, among other things, grant awards and adopt, amend and repeal such administrative rules, guidelines and

practices relating to the 2018 Plan as it deems advisable. The plan administrator may construe and interpret the terms of the 2018 Plan and any award agreements entered into under the 2018 Plan. In addition, the plan administrator may correct any defect, supply any omission or reconcile any inconsistency in the 2018 Plan or any award.

Stock Options. The exercise price per share of all stock options granted under the 2018 Plan may not equal less than 100% of the fair market value per share of Tvardi's common stock on the date of grant. Options vest as determined by the plan administrator. The plan administrator will determine the methods of payment of the exercise price of an option, which may include cash, check, shares or certain other property or other consideration acceptable to the plan administrator. The term of a stock option may not exceed ten years, and in no event may an option be exercised later than the expiration of its term.

Changes to Capitalization. In the event of certain specified changes in the capital structure of Tvardi's common stock, such as a stock split, reverse stock split, stock dividend, reclassification or any other similar event or change in capital structure, (i) the number and class of securities available under the 2018 Plan, (ii) the number and class of securities and exercise price per share of each outstanding option and (iii) the number of shares subject to and the repurchase price per share subject to each outstanding award of restricted stock will be equitably adjusted by Tvardi in the manner determined by the plan administrator.

Reorganization Events. In the event of a reorganization event (as described below) the plan administrator may take one or more of the following actions with respect to all or any (or any portion of) options granted under the 2018 Plan (unless provided otherwise in a relevant option agreement or other agreement between Tvardi and a participant): (i) provide that such options be assumed or substituted for by the acquiring or succeeding corporation (or an affiliate thereof); (ii) upon written notice to a participant, provide that all of the participant's unexercised and/or unvested options be terminated immediately prior to such reorganization event unless exercised by the participant within a specified period; (iii) provide that outstanding options become exercisable in whole or in part prior to or upon such reorganization event; (iv) in the event of a reorganization event under the terms of which Tvardi common stock holders will receive a cash payment (referred to as the acquisition price) for each surrendered share, make or provide for a cash payment to participants with respect to each option held by a participant equal to (A) the number of shares of its common stock subject to the vested portion of the option (after giving effect to any vesting acceleration that occurs upon or immediately prior to such reorganization event) multiplied by (B) the excess, if any, of (1) the acquisition price over (2) the exercise price of such award and any applicable tax withholdings, in exchange for the termination of such option; (v) provide that, in connection with its liquidation or dissolution, options be converted into the right to receive liquidation proceeds or (vi) any combination of the foregoing.

For purposes of the 2018 Plan, a "reorganization event" means: (a) any merger or consolidation of the Company with or into another entity as a result of which all of its common stock is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of its common stock for cash, securities or other property pursuant to a share exchange or other transaction or (c) Tvardi's liquidation or dissolution.

The administrator is not obligated to treat all awards in the same manner. The administrator has the discretion, at any time, to provide that an award under the 2018 Plan will vest on an accelerated basis in connection with a corporate transaction or to amend or modify an award so long as such amendment or modification is not inconsistent with the terms of the 2018 Plan or would not result in the impairment of a participant's rights without the participant's consent.

Transferability. The 2018 Plan generally does not allow for the transfer or assignment of awards, other than, at the discretion of the plan administrator, by gift to family members or (other than ISOs) domestic relations orders or to an executor or guardian upon the death or disability of the participant.

Plan Amendment or Termination. Tvardi's plan administrator may amend, suspend or terminate the 2018 Plan at any time and for any reason, provided that (i) any modification or amendment does not materially and adversely affect the rights of participants under the 2018 Plan and (ii) stockholder approval is obtained where such approval is required by applicable law.

Non-Employee Director Compensation

Tvardi provides a \$25,000 annual cash retainer, paid in arrears in four quarterly installments, to Mr. Shah and Mr. Wyzga for their service on its board of directors. It also has a policy of reimbursing all of its non-employee directors for their reasonable out-of-pocket expenses in connection with attending board of directors and committee meetings.

It also from time to time provides equity compensation to certain non-employee directors for their service on its board of directors.

Tvardi has reimbursed and will continue to reimburse all of its non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

The following table sets forth information regarding compensation earned with respect to the fiscal year ended December 31, 2023, by each individual who served as a non-employee director during such fiscal year.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) ⁽²⁾⁽⁴⁾	All Other Compensation (\$) ⁽³⁾	Total (\$)
Sujal Shah ⁽¹⁾	25,000		1,173	26,173
Wallace Hall	_			_
Jamie McNab		_		
Michael Wyzga	25,000	50,402	2,716	78,118
Shaheen Wirk			—	

- (1) Mr. Shah is paid an annual cash retainer of \$25,000, payable in arrears in four quarterly installments, pursuant to the terms of a letter agreement with Tvardi. Tvardi intends to terminate Mr. Shah's letter agreement in connection with this Merger.
- (2) Amounts reflect the full grant-date fair value of options awards granted during 2023 computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718, rather than the amounts paid to or realized by the named individual. See Note 10 to Tvardi's financial statements included elsewhere in this proxy statement/prospectus for a discussion of the assumption used in the calculation. This amount does not reflect dollar amounts actually received by the nonemployee director or the economic value that may be received by a non-employee director.
- (3) Amounts shown represent \$1,173 and \$2,716 in travel expenses incurred in attending meetings of Tvardi's board of directors for Mr. Shah and Mr. Wyzga, respectively.
- (4) The following table provides information regarding the number of shares of common stock underlying options held by Tvardi non-employee directors that were outstanding as of December 31, 2023:

Name	Shares Underlying Outstanding Options as of December 31, 2023
Sujal Shah	137,500
Wallace Hall	
Jamie McNab	
Michael Wyzga	137,500
Shaheen Wirk	15,000



RELATED PERSON TRANSACTIONS OF THE COMBINED COMPANY

Cara Related Party Transactions

In addition to the information included below, you should review the "*Certain Relationships and Related Party Transactions*" section of Cara's Definitive Proxy Statement filed pursuant to Regulation 14A on April 22, 2024, which is filed with the SEC and incorporated by reference into this proxy statement/ prospectus.

Tvardi Related Party Transactions

The following includes a summary of transactions since January 1, 2021, and any currently proposed transactions to which Tvardi has been or is to be a party in which the amount involved exceeded or will exceed the lesser of \$120,000 or 1% of the average of its total assets as of December 31, 2022 and 2023, and in which any of its directors, executive officers or, to its knowledge, beneficial owners of more than 5% of its capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under the section titled "*Executive and Director Compensation*." Tvardi also describes below certain other transactions with its directors, executive officers and stockholders.

Convertible Notes

In multiple closings to be held between December 5, 2024 and December 31, 2024, Tvardi issued and sold or will issue and sell an aggregate of \$28,297,679. The following table summarizes the Convertible Notes purchased by holders of more than 5% of Tvardi's capital stock and entities affiliated with its executive officers and members of its board of directors.

Participants ⁽¹⁾	Aggregate Principal Amount of the Convertible Notes (\$)
Entities affiliates with Slate Path ⁽²⁾	2,000,000
BioMatrix Partners Ltd. ⁽⁶⁾	1,000,000

(1) Additional details regarding these stockholders and their equity holdings are included in this proxy statement/prospectus under the section titled "Principal Stockholders of Tvardi."

- (2) Consists of (i) \$1,768,000 in Convertible Notes purchased by Slate Path Master Fund LP and (ii) \$232,000 in Convertible Notes purchased by SPB Master Fund LP (together with Slate Path Master Fund LP and other affiliates, Slate Path). Jamie McNab is a member of Tvardi's board of directors and a Partner of Slate Path Capital LP, which is the investment manager of Slate Path Master Fund LP and SPB Master Fund LP. Mr. McNab may be deemed to share the power to direct the disposition and vote of any shares received by Slate Path in the conversion of such Convertible Notes, but disclaims beneficial ownership of all shares held by Slate Path except to any pecuniary interest therein.
- (3) Wallace Hall is a member of Tvardi's board of directors and a general partner of BioMatrix Partners Ltd. Mr. Hall may be deemed to share the power to direct the disposition and vote of any shares received by BioMatrix Partners Ltd. in the conversion of such Convertible Notes, but disclaims beneficial ownership of all shares held by BioMatrix Partners Ltd. except to any pecuniary interests therein.

Series B Preferred Stock Financing

In multiple closings held between June 3, 2021 and June 17, 2021, Tvardi issued and sold an aggregate of 20,055,539 shares of its Series B redeemable convertible preferred stock, \$0.001 par value per share, or Series B Preferred Stock at a purchase price of \$3.8095 per share for an aggregate purchase price of \$74,418,281.20.

The following table summarizes the Series B Preferred Stock purchased by holders of more than 5% of Tvardi's capital stock and entities affiliated with its executive officers and members of its board of directors.

Participants ⁽¹⁾	Shares of Series B Preferred Stock Purchased (#)	Aggregate Purchase Price (\$)
Entities affiliates with Slate Path ⁽²⁾	5,250,032	19,999,996.91
Entities affiliated with Sporos ⁽³⁾	4,684,679	17,077,031.89
David J. Tweardy	53,695	163,643.82
Entities affiliated with Palkon ⁽⁴⁾	3,274,707	12,474,996.33
Shaheen Wirk ⁽⁵⁾	31,252	105,830.12
BioMatrix Partners Ltd. ⁽⁶⁾	173,448	528,602.73

⁽¹⁾ Additional details regarding these stockholders and their equity holdings are included in this proxy statement/prospectus under the section titled "Principal Stockholders of Tvardi."

- (2) Consists of (i) 4,662,044 shares of Series B Preferred Stock held by Slate Path Master Fund LP and (ii) 587,988 shares of Series B Preferred Stock held by SPB Master Fund LP. Jamie McNab is a member of Tvardi's board of directors and a Partner of Slate Path Capital LP, which is the investment manager of Slate Path Master Fund LP and SPB Master Fund LP. Mr. McNab may be deemed to share the power to direct the disposition and vote of the shares held by Slate Path, but disclaims beneficial ownership of all shares held by Slate Path except to any pecuniary interest therein.
- (3) Consists of (i) 3,450,397 shares of Series B Preferred Stock held by Sporos Bioventures LLC and (ii) 1,234,282 shares of Series B Preferred Stock held by Sporos Co-Invest T1 LLC (together with Sporos Bioventures LLC and other affiliates, Sporos).
- (4) Consists of (i) 1,312,508 shares of common stock issuable upon the conversion of Series B Preferred Stock held by Palkon Holdings, LLC and (ii) 1,962,199 of common stock issuable upon the conversion of Series B Preferred Stock held by Palkon TT Holdings, LLC. Palkon GP, LLC is the general partner of Palkon TT Holdings, LLC and Palkon Capital LP, which is the sole member of Palkon Holdings, LLC. The address for Palkon entities is 1688 Meridian Ave, Suite 700, Miami Beach, FL 33139. Shaheen Wirk is a Manager of the Palkon entities. Dr. Wirk may be deemed to share the power to direct the disposition and vote of the shares held by the Palkon entities, but disclaims beneficial ownership of all shares held by the Palkon entities except to any pecuniary interest therein.
- (5) Consists of 31,252 shares of Series B Preferred Stock held by Dr. Wirk. Dr. Wirk is a member of Tvardi's board of directors.
- (6) Consists of 173,448 shares of Series B Preferred Stock held by BioMatrix Partners Ltd. Wallace Hall is a member of Tvardi's board of directors and a general partner of BioMatrix Partners Ltd. Mr. Hall may be deemed to share the power to direct the disposition and vote of the shares held by BioMatrix Partners Ltd., but disclaims beneficial ownership of all shares held by BioMatrix Partners Ltd. except to any pecuniary interests therein.

Founder Royalty Payments

Pursuant to Tvardi founder restricted stock purchase agreements with each of its founders, David J. Tweardy, M.D., and Ron DePinho, M.D., Tvardi is obligated to pay royalties to each such founder in an amount equal to 1% each on the worldwide net sales of TTI-101 and any derivative formulations, or Royalty Bearing Product. These royalty obligations last, on a country-by-country basis, for the later of (i) the date on which the sale of Royalty Bearing Product is no longer covered by a Covered Patent (as defined below) in such country, or 15 years after the first commercial sale of Royalty Bearing Product in such country. The timing of when its royalty payments will actually be made is uncertain as the payments are contingent upon future activities, including the successful development, regulatory approval and commercialization of a Royalty Bearing Product. A Covered Patent means, subject to certain customary exceptions, an issued patent that is owned by Tvardi or an affiliate, or for which all rights to develop and commercialize pharmaceutical products for the treatment of any human disorder, are exclusively licensed to Tvardi or an affiliate by the owner of such patent, with its right or its affiliate's right to grant sublicenses.

Employment Agreements and Stock Option Grants to Directors and Executive Officers

Tvardi has entered into employment agreements with certain of its named executive officers, and granted stock options to its named executive officers and certain of its directors, as more fully described in the section titled "*Tvardi's Executive and Director Compensation*."

Investor Agreements

In connection with Tvardi's Series B financing, Tvardi entered into an amended and restated investors' rights agreement, amended and restated voting agreement, as amended, and amended and restated right of first refusal and co-sale agreement, which contain registration rights, information rights, voting rights and rights of first refusal and co-sale, among other things, with certain of its stockholders. Pursuant to its voting agreement, as amended, certain of its stockholders have the right to designate member(s) to be elected to its board of directors. The foregoing agreements will terminate upon the completion of this Merger, except for the registration rights set forth in the investors' rights agreement.

Limitations on Liability and Indemnification Agreements

Tvardi's amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and its amended and restated bylaws will provide that it will indemnify each of Tvardi's directors and officers to the fullest extent permitted under Delaware law. Tvardi's amended and restated certificate of incorporation and amended and restated bylaws will also provide its board of directors with discretion to indemnify its employees and other agents when determined appropriate by the board. In addition, Tvardi has entered into or intends to enter into an indemnification agreement with each of its directors and executive officers, which will require Tvardi to indemnify them. For more information regarding these agreements, see the section titled *"Tvardi's Executive and Director Compensation — Limitations on Liability and Indemnification."*

Policies and Procedures for Transactions with Related Persons

Following the consummation of the Merger, Tvardi executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of its common stock and any members of the immediate family of any of the foregoing persons will not be permitted to enter into a related person transaction with Tvardi without the approval or ratification of its board of directors or its audit committee. Any request for Tvardi to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of its common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 (or, if less, 1% of the average of its total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to its board of directors or its audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

COMPARISON OF RIGHTS OF HOLDERS OF CARA STOCK AND TVARDI STOCK

General

Tvardi and Cara are both incorporated under the laws of the State of Delaware. The rights of Tvardi stockholders and Cara stockholders are generally governed by the DGCL. Upon completion of the Merger, Tvardi stockholders will become Cara stockholders, and their rights will be governed by the DGCL, the amended and restated bylaws of Cara and the amended and restated certificate of incorporation of Cara, as amended.

The material differences between the current rights of Tvardi stockholders under Tvardi's amended and restated certificate of incorporation and bylaws and their rights as Cara stockholders, after the Merger, under Cara's amended and restated certificate of incorporation and its amended and restated bylaws, both as will be in effect immediately following the completion of the Merger without giving effect to the Authorized Share Proposal, are summarized below. The summary below does not purport to be complete and is subject to, and qualified in its entirety by reference to, the DGCL and the governing corporate instruments that are subject to amendment in accordance with their terms. You should carefully read this entire document and the other referenced documents, including the governing corporate instruments, for a more complete understanding of the differences between being a stockholder of Tvardi or Cara before the Merger and being an Cara stockholder following the completion of the Merger. For more information on how to obtain these documents, see the section titled "*Where You Can Find More Information*" beginning on page <u>284</u> of this proxy statement/prospectus.

Authorized Common Stock

Tvardi

Tvardi's amended and restated certificate of incorporation authorizes the issuance of up to 58,251,629 shares of common stock, \$0.001 par value per share, and 29,723,540 shares of preferred stock, \$0.001 par value per share (Tvardi Preferred Stock), of which 9,499,999 shares are designated Series A Preferred Stock and 20,223,541 shares are designated Series B Preferred Stock.

Cara

Cara's authorized capital stock consists of 200,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share.

The Merger Agreement contemplates an amendment to Cara's amended and restated certificate of incorporation in connection with the closing of the Merger to implement the Reverse Stock Split.

Conversion Rights, Liquidation Preferences, and Protective Provisions

Tvardi

The amended and restated certificate of incorporation of Tvardi provides that each holder of shares of Tvardi Preferred Stock shall, subject to certain conditions, have the right to convert such shares into shares of Tvardi common stock at any time in accordance with the amended and restated certificate of incorporation of Tvardi. Each share of Tvardi Preferred Stock is convertible into 1.00 share of Tvardi common stock. The applicable conversion rates of each series of Tvardi Preferred Stock are subject to further adjustment if Tvardi issues additional shares of Tvardi common stock at a price per share below the applicable conversion price of a series of Tvardi Preferred Stock, subject to certain customary exceptions. The current conversion prices of the Tvardi Preferred Stock are: \$1.00 for the Tvardi Series A Preferred Stock and \$3.8095 for the Tvardi Series B Preferred Stock.

The amended and restated certificate of incorporation of Tvardi provides that for so long as any shares of Series B Preferred Stock shall be outstanding, Tvardi shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without the written consent or affirmative vote of the holders of a majority of the outstanding shares of Tvardi Series B Preferred Stock, voting together on

a single class and on an as-converted to Tvardi common stock basis, given in writing or by vote at a meeting: (a) liquidate, dissolve or wind-up the business and affairs of Tvardi, (ii) amend, alter or repeal any provision of Tvardi's amended and restated certificate of incorporation or bylaws; (c) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Tvardi Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of Tvardi, the payment of dividends and rights of redemption, other than additional shares of Tvardi Preferred Stock; (d) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the other than (i) redemptions of or dividends or distributions on the Tvardi Preferred Stock as expressly authorized in Tvardi's amended and restated certificate of incorporation, (ii) dividends or distributions payable on Tvardi common stock solely in the form of additional shares of Tvardi common stock, (iii) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for Tvardi or any subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the then current fair market value thereof or (iv) as approved by the Tvardi Board; (e) create, adopt, amend, terminate or repeal any equity (or equity-linked) compensation plan or amend or waive any of the terms of any option or other grant pursuant to any such plan; (f) create, or authorize the creation of, or issue, or authorize the issuance of any debt security or create any lien or security interest or incur other indebtedness for borrowed money, including but not limited to obligations and contingent obligations under guarantees, or permit any subsidiary to take any such action with respect to any debt security lien, security interest or other indebtedness for borrowed money other than equipment leases, bank lines of credit or trade payables incurred in the ordinary course unless such debt security has received the prior approval of the Tvardi Board; (g) create, or hold capital stock in, any subsidiary that is not wholly owned by Tvardi, or permit any subsidiary to create, or authorize the creation of, or issue or obligate itself to issue, any shares of any class or series of capital stock, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of Tvardi, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary; or (h) increase or decrease the authorized number of directors constituting the Tvardi Board, or change the number of votes entitled to be cast by any director or directors on any matter. The amended and restated certificate of incorporation of Tvardi provides that for so long as 1,250,000 shares of Tvardi Series A Preferred Stock shall be outstanding, Tvardi shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of (a) to (d) above, except in the case of (d), with respect to issuance of any additional class or series of capital stock unless the same ranks junior to the Tvardi Series A Preferred Stock, without the written consent or affirmative vote of the holders of a majority of the outstanding shares of Tvardi Series A Preferred Stock, voting together on a single class and on an as-converted to Tvardi common stock basis, given in writing or by vote at a meeting.

The amended and restated certificate of incorporation of Tvardi provides that for so long as any shares of Tvardi Preferred Stock remain outstanding, Tvardi may not without the written consent or affirmative vote of the holders of a majority of the outstanding shares of Tvardi Preferred Stock, voting together on a single class and on an as-converted to Tvardi common stock basis, given in writing or by vote at a meeting, effect a deemed liquidation event, defined as (a) merger or consolidation of Tvardi or any of its subsidiaries or (b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by Tvardi or any of its subsidiaries of all or substantially all the assets of such entities taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of Tvardi if substantially all of the assets of Tvardi and its subsidiaries taken as a whole are held by such subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of Tvardi.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of Tvardi, the holders of shares of Tvardi Series B Preferred Stock then outstanding shall be entitled to be paid out of the assets of Tvardi available for distribution to its stockholders before any payment shall be made to the holders of Tvardi Series A Preferred Stock or Tvardi common stock, an amount per share equal to the greater of (i) \$3.8095, or (ii) such amount per share as would have been payable had all shares of Tvardi Series B Preferred Stock been converted into Tvardi common stock. After the payment to any holders of shares of Tvardi Series B Preferred Stock, holders of shares of Tvardi Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of Tvardi available for distribution to its stockholders

before any payment shall be made to the holders of Tvardi common stock, an amount per share equal to the greater of (i) \$1.00, or (ii) such amount per share as would have been payable had all shares of Tvardi Series B Preferred Stock been converted into Tvardi common stock. If upon any such liquidation, dissolution or winding up of Tvardi, the assets of Tvardi available for distribution to its stockholders shall be insufficient to pay the holders of all shares of Tvardi Preferred Stock, then distributions shall be made ratably first to holders of shares of Tvardi Series B Preferred Stock, and upon satisfaction of the preferential amounts required to be paid to the holders of the Tvardi Series B Preferred Stock, ratably to holders of shares of Stock. After the payment of all preferential amounts required to be paid to the holders of shares of the Corporation available for distribution to its stockholders shall be distributed among the holders of shares of Common Stock, pro rata based on the number of shares held by each such holder.

Cara

Holders of Cara common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to Cara common stock. The rights, preferences and privileges of the holders of Cara common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of Cara preferred stock that it may designate in the future.

The Cara Board is authorized, subject to limitations prescribed by Delaware law, to issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to determine or alter for each such series, such voting powers, full or limited, or no voting powers and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof. The Cara Board can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by the company's stockholders. The Cara Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change of control of Cara or other rights of the holders of the market price of Cara's common stock and the voting and other rights of the holders of common stock.

Number of Directors

Tvardi

Tvardi's bylaws, as amended, provide that Tvardi's authorized number of directors shall be determined from time to time by resolution of the Tvardi Board. The Tvardi Board currently has six members.

Cara

Cara's amended and restated certificate of incorporation and amended and restated bylaws provide that, subject to any special rights of the holders of any series of preferred stock to elect directors, Cara's authorized number of directors shall be determined from time to time by resolution of the Cara Board. The Cara Board currently has six members.

Stockholder Nominations and Proposals

Tvardi

None.

Cara

Cara's amended and restated bylaws provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide written notice on a timely basis and also specify requirements as to the form and content of a stockholder's notice.

Classification of Board of Directors

Tvardi

Tvardi's amended and restated certificate of incorporation and bylaws do not provide for the division of the Tvardi Board into staggered classes.

Cara

Cara's amended and restated certificate of incorporation provides that the directors shall be divided into three classes, with each class having a three-year term expiring on a staggered basis.

Removal of Directors

Tvardi

Tvardi's bylaws provide that, any director may be removed from the Tvardi Board at any time, with or without cause, by the holders of a majority of the shares then entitled to vote in an election of directors.

Tvardi's amended and restated certificate of incorporation provides that the holders of record of the shares of Tvardi Series B Preferred Stock, exclusively and as a separate class, shall be entitled to elect one director of Tvardi, the holders of record of the shares of Tvardi Series A Preferred Stock, exclusively and as a separate class, shall be entitled to elect two directors of Tvardi and the holders of record of the shares of common stock, exclusively and as a separate class, shall be entitled to elect two directors of Tvardi and the holders of record of the shares of common stock, exclusively and as a separate class, shall be entitled to elect one director Tvardi. Tvardi's amended and restated certificate of incorporation provides that the balance of the number of directors shall be elected by holders of record of the shares of Tvardi common stock and of any other class or series of voting stock (including the Tvardi Preferred Stock), exclusively and voting together as a single class.

Cara

Cara's amended and restated certificate of incorporation provides that, except as may otherwise be provided by the DGCL and subject to the special rights of the holders of any series of preferred stock to elect directors, any individual Cara director may be removed only for cause and requires a stockholder vote by the holders of at least a two-thirds of the voting power of the then outstanding voting stock.

Vacancies on the Board of Directors

Tvardi

Tvardi's bylaws provide that vacancies occurring on its board of directors may be filled by affirmative vote of the majority of directors then in office, even if less than a quorum. If the holders of any class or classes of stock are entitled to elect one or more directors by the provisions of Tvardi's amended and restated certificate of incorporation, a majority of the directors elected by such class or classes then in office may fill such vacancy or vacancies. Tvardi's certificate of incorporation provides that if the holders of the shares of one or more series of voting capital stock fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, then any directorship not so filled shall remain vacant until such time as the holders of the shares of the applicable class or series of voting capital stock entitled to elect a person to fill such directorship.

Cara

Cara's amended and restated certificate of incorporation and amended and restated bylaws provide that, subject to any limitations imposed by the DGCL and the rights of the holders of any series of preferred stock, any vacancies on the Cara Board resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Cara Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders, except as otherwise provided by law, be filled only by the affirmative

vote of a majority of the directors then in office, even though less than a quorum or by the sole remaining director, and not by the stockholders.

Voting Stock

Tvardi

Tvardi's amended and restated certificate of incorporation provides that every stockholder shall be entitled to one vote for each share of common stock of Tvardi held by them (including all Tvardi Preferred Stock on an as-converted basis) as of the record date for such meeting.

Cara

The Cara common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders.

Stockholder Action by Written Consent

Tvardi

Tvardi's bylaws provide that any action taken at any annual or special meeting of stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

Cara

Cara's amended and restated certificate of incorporation and its amended and restated bylaws do not provide for the right of stockholders to act by written consent without a meeting.

Notice of Stockholder Meeting

Tvardi

Tvardi's bylaws provide that except as otherwise provided by statute, its amended and restated certificate of incorporation, as amended, or the bylaws, notice of each annual or special meeting of the stockholders shall be given to each stockholder of record entitled to vote at such meeting not less than ten and nor more than 60 days before the day of the meeting to each stockholder entitled to vote at such meeting. Every such notice shall state the place, if any, date and time of the meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called and no other business may be transacted at such meeting except that referred to in the notice.

Notice shall be deemed given when deposited in the mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of Tvardi, or if given by electronic transmission, such notice shall be deemed given at the time the notice is directed to such stockholder's electronic mail address. Notices need not be given to any stockholder who submits a written waiver of notice signed by him or her before or after the time stated therein. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

Cara

Cara's amended and restated bylaws provide that written notice of a meeting of the stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting. The notice shall specify the place, if any, date and hour, in the case of special meetings,

the purpose or purposes of the meeting, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at any such meeting.

If mailed, notice is given when deposited in the U.S. mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the Cara's records. Notice of the time, place, if any, and purpose of any meeting of stockholders may be waived in writing, signed by the person entitled to notice thereof, or by electronic transmission by such person, either before or after such meeting, and will be waived by any stockholder by his or her attendance thereat in person, by remote communication, if applicable, or by proxy, except when the stockholder attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of such meeting shall be bound by the proceedings of any such meeting in all respects as if due notice thereof had been given.

Special Stockholder Meetings

Tvardi

Tvardi's bylaws provide that a special meeting of the stockholders may be called at any time by the Tvardi Board, Chairperson of the Tvardi Board, the Chief Executive Officer or the President of Tvardi.

Cara

Cara's amended and restated bylaws provide that a special meeting of stockholders may be called for any purpose as if a proper matter for stockholder action under the DGCL by the chairperson of the Cara Board, Cara's Chief Executive Officer or the Cara Board pursuant to a resolution adopted by a majority of the total number of authorized directors. The Cara Board shall determine the time and place, if any, of such special meeting

Indemnification

Tvardi

Tvardi has entered into separate indemnification agreements with certain of its directors and executive officers, in addition to the indemnification provided for in Tvardi's amended and restated certificate of incorporation and bylaws. The indemnification agreements and Tvardi's amended restated certificate of incorporation and bylaws that will be in effect upon the closing of this merger require the combined company to indemnify its directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law.

Cara

Cara's amended and restated certificate of incorporation and amended and restated bylaws provide that to the fullest extent permitted by law, Cara is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of Cara (and any other persons to which applicable law permits Cara to provide indemnification) through bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise in excess of the indemnification and advancement otherwise permitted by such applicable law.

Cara has entered into separate indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in Cara's amended and restated certificate of incorporation and amended and restated bylaws.

Amendment of Certificate of Incorporation

Tvardi

The Tvardi Board and stockholders may amend, alter, change or repeal any provision of Elicio's amended and restated certificate of incorporation, as amended, in a manner prescribed by statue; provided

that (i) any such amendment may be subject to the protective provisions described above and (ii) any repeal or modification of Article Tenth of Tvardi's amended and restated certificate of incorporation shall not adversely affect any right or protection of any director, officer or other agent of Tvardi existing at the time of such repeal or modification or increase the liability of any director of Tvardi with respect to any acts or omissions of such director, officer or agent occurring prior to, such repeal or modification.

Cara

Notwithstanding any other provisions in Cara's amended and restated certificate of incorporation or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of stock of Cara required by law or by Cara's amended and restated certificate of incorporation or any certificate of designation filed with respect to a series of preferred stock, the affirmative vote of the holders of at least 66²/₃% of the voting power of all of the then outstanding shares of common stock of Cara entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Articles V, VI, VII and VIII of Cara's amended and restated certificate of incorporation.

Amendment of Bylaws

Tvardi

Under Tvardi's amended and restated certificate of incorporation and bylaws, the Tvardi Board is expressly authorized to make, repeal, alter, amend and rescind any or all of Tvardi's bylaws, subject to the protective provisions described above. Tvardi's bylaws further provide that the bylaws may be adopted, amended or repealed by the vote of the holders of the majority of the stock entitled to vote at a meeting.

Cara

Cara's amended and restated certificate of incorporation and amended and restated bylaws provide that the Cara Board is expressly empowered to adopt, amend or repeal Cara's amended and restated bylaws. Any adoption, amendment or repeal of the Cara amended and restated bylaws by the Cara Board shall require the approval of a majority of the authorized number of directors. Cara's amended and restated certificate of incorporation also provides that the Cara stockholders shall also have power to adopt, amend or repeal Cara's amended and restated bylaws; *provided, however*, that, in addition to any vote of the holders of any class or series of stock of Cara required by law or by Cara's amended and restated certificate of incorporation, such action by stockholders shall require the affirmative vote of the holders of at least 66 ^{2/3}% of the voting power of all of the then-outstanding shares of Cara common stock entitled to vote generally in the election of directors, voting together as a single class.

Forum Selection

Tvardi

Tvardi's amended and restated certificate of incorporation provides that unless Tvardi consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of Tvardi, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of Tvardi to Tvardi or its stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or Tvardi's amended and restated certificate of incorporation or bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine.

Cara

Cara's amended and restated certificate of incorporation and amended and restated bylaws provide that, unless Cara consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall be the sole and exclusive forum for (A) any derivative claim or cause action brought on Cara's behalf; (B) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of Cara, to Cara or Cara's stockholders; (C) any action asserting a claim against Cara or any current or former director, officer or other employee of Cara, arising out of or pursuant to any provision of the DGCL, Cara's amended and restated certificate of incorporation or amended and restated bylaws (as each may be amended from time to time); or (D) any action asserting a claim against Cara governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. Notwithstanding the foregoing, these forum selection provisions do not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act or the Exchange Act, or any other claim for which the federal courts of the United States have exclusive jurisdiction.

SECURITIES ACT RESTRICTIONS ON RESALE OF COMBINED COMPANY COMMON STOCK

Pursuant to Rule 144, a person who has beneficially owned restricted combined company common stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been an affiliate of the combined company at the time of, or at any time during the three months preceding, a sale and (ii) combined company is subject to the Exchange Act periodic reporting requirements for at least three months before the sale and have filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as combined company was required to file reports) preceding the sale.

Persons who have beneficially owned restricted combined company common stock shares for at least six months but who are affiliates of combined company at the time of, or at any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- 1% of the total number of combined company common stock then outstanding; or
- the average weekly reported trading volume of the combined company common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by affiliates of combined company under Rule 144 are also limited by manner of sale provisions and notice requirements and to the availability of current public information about the combined company.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

We anticipate that following the consummation of the Merger, the combined company will no longer be a shell company, and so, once the conditions set forth in the exceptions listed above are satisfied, Rule 144 will become available for the resale of the above noted restricted securities.

PRINCIPAL STOCKHOLDERS OF CARA

The following table sets forth certain information regarding the ownership of Cara's common stock as of December 1, 2024 by: (i) each director and nominee for director; (ii) each of the executive officers named in the Summary Compensation Table; (iii) all executive officers and directors of Cara as a group; and (iv) all those known by Cara to be beneficial owners of more than five percent of its common stock.

The percentage of common stock outstanding is based on 54,855,514 shares of our common stock outstanding as of December 1, 2024. For purposes of the table below, and in accordance with the rules of the SEC, we deem shares of common stock subject to options that are currently exercisable or exercisable within 60 days of December 1, 2024 to be outstanding and to be beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise noted, each of the persons or entities in this table has sole voting and investing power with respect to all of the shares of common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise noted below, the street address of each beneficial owner is c/o Cara Therapeutics, Inc., 400 Atlantic Street, Suite 500, Stamford, CT 06901.

Name of beneficial owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders		
Vifor (International) Ltd ⁽¹⁾	7,396,770	13.5%
Executive Officers and Directors		
Christopher Posner ⁽²⁾	857,430	1.5%
Ryan Maynard ⁽³⁾	176,387	*
Scott Terrillion ⁽⁴⁾	467,038	*
Martin Vogelbaum ⁽⁵⁾	347,328	*
Helen M. Boudreau ⁽⁶⁾	64,894	*
Jeffrey L. Ives, Ph.D. ⁽⁷⁾	173,395	*
Susan Shiff, Ph.D. ⁽⁸⁾	162,195	*
Lisa von Moltke, M.D. ⁽⁹⁾	107,883	*
Joana Goncalves, M.D. ⁽¹⁰⁾	53,365	*
All current executive officers and directors as a group (8 persons) ⁽¹¹⁾	2,356,550	4.2%

^{*} Represents beneficial ownership of less than 1%.

⁽¹⁾ Based solely on Schedule 13D filed by Vifor (International) Ltd. and CSL Limited on October 30, 2024. Vifor (International) Ltd. and CSL Limited have shared voting power and dispositive power as to all of the shares. The address of Vifor (International) Ltd. is Rechenstrasse 37 CH-9014, St. Gallen Switzerland. The address of CSL Limited is 655 Elizabeth Street, Melbourne VIC, 3000 (AU).

⁽²⁾ Consists of 120,268 shares held directly by Mr. Posner, 8,875 RSUs that vest within 60 days of December 1, 2024 and 728,287 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.

²⁷⁸

- (3) Consists of 8,012 shares held directly by Mr. Maynard and 168,375 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.
- (4) Consists of 81,581 shares held directly by Mr. Terrillion and 385,457 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.
- (5) Consists of 109,712 shares held directly by Mr. Vogelbaum and 237,616 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.
- (6) Consists of 64,894 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.
- (7) Consists of 47,838 shares held directly by Dr. Ives and 125,557 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.
- (8) Consists of 51,438 shares held directly by Dr. Shiff and 110,757 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.
- (9) Consists of 32,362 shares of common stock held directly by Dr. Moltke and 75,521 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.
- (10) Based solely on the Form 4 filed by Dr. Goncalves on April 9, 2024. Dr. Goncalves resigned from her role as Chief Medical Officer of Cara effective April 16, 2024.
- (11) Includes 451,211 shares of common stock, 8,875 RSUs that vest within 60 days of December 1, 2024, and 1,896,464 shares of common stock underlying options that are vested and exercisable within 60 days of December 1, 2024.

PRINCIPAL STOCKHOLDERS OF TVARDI

The following table sets forth information regarding beneficial ownership of Tvardi's capital stock as of December 1, 2024 by:

- each person, or group of affiliated persons, known by Tvardi to beneficially own more than 5% of its common stock;
- each of Tvardi's directors;
- · each of Tvardi's named executive officers; and
- all of Tvardi's current executive officers and directors as a group.

Tvardi has determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, Tvardi believes, based on information furnished to Tvardi, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 48,753,452 shares of Tvardi's common stock outstanding as of December 1, 2024, after giving effect to the automatic conversion of outstanding shares of its redeemable convertible preferred stock into 29,555,538 shares of its common stock but without giving effect to the conversion of any Convertible Notes.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Tvardi Therapeutics, Inc., 3 Sugar Creek Ctr Blvd, Ste 525, Sugar Land, TX 77478.

Name of Beneficial Owner	Number of Shares Beneficially Owned (#)	Percentage of Shares Beneficially Owned Before this Offering (%)
Greater than 5% Holders:		
Entities affiliated with David J. Tweardy ⁽¹⁾	11,925,202	24.45%
Ronald DePinho ⁽²⁾	5,750,000	11.79%
Entities affiliated with Slate Path ⁽³⁾	5,250,032	10.77%
Entities affiliated with Sporos ⁽⁴⁾	8,440,962	17.31%
Entities affiliated with Palkon ⁽⁵⁾	3,274,707	6.72%
Directors and Named Executive Officers:		
Imran Alibhai ⁽⁶⁾	2,640,000	5.14%
Dan Conn ⁽⁷⁾	498,000	1.0114%
John Kauh ⁽⁸⁾	276,064	*
Sujal Shah ⁽⁹⁾	131,250	*
Wallace Hall ⁽¹⁰⁾	1,423,448	2.92%
Jamie McNab ⁽¹¹⁾	5,250,032	10.77%
Shaheen Wirk, M.D. ⁽¹²⁾	3,320,959	6.81%
Michael Wyzga ⁽¹³⁾	94,531	*
All directors and executive officers as a group (10 persons) ⁽¹⁴⁾	13,893,658	26.38%

^{*} Represents beneficial ownership of less than 1%.

Consists of (i) 2,300,000 shares of common stock and 53,600 shares of common stock issuable upon the conversion of Series A Preferred Stock held by Benjamin John Tweardy 2020 Gift Trust;
 (ii) 2,300,000 shares of common stock and 53,600 shares of common stock issuable upon the conversion of Series A Preferred Stock held by Daniel James Tweardy 2020 Gift Trust;
 (iii) 2,300,000 shares of common stock and 53,600 shares of common stock issuable upon the conversion of Series A Preferred Stock held by Daniel James Tweardy 2020 Gift Trust;
 (iii) 2,300,000 shares of common stock and 53,600 shares of common stock issuable upon the conversion of Series A Preferred Stock held by Daniel James Tweardy 2020 Gift Trust;

held by Samuel David Tweardy 2020 Gift Trust; (iv) 4,677,791 shares of common stock, 107,916 shares of common stock issuable upon the conversion of Series A Preferred Stock and 53,695 shares of common stock issuable upon the conversion of Series B Preferred Stock held by David J. Tweardy; and (v) 25,000 shares common stock issuable upon the exercise of stock options held by David J. Tweardy that are exercisable within 60 days of December 1, 2024. David J. Tweardy is the Trustee of the Benjamin John Tweardy 2020 Gift Trust, the Daniel James Tweardy 2020 Gift Trust and the Samuel David Tweardy 2020 Gift Trust.

- (2) Consists of (i) 5,725,000 shares of common stock and (ii) 25,000 shares common stock issuable upon the exercise of stock options within 60 days of December 1, 2024.
- (3) Consists of (i) 4,662,044 shares of common stock issuable upon the conversion of Series B Preferred Stock held by Slate Path Master Fund LP; and (ii) 587,988 shares of common stock issuable upon the conversion of Series B Preferred Stock held by SPB Master Fund LP. Slate Path Capital LP, a Delaware limited partnership, is the investment manager of Slate Path Master Fund LP, a Cayman Islands exempted limited partnership, and SPB Master Fund LP, a Cayman Islands exempted limited partnership. David Greenspan is the managing member of Slate Path Capital GP LLC, a Delaware limited liability company and the general partner of Slate Path Capital LP. The address for Slate Path and Mr. Greenspan is 717 Fifth Avenue, 16th Floor, New York, NY 10022.
- (4) Consists of (i) 3,756,283 shares of common stock issuable upon the conversion of Series A Preferred Stock and 3,450,397 shares of common stock issuable upon the conversion of Series B Preferred Stock held by Sporos Bioventures LLC; and (ii) 1,234,282 shares of common stock issuable upon the conversion of Series B Preferred Stock held by Sporos Co-Invest T1 LLC. The board of managers of Sporos Bioventures LLC consists of Alex Cranberg, Peter Feinberg, Harold Levy, and Rachel Humphrey. The manager of Sporos Co-Invest T1 LLC is Sporos Bioventures, Inc. The board of directors of Sporos Bioventures, Inc. consists of Alex Cranberg. The address for Sporos is 3139 West Holcombe Blvd, Houston, TX 77025.
- (5) Consists of (i) 1,312,508 shares of common stock issuable upon the conversion of Series B Preferred Stock held by Palkon Holdings, LLC and (ii) 1,962,199 shares of common stock issuable upon the conversion of Series B Preferred Stock held by Palkon TT Holdings, LLC. Palkon GP, LLC is the general partner of Palkon TT Holdings, LLC and Palkon Capital LP, which is the sole member of Palkon Holdings, LLC. Shaheen Wirk is the managing member of Palkon Holdings, LLC and Palkon TT Holdings, LLC. The address for Palkon entities is 1688 Meridian Ave, Suite 700, Miami Beach, FL 33139.
- (6) Consists of stock options exercisable within 60 days of December 1, 2024.
- (7) Consists of stock options exercisable within 60 days of December 1, 2024.
- (8) Consists of stock options exercisable within 60 days of December 1, 2024.
- (9) Consists of stock options exercisable within 60 days of December 1, 2024.
- (10) Consists of (i) 250,000 shares of Series A Preferred Stock held by Firepit Partners, LP over which Mr. Hall holds sole voting and dispositive power, (ii) 1,000,000 shares of Series A Preferred Stock held by BioMatrix Partners Ltd. over which Mr. Hall shares voting and dispositive power and (iii) 173,448 shares of Series B Preferred Stock held by BioMatrix Partners Ltd. over which Mr. Hall shares voting and dispositive power. Mr. Hall is the general partner of Firepit Partners, LP. The address for Firepit Partners, LP is 5956 Sherry Lane, Suite 1810, Dallas, TX 75225. Mr. Hall and George Houston Hall are the general partners of BioMatrix Partners Ltd. and share voting and dispositive power. The address for BioMatrix Partners Ltd. is 5956 Sherry Lane, Suite 1810, Dallas, TX 75225. Mr. Hall may be deemed to share the power to direct the disposition and vote of the shares held by Firepit Partners, LP and BioMatrix Partner Ltd. but disclaims beneficial ownership of all shares held by such entities except to any pecuniary interest therein.
- (11) Consists of shares reported in footnote (3). Jamie McNab is a Partner of Slate Path Capital LP, which is the investment manager of Slate Path Master Fund LP and SPB Master Fund LP. Mr. McNab may be deemed to share the power to direct the disposition and vote of the shares held by Slate Path, but disclaims beneficial ownership of all shares held by Slate Path except to any pecuniary interest therein.
- (12) Consists of (i) 31,252 shares of common stock issuable upon the conversion of Series B Preferred

Stock and 15,000 shares common stock issuable upon the exercise of stock options within 60 days of December 1, 2024 held by Dr. Wirk and (ii) the shares reported in footnote (5). Shaheen Wirk is the founder of Palkon Holdings, LLC. Dr. Wirk may be deemed to share the power to direct the disposition and vote of the shares held by Palkon Holdings, LLC, but disclaims beneficial ownership of all shares held by Palkon Holdings, LLC except to any pecuniary interest therein.

- (13) Consists of stock options exercisable within 60 days of December 1, 2024.
- (14) Consists of (i) 1,250,000 shares of common stock issuable upon the conversion of Series A Preferred Stock beneficially held by Tvardi's current directors and executive officers as a group, (ii) 8,729,439 shares of common stock issuable upon the conversion of Series B Preferred Stock beneficially held by Tvardi's current directors and executive officers as a group, and (iii) 3,914,219 shares common stock issuable upon the exercise of stock options held by Tvardi's current directors and executive officers that are exercisable within 60 days of December 1, 2024.

PRINCIPAL STOCKHOLDERS OF THE COMBINED COMPANY

The following table and the related notes present certain information with respect to the beneficial ownership of the common stock of the combined company upon consummation of the Merger, assuming the closing of the Merger occurred on __________, by: (i) each person or group of affiliated persons known by Cara or Tvardi to become the beneficial owner of more than 5% of the common stock of the combined company upon the closing of the Merger; (ii) each of the directors of the combined company; (iii) each of the executive officers of the combined company; and (iv) all executive officers and directors of the combined company as a group.

Unless otherwise indicated in the footnotes to this table, Cara and Tvardi believe that each of the persons named in this table have sole voting and investment power with respect to the shares indicated as beneficially owned.

The following table assumes (i) no exercise of outstanding options or warrants to purchase shares of Cara common stock or Tvardi common stock prior to the closing of the Merger, (ii) an Exchange Ratio of 4.8997, (iii) a number of Convertible Shares equal to 46,115,173 and (iv) the closing of the Merger. Based on these assumptions, there will be a total of shares of combined company common stock outstanding upon the closing of the Merger.

Shares of the combined company's common stock that may be acquired by an individual or group within 60 days of , pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of the combined company's common stock of any other person shown in the table. Unless otherwise indicated, the address for the following stockholders is: c/o Cara Therapeutics, Inc., 400 Atlantic Street, Suite 500, Stamford, CT 06901.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders		
		%
		%
		%
Executive Officers and Directors		
		%
		%
		%
		%
		%
All executive officers and directors as a group (persons)		%

* Represents beneficial ownership of less than 1%.

LEGAL MATTERS

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. will pass upon the validity of the Cara common stock offered by this proxy statement/prospectus.

EXPERTS

Cara

The financial statements of Cara Therapeutics, Inc. as of December 31, 2023 and 2022 and for the years then ended and incorporated by reference in this proxy statement/prospectus have been audited by audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon. Such financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

Tvardi

The financial statements of Tvardi Therapeutics, Inc. as of December 31, 2023 and 2022 and for each of the two years in the period ended December 31, 2023, included in this proxy statement/prospectus have been audited by Deloitte & Touche LLP, independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Cara has filed with the SEC the Registration Statement, of which this proxy statement/prospectus forms a part. The Registration Statement registers the shares of Cara common stock to be issued to Tvardi stockholders in connection with the Merger. The Registration Statement, including the attached exhibits and schedules, contains additional relevant information about Cara common stock. The rules and regulations of the SEC allow Cara to omit certain information included in the Registration Statement from this proxy statement/prospectus. This proxy statement/prospectus is a part of the Registration Statement and constitutes a prospectus of Cara, as well as a proxy statement of Cara for its special meeting.

This proxy statement/prospectus does not contain all the information set forth in the Registration Statement. For further information about Cara and the shares of common stock to be registered in the Merger, you should refer to the Registration Statement. Statements contained in this proxy statement/ prospectus relating to the contents of any contract, agreement or other document are not necessarily complete and are qualified in all respects by the complete text of the applicable contract, agreement or other document, a copy of which has been filed as an exhibit to the Registration Statement.

Cara is subject to the reporting and information requirements of the Exchange Act and, as a result, files, or will file, periodic reports, proxy statements and other information with the SEC. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The SEC's internet site can be found at http://www.sec.gov. Cara also maintains a website at http://www.Caratherapeutics.com and makes available free of charge through this website Cara's annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. Cara make these reports available through Cara's website as soon as reasonably practicable after Cara electronically files such reports with, or furnishes such reports to, the SEC. The information contained on, or that can be accessed through, Cara's website is not a part of this proxy statement/prospectus.

This proxy statement/prospectus does not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this proxy statement/prospectus, or the solicitation of a proxy, in any jurisdiction to or from any person to whom or from whom it is unlawful to make such offer, solicitation of an offer or proxy solicitation in such jurisdiction. Neither the delivery of this proxy statement/prospectus nor any distribution of securities pursuant to this proxy statement/prospectus shall, under any circumstances, create any implication that there has been no change in the information set forth or incorporated into this proxy statement/prospectus by reference or in Cara's affairs since the date of this proxy statement/prospectus.

Cara has supplied all information contained in this proxy statement/prospectus relating to Cara and its business, and Tvardi has supplied all information contained in this proxy statement/prospectus relating to Tvardi and its business.

In addition, the SEC allows Cara to disclose important information to you by referring you to other documents filed separately with the SEC, which we refer to as incorporated documents. Information contained in incorporated documents is considered to be a part of this proxy statement/prospectus, except as otherwise specified below.

This proxy statement/prospectus incorporates by reference the documents listed below that Cara has previously filed with the SEC; provided, however, that we are not incorporating by reference, in each case, any documents, portions of documents or information deemed to have been furnished and not filed in accordance with SEC rules. They contain important information about Cara, its financial condition or other matters.

- Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 6, 2024.
- Proxy Statement on Schedule 14A filed April 20, 2023.
- Quarterly Reports on Form 10-Q for the quarterly period ended March 31, 2024, filed on <u>May 13, 2024</u>, for the quarterly period ended June 30, 2024, filed on <u>August 14, 2024</u> and for the quarterly period ended September 30, 2024, filed on <u>November 14, 2024</u>.
- Current Reports on Form 8-K, filed on January 22, 2024, February 2, 2024, March 22, 2024, June 7, 2024, June 12, 2024, June 18, 2024, August 1, 2024, November 22, 2024, and December 18, 2024 (other than items, documents or portions of those documents not deemed to be filed).
- The description of Cara's common stock contained in the Registration Statement on Form 8-A, filed with the Commission on January 27, 2014 (File No. 001-36279) under the Exchange Act, including any amendment or report filed for the purpose of updating such description.

In addition, Cara incorporates by reference herein any future filings it makes with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this proxy statement/prospectus and prior to the date of the Cara special meeting, and after the date of Registration Statement and prior to the effectiveness of the Registration Statement, except that Cara is not incorporating any information that has been or will be furnished pursuant to Item 2.02 or Item 7.01 of a Current Report on Form 8-K or the exhibits related thereto under Item 9.01, unless such information is expressly incorporated herein by reference to a furnished Current Report on Form 8-K or other furnished document. Such documents are considered to be a part of this proxy statement/prospectus, effective as of the date such documents are filed. In the event of conflicting information in these documents, the information in the latest filed document should be considered correct.

Neither Cara nor Tvardi has authorized anyone to give any information or make any representation about the Merger or Cara or Tvardi that is different from, or in addition to, that contained in this proxy statement/prospectus or in any of the incorporated documents that Cara has incorporated by reference into this proxy statement/prospectus. Therefore, if anyone does give you information of this sort, you should not rely on it. The information contained in this proxy statement/prospectus speaks only as of the date of this proxy statement/prospectus unless the information specifically indicates that another date applies.

If you would like to request documents from Cara or Tvardi, please send a request in writing or by telephone to either Cara or Tvardi at the following addresses or telephone numbers:

Cara Therapeutics, Inc. 400 Atlantic Street Suite 500 Stamford, CT 06901 (203) 406-3700 Attn: Investor Relations Tvardi Therapeutics, Inc. 3 Sugar Creek Center Blvd. Suite 525 Sugarland, TX 77478 (713) 489-8654 Attn: Investor Relations

You may also request additional copies from Cara's proxy solicitor using the following contact information:

ALLIANCE ADVISORS, LLC Stockholders call toll-free: 844-876-6183

Email: CARA@allianceadvisors.com

Householding of Proxy Materials

The SEC has adopted rules that permit companies and intermediaries (*e.g.*, brokers) to satisfy the delivery requirements for proxy statements and annual reports with respect to two or more stockholders sharing the same address by delivering a single proxy statement addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

A number of brokers with account holders who are Cara stockholders will be householding Cara's proxy materials. A single proxy statement/prospectus will be delivered to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once a stockholder has received notice from its broker that they will be householding communications to such stockholder's address, householding will continue until such stockholder is notified otherwise or until it revokes its consent. If, at any time, a stockholder no longer wishes to participate in householding and would prefer to receive a separate proxy statement/prospectus and annual disclosure documents, it may notify its broker, and direct its written request to Cara Therapeutics, Inc. at Cara's principal executive offices at 400 Atlantic Street, Suite 500, Stamford, CT 06901, Attention: Investor Relations. Stockholders who currently receive multiple copies of the proxy statement/prospectus and annual disclosure documents at their address and would like to request householding of their communications should contact their broker.

Stockholder Communication with the Cara Board

The Board has adopted a formal process by which stockholders may communicate with the Cara Board or any of its directors. Stockholders wishing to communicate with the Cara Board or an individual director may send a written communication to the Cara Board or such director c/o Cara Therapeutics, Inc., 400 Atlantic Street, Suite 500, Stamford, CT 06901, Attn: Secretary.

Each communication must set forth:

- the name and address of the stockholder on whose behalf the communication is sent; and
- the number and class of shares of Cara common stock that are owned beneficially by such stockholder as of the date of the communication.

The Secretary will review each communication. The Secretary will forward such communication to the Cara Board or to any individual director to whom the communication is addressed unless the communication contains advertisements or solicitations or is unduly hostile, threatening or similarly inappropriate, in which case the Secretary shall discard the communication.



Code of Business Conduct and Ethics

Cara has adopted a Code of Business Conduct and Ethics that applies to all of its officers, directors and employees, including its Chief Executive Officer, Chief Financial Officer and other senior financial officers. The Code of Business Conduct and Ethics provides a framework for sound ethical business decisions and sets forth Cara's expectations on a number of topics, including conflicts of interest, compliance with laws, use of Cara's assets and business ethics. Cara's Code of Business Conduct and Ethics is available on Cara's website at *www.Caratherapeutics.com* in the Investors section under Corporate Governance. If Cara ever were to amend or waive any provision of its Code of Business Conduct and Ethics that applies to Cara's principal executive officer, principal financial officer, principal accounting officer or any person performing similar functions, Cara intends to satisfy its disclosure obligations, if any, with respect to any such waiver or amendment by posting such information on its website set forth above rather than by filing a Current Report on Form 8-K. In the case of a waiver for an executive officer or a director, the disclosure required under applicable Nasdaq listing standards also will be made available on Cara's website.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

Defined terms included below shall have the same meaning as terms defined and included elsewhere in this proxy statement/prospectus.

On December 17, 2024, Cara, Tvardi, and Merger Sub entered into the Merger Agreement, pursuant to which Merger Sub will merge with and into Tvardi, with Tvardi surviving as a wholly-owned subsidiary of Cara (such transaction, the Merger). Upon completion of the Merger, the business of Tvardi will continue as the business of the surviving corporation, referred to herein as the combined company. After the completion of the Merger, Cara will change its corporate name to Tvardi Therapeutics, Inc.

At the Closing and the closing of the related transactions, (i) each outstanding share of common stock of Tvardi (including the shares of common stock issuable upon conversion of all shares of preferred stock of Tvardi prior to the Merger), \$0.001 par value per share (Tvardi common stock), will be converted into the right to receive 284,993,054 shares of common stock of Cara, \$0.001 par value per share (Cara common stock) in the aggregate, based on an assumed Exchange Ratio of 4.8997 (as more fully described in the section titled *Merger Agreement* — *Merger Consideration and Exchange Ratio* included elsewhere in this proxy statement/prospectus), and (ii) the outstanding Convertible Notes of Tvardi will be converted into approximately 46,115,173 shares of Cara common stock, assuming interest on the Convertible Notes is accrued through an anticipated Closing of March 31, 2025, subject to adjustment for the Reverse Stock Split. Cara will assume outstanding and unexercised options to purchase shares of Cara common stock, and in connection with the Merger, they will be converted into options to purchase shares of Cara common stock based on the Exchange Ratio. As of the Effective Time, Cara's stockholders will continue to own and hold their then existing shares of Cara common stock, subject to adjustment for the Reverse Stock Split.

The preliminary assumed Exchange Ratio reflects the assumption that Cara Net Cash as of Closing will be \$23.0 million. Pursuant to the Merger Agreement, Cara Net Cash as of Closing is expected to be approximately \$22.875 million to \$23.125 million (see Note 1 of the accompanying notes for additional discussion). Also refer to the section titled *Merger Agreement — Merger Consideration and Exchange Ratio* included elsewhere in this proxy statement/prospectus, which includes an illustrative table of how the Exchange Ratio and post-Merger equity ownership may change if Cara Net Cash is between \$20.0 million and \$25.0 million as of Closing.

Cara will ask its stockholders to approve an amended and restated certificate of incorporation, including to effect the Reverse Stock Split and increase in authorized shares, for which approvals are also necessary to complete the transactions contemplated by the Merger Agreement. Upon the effectiveness of the amended and restated certificate of incorporation effecting the Reverse Stock Split, the outstanding shares of Cara common stock will be combined into a lesser number of shares in the range to be determined by Cara's Board and agreed to by Tvardi prior to the Effective Time of such amended and restated certificate of incorporation and public announcement by Cara. Because the reverse stock split ratio has not been determined, the unaudited pro forma condensed combined financial statements do not reflect the Reverse Stock Split. Once the Reverse Stock Split has been agreed to, the unaudited pro forma condensed combined financial statement disclosures shall be revised accordingly.

The pro forma adjustments reflect (i) Cara pre-Merger accounting adjustments, referred to as "Transaction Accounting Adjustments — Asset Disposition and Other Adjustments," that occur prior to Closing, (ii) Tvardi pre-Merger accounting adjustments, referred to as "Transaction Accounting Adjustments — Convertible Note Financing," and (iii) transaction accounting adjustments, referred to as "Transaction Accounting Adjustments — Reverse Merger," that occur in connection with the Merger.

- "Transaction Accounting Adjustments Asset Disposition and Other Adjustments" include (i) the wind-down of Cara's operations, including the transfer of its lease to a third-party, (ii) the transfer of certain of Cara's operating assets and liabilities to a third-party in connection with its APA, and (iii) other wind-down activities for Cara's remaining operating assets and liabilities.
- "Transaction Accounting Adjustments Convertible Note Financing" includes Tvardi's issuance of Convertible Notes.
- "Transaction Accounting Adjustments Reverse Merger" includes the (i) conversion of each share of Tvardi convertible preferred stock, (ii) the conversion of the Convertible Notes (both, together with the Merger, the Transactions), and (iii) other Merger related items.

The unaudited pro forma condensed combined balance sheet combines the historical balance sheets of Cara and Tvardi as of September 30, 2024, and depicts the accounting of the Transactions under U.S. GAAP. The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2024 and for the year ended December 31, 2023 combine the historical results of Cara and Tvardi for those periods and depict the pro forma balance sheet transaction accounting adjustments assuming that those adjustments were made as of January 1, 2023. Collectively, pro forma balance sheet transaction accounting adjustments and pro forma statements of operations transaction accounting adjustments." The unaudited pro forma condensed combined financial information was prepared pursuant to the rules and regulations of Article 11 of SEC Regulation S-X, as amended.

The unaudited pro forma condensed combined financial information and related notes have been derived from and should be read in conjunction with:

- the historical unaudited financial statements for Tvardi for the nine months ended September 30, 2024 and 2023 and related notes included elsewhere in this proxy statement/prospectus;
- the historical audited financial statements for Tvardi for the years ended December 31, 2023 and 2022 and related notes included elsewhere in this proxy statement/prospectus;
- the historical unaudited consolidated financial statements for Cara for the nine months ended September 30, 2024 and 2023 and related notes as incorporated elsewhere in this proxy statement/ prospectus;
- the historical audited consolidated financial statements for Cara for years ended December 31, 2023 and 2022 and related notes as incorporated elsewhere in this proxy statement/prospectus;
- the sections titled "Cara's Management's Discussion and Analysis of Financial Condition and Results of Operations," "Tvardi's Management's Discussion and Analysis of Financial Condition and Results of Operation," and other financial information relating to Cara and Tvardi included or incorporated by reference elsewhere in this proxy statement/prospectus.

The unaudited pro forma condensed combined financial information is based on the assumptions and pro forma adjustments that are described in the accompanying notes. The pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed, and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the Closing, may occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information is not necessarily indicative of the financial position or results of operations in the future periods or the result that actually would have been realized had Cara and Tvardi been a combined organization during the specified periods. The actual results reported in periods following the Merger may differ significantly from those reflected in the unaudited condensed combined pro forma financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare the unaudited pro forma condensed combined financial information.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. The accounting policies of Cara may materially vary from those of Tvardi. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the Merger, management will conduct a final review of Cara's accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Cara's results of operations or reclassification of assets or liabilities to conform to Tvardi's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET AS OF SEPTEMBER 30, 2024

(In thousands, except share and per share amounts)

	Historical			As Adjusted	Historical			As Adjusted			
	6(A) Cara Therapeutics, Inc.	Transaction Accounting Adjustments – Asset Disposition and Other Adjustments		Cara Therapeutics, Inc.	6(B) Tvardi Therapeutics, Inc.	Transaction Accounting Adjustments – Convertible Note Financing	_	Tvardi Therapeutics, Inc.	Transaction Accounting Adjustments – Reverse Merger	_	Pro Forma Combined
Assets											
Current assets:											
Cash and cash equivalents	\$ 37,061	\$		\$ 30,933	\$ 9,438	\$28,298	6(g)	\$ 37,736	\$ (2,763)	6(i)	\$ 64,770
		(2,375)	6(c)						(1,136)	6(i)	
		1,500	6(b)								
		1,369 (6,622)	6(d) 6(f)								
Marketable securities	4,975	(0,022)	0(1)	4,975	_			_			4,975
Accounts receivable, net -	.,,,,,			.,,, , , ,							.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
related party	435	(435)	6(d)	_	_			_			—
Inventory, net	625	(625)	6(c)	_	_			—			_
Other receivables	934	(934)	6(d)	_	_			_			_
Prepaid expenses and other											
current assets	2,382	(2,382)	6(e)	-	1,265			1,265			1,265
Restricted cash	1,500	(1,500)	6(b)								
Total current assets	47,912	(12,004)		35,908	10,703	28,298		39,001	(3,899)		71,010
Property, equipment and improvements, net	3,417	(3,417)	6(a)	_	92			92			92
Intangible assets, net					401			401			401
Operating lease right-of-use assets	_			_	218			218			218
Deferred offering costs	_			_	1,083			1,083	(1,083)	6(j)	_
Other non-current assets	_			_	17			17			17
Total assets	\$ 51,329	\$(15,421)		\$ 35,908	\$ 12,514	\$28,298		\$ 40,812	\$ (4,982)		\$ 71,738
Liabilities, Convertible Preferred Stock and Stockholders' Deficit											
Current liabilities:											
Accounts payable and accrued expenses	\$ 6,622	\$ (6,622)	6(f)	s —	\$ 5,215	\$ 100	6(g)	\$ 5,315	\$ 7,900	6(h)	\$ 17,229
expenses	\$ 0,022	\$ (0,022)	0(1)	Ψ	φ 5,215	ψ 100	0(5)	φ 5,515	4,014	6(j)	ψ 17,229
Operating lease liability –									1,011	0())	
current portion	3,417	(3,417)	6(a)	\$	92			92			92
Convertible Notes	_				_	28,298	6(g)	28,298	7,254	6(n)	_
									(35,552)	6(n)	
Total current liabilities	10,039	(10,039)			5,307	28,398		33,705	(16,384)		17,321
Liability related to sales of future royalties and	. ,					- ,			(-))		
milestones, net	40,583	(40,583)	6(c)	_	_			_			_
Operating lease liability – net of current portion					207			207			207
Total liabilities	50,622	(50,622)		_	5,514	28,398		33,912	(16,384)		17,528
Tvardi redeemable convertible preferred stock (Series A, B), \$0.001 par value					85,503			85,503	(85,503)	6(k)	

	Historical			As Adjusted	Historical			As Adjusted			
	6(A) Cara Therapeutics, Inc.	Transaction Accounting Adjustments – Asset Disposition and Other Adjustments	Т	Cara 'herapeutics, Inc.	6(B) Tvardi Therapeutics, Inc.	Transaction Accounting Adjustments – Convertible Note Financing		Tvardi Therapeutics, Inc.	Transaction Accounting Adjustments – Reverse Merger	_	Pro Forma Combined
Stockholders' equity (deficit):											
Cara preferred stock; \$0.001 par value	_			_	_			_	_		_
Cara common stock; \$0.001 par value	54			54	_			_	1	6(1)	286
									46	6(n)	
									(54)	6(m)	
									239	6(m)	
Tvardi common stock, \$0.001 par value	_				19			19	30	6(k)	_
									(49)	6(m)	
Additional paid-in capital	748,611			748,611	1,007			1,007	85,473	6(k)	140,832
									35,506	6(n)	
									(5,097)	6(j)	
									117	6(1)	
									(724,785)	6(m)	
Accumulated other comprehensive loss	(25)			(25)	_			_			(25)
Accumulated deficit	(747,933)	37,583	6(c)	(712,732)	(79,529)	(100)	6(g)	(79,629)	(118)	6(1)	(86,883)
		(2,382)	6(e)						(7,900)	6(h)	
									(2,763)	6(i)	
									(1,136)	6(i)	
									724,649	6(m)	
									(7,254)	6(n)	
Total stockholders' equity (deficit)	707	35,201		35,908	(78,503)	(100)		(78,603)	96,905		54,210
Total liabilities and stockholders' equity (deficit)	\$ 51,329	\$(15,421)		\$ 35,908	\$ 12,514	\$28,298		\$ 40,812	\$ (4,982)		\$ 71,738

See accompanying Notes to the Unaudited Pro Forma Condensed Combined Financial Information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

(In thousands, except share and per share amounts)

	Hi	storical			As Ad	justed	Hi	storical				
		7(A) Cara rapeutics, Inc.	Transaction Accounting Adjustments - Asset Disposition and Other Adjustments		Ca Therap In	eutics,	Т	7(B) `vardi 'apeutics, Inc.	Acco Adjust Rev	saction unting tments - verse erger		Forma mbined
Revenue:												
Collaborative revenue	\$	2,086	\$(2,086)	7(b)	\$	—	\$	_	\$	—	\$	—
Commercial supply revenue		640	(640)	7(b)		—		—				_
Clinical compound revenue		84	(84)	7(b)		—		-				-
Other revenue		2,872	(2,872)	7(b)								—
Total revenue		5,682	(5,682)			_		_		_		_
Operating expenses:												
Cost of goods sold		620	(620)	7(b)		—		_				—
Research and development		32,634				,634		15,047				47,681
General and administrative		19,699				,699		2,258				21,957
Restructuring		5,689			5	,689						5,689
Total operating expenses		58,642	(620)		58	,022		17,305		_		75,327
Operating loss		(52,960)	(5,062)		(58	,022)		(17,305)		—		(75,327)
Other income, net		2,407			2	,407		_				2,407
Interest income		—				_		615				615
Impairment of long-lived assets		(4,274)			(4	,274)		_				(4,274)
Inventory write-down		(2,509)			(2	,509)		_				(2,509)
Non-cash interest expense on liability related to sales of future royalties and milestones		(5,852)	5,852	7(b)		_		_				_
Net loss	\$	(63,188)	\$ 790		\$(62	,398)	\$	(16,690)	\$	_	\$	(79,088)
Net loss per share:												
Basic and Diluted	\$	(1.15)					\$	(0.87)			\$	(0.23)
Weighted average shares:	_											
Basic and Diluted	54	,719,330					19	,192,595			339	9,686,320 7(h)

See accompanying Notes to the Unaudited Pro Forma Condensed Combined Financial Information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2023

	Historical			As Adjusted	Historical		_	As Adjusted			
	7(C) Cara Therapeutics, Inc.	Transaction Accounting Adjustments – Asset Disposition and Other Adjustments	_	Cara Therapeutics, Inc.	7(D) Tvardi Therapeutics, Inc.	Transaction Accounting Adjustments - Convertible Note Financing		Tvardi Therapeutics, Inc.	Transaction Accounting Adjustments – Reverse Merger	_	Pro Forma Combined
Revenue: Collaborative											
revenue	\$ 12,936	\$(12,936)	7(b)	s —	s —	\$ —		s —	s —		s —
Commercial supply revenue	5,843	(5,843)	7(b)			ţ		ф —	ψ		
License and milestone fees	910	(910)	7(b)	_	_			_			_
Royalty revenue	415	(415)	7(b)	_	_			_			_
Clinical compound											
revenue	165	(165)	7(b)	_	_			_			_
Other revenue	699	(699)	7(b)								
Total revenue	20,968	(20,968)									
Operating expenses: Cost of goods sold	6,174	(6,174)	7(b)	_	_			_			_
Research and development	108,510	1,650	7(a)	110,160	15,866			15,866			126,026
General and	100,010	1,000	, (u)	110,100	10,000			10,000			120,020
administrative	27,779	732	7(a)	28,511	2,799			2,799	2,763 1,136	7(d) 7(d)	43,227
									7,900	7(e)	
									118	7(f)	
Total operating expenses	142,463	(3,792)		138,671	18,665	_		18,665	11,917		169,253
Operating loss	(121,495)	(17,176)		(138,671)	(18,665)			(18,665)	(11,917)		(169,253)
Gain in connection with extinguishment of liability related to sales of future royalties and milestones	_	37,583	7(b)	37,583	_			_			37,583
Other income, net	3,586	,	.(-)	3,586	_			_			3,586
Other expense						(100)	7(c)	(100)			(100)
Interest income	_			_	1,318			1,318			1,318
Change in fair value of the Convertible Notes	_			_					(7,254)	7(g)	(7,254)
Non-cash interest expense on liability related to sales of future royalties and milestones	(604)	604	7(b)	_	_			_			_
Net loss	\$ (118,513)	\$ 21,011	7(0)	\$ (97,502)	\$ (17,347)	\$(100)		\$(17,447)	\$(19,171)		\$ (134,120)
Net loss per share:	. (,			. (,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	. (,,,,,,,)	+()			+(,)		. (,)
Basic and Diluted	\$ (2.19)				\$ (0.91)						\$ (0.40)
Weighted average shares:											
Basic and Diluted	54,149,059				19,134,096						338,829,423 7(h)

(In thousands, except share and per share amounts)

See accompanying Notes to the Unaudited Pro Forma Condensed Combined Financial Information.

NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of the Merger

Transaction

On December 17, 2024, Cara, Tvardi and Merger Sub entered into the Merger Agreement pursuant to which Merger Sub will merge with and into Tvardi, with Tvardi surviving as a wholly owned subsidiary of Cara. Subject to the terms and conditions of the Merger Agreement, at the Closing:

- each outstanding share of Tvardi common stock, after giving effect to the conversion of Tvardi's preferred stock into common stock, will be converted into the right to receive a number of shares of Cara common stock, based on the Exchange Ratio;
- b) the outstanding Convertible Notes will be converted into 46,115,173 shares of Cara common stock, in accordance with the terms discussed below; and
- c) each outstanding and unexercised option to purchase shares of Tvardi common stock (Tvardi options) immediately prior to the Closing will be assumed by Cara and will be converted to an option to purchase shares of Cara common stock, with necessary adjustments to the number of shares and exercise price to reflect the Exchange Ratio.

Under the terms of the Merger Agreement, the board of directors of Cara will take actions to accelerate the vesting of (i) certain options to purchase Cara common stock held by non-executive employees or directors as of the closing of the Merger and (ii) Cara's restricted stock units (RSUs) that vest solely on the basis of time. The options of Cara's remaining executives will accelerate upon the closing of the Merger, pursuant to change-in-control language within the preexisting employment agreements or separation arrangements of the executives. Of the total incremental fair value associated with the modification to accelerate vesting of Cara's options and RSUs, \$0.1 million is included as consideration of the Merger and \$0.1 million is included as an adjustment to the unaudited pro forma condensed combined financial information.

Immediately following the Merger, Cara stockholders as of immediately prior to the Merger are expected to own approximately 16.38% of the outstanding capital stock of the combined company on a diluted basis, and former Tvardi stockholders are expected to own approximately 83.62% of the outstanding capital stock of the combined company on a diluted basis, of which 13.53% represents Tvardi investors who participated in Convertible Notes. Tvardi stockholders are expected to receive approximately 284,993,054 shares of Cara common stock in connection with the Merger. The 284,993,054 shares are based on the number of shares of Tvardi (i) common stock outstanding immediately prior to the Merger, (ii) convertible preferred stock outstanding as of September 30, 2024, which will be converted into shares of Tvardi common stock on a one-for-one basis immediately prior to the Closing of the Merger, and (iii) Convertible Notes, which will be converted into shares of Cara common stock upon the Closing (as further described below). These estimates are subject to certain inputs, which includes, but is not limited to, the assumption that Cara Net Cash at the Closing will be approximately \$23.0 million.

The following table summarizes the pro forma number of shares of common stock of the combined company outstanding following the consummation of the Transactions.

	Assuming Cara Closing of \$23	
Equity Capitalization Summary Upon Consummation of the Merger	Number of Shares Owned	% Ownership
Tvardi stockholders	238,877,881	70.09%
Cara stockholders	55,814,563	16.38%
Investors participating in the Convertible Notes	46,115,173	13.53%
Total common stock of the combined company	340,807,617	100.00%

If Cara holds between \$22.875 million and \$23.125 million of net cash at the closing of the Merger, the equity holders of Cara (pre-Merger) are expected to hold approximately 16.34% to 16.42% of the outstanding shares of Cara common stock on a diluted basis, subject to adjustment for the reverse stock split.

The following table summarizes the pro forma number of shares of common stock of the combined company outstanding following the consummation of the Transactions on a fully diluted basis, which includes In-the-Money Cara stock options (as defined elsewhere in this proxy statement/prospectus) and Tvardi options outstanding.

	Assuming Cara Closing of \$23	
Equity Capitalization Summary (fully diluted basis)	Number of Shares Owned	% Ownership
Tvardi stockholders ⁽¹⁾	265,585,923	72.21%
Cara stockholders ⁽²⁾	56,076,092	15.25%
Investors participating in the Convertible Notes	46,115,173	12.54%
Total common stock of the combined company	367,777,188	100.00%

(1) Includes 26,708,042 Tvardi options outstanding as of September 30, 2024, after applying the Exchange Ratio.

(2) Includes 261,529 In-the-Money Cara stock options.

If Cara holds between \$22.875 million and \$23.125 million of net cash at the closing of the Merger, the equity holders of Cara (pre-Merger) are expected to hold approximately 15.21% to 15.28% of the outstanding shares of Cara common stock on a fully diluted basis, subject to adjustment for the reverse stock split.

Consummation of the Merger is subject to certain closing conditions, including, among other things, (i) approval by the stockholders of each party of the adoption and approval of the Merger Agreement and the transactions contemplated thereby, (ii) Nasdaq's approval of the listing of the shares of Cara common stock to be issued in connection with the Merger, (iii) the effectiveness of a registration statement filed with the SEC in connection with the Merger, and (iv) Cara Net Cash at the Closing of at least \$18.0 million.

The pre-Merger employment agreements or Severance Plan (as defined elsewhere in this proxy/ prospectus) arrangements for Cara's remaining executives include entitlement to change-in-control and severance payments and the retention agreements for the remaining Cara non-executive employees include severance and retention bonus payments. The aggregate of these change-in-control, severance, and retention bonus payments will be treated as pre-Merger compensation expense of Cara and will be reflected as an increase to accrued expenses of Cara, which will be paid prior to the Closing Date.

Related events that occurred in connection with the Merger are discussed in more detail below:

Prior to the Closing, (i) Cara transferred its operating lease to a third-party, (ii) discontinued its research and development activities, (iii) entered into an APA to sell certain of its remaining operating assets and liabilities (referred to herein as Cara's Asset Disposition), and (iv) settled its other remaining operating assets and liabilities. Additionally, at Closing, Cara's current Directors & Officers (D&O) policy will be fully utilized. Also prior to the Closing, Tvardi issued \$28.3 million of Convertible Notes to certain of its investors. Cara's Asset Disposition and Tvardi's Convertible Notes are discussed in more detail below.

Asset Disposition

Cara and its subsidiary, Cara Royalty Sub, LLC, entered into an APA with CSL Vifor, pursuant to which CSL Vifor will acquire certain assets and rights for the development, manufacture and commercialization of difelikefalin, as well as certain associated liabilities (the Asset Disposition). The APA is expected to close concurrently with the close of the Merger.

Pursuant to the APA, in connection with the consummation of the Asset Disposition, CSL Vifor and HCR have agreed to enter into an amended and restated agreement to amend and replace the existing Purchase and Sale Agreement.

Additionally, pursuant to the APA, at the consummation of the Asset Disposition, Cara has agreed to pay CSL Vifor \$3.0 million to compensate CSL Vifor for the estimated incremental future expenses to be incurred by CSL Vifor as a result of the transfer of the assets to be acquired and the liabilities to be assumed by it in connection with the Asset Disposition. See the section titled *Asset Sale* included elsewhere in this proxy statement/prospectus for further detail.

CSL Vifor's assumption of Cara's liabilities refers to Cara's "liability related to sales of future royalties and milestones, net" of \$40.6 million, as included on Cara's unaudited condensed balance sheet, as incorporated by reference elsewhere in this proxy statement/prospectus, as of September 30, 2024.

Pursuant to the terms of the Asset Disposition, Cara is to be released of its obligation to transfer royalty payments to HCR (as further discussed within the notes to Cara's historical unaudited condensed financial statements as of and for the nine months ended September 30, 2024, incorporated by reference). In connection with Cara's release of its \$40.6 million liability, Cara will recognize a gain on the extinguishment of the related obligation. Also pursuant to the terms of the APA, as discussed above, pay CSL Vifor \$3.0 million to compensate CSL Vifor for the estimated incremental future expenses to be incurred by CSL Vifor as a result of the transfer of the assets to be acquired and the liabilities to be assumed by it in connection with the Asset Disposition.

The treatment of the APA within Cara's financial statements is still being assessed. For purposes of the pro formas, Cara has preliminarily concluded that the disposal will not qualify as discontinued operations under ASC 205.

Convertible Notes

In December 2024, Tvardi entered into a note purchase agreement to issue and sell Convertible Notes in an aggregate principal amount of \$28.3 million. The Convertible Notes accrue interest at 8% per annum and mature on December 31, 2026. Tvardi will account for the Convertible Notes using the fair value option, and recorded the Convertible Notes based on their fair value upon issuance.

Upon the Closing of the Merger, the outstanding balance of the Convertible Notes and all accrued interest will be automatically converted into shares of Cara common stock, at a conversion price equal to 80% of the implied valuation of the combined company common stock in the Merger. Assuming interest on the Convertible Notes is accrued through the anticipated Closing of March 31, 2025, immediately prior to the Closing, the Convertible Notes and accrued interest will convert into 46,115,173 shares of Cara common stock.

2. Basis of Presentation

The unaudited pro forma condensed combined financial information is prepared in accordance with Article 11 of SEC Regulation S-X. The adjustments presented in the unaudited pro forma condensed combined financial information have been identified and presented to provide relevant information necessary for an understanding of the combined company upon consummation of the Merger.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary accounting conclusions and estimates and the final accounting conclusions and amounts may occur as a result of, among other reasons: (i) changes in initial assumptions in the determination of the accounting acquirer and related accounting, (ii) changes in the amount of cash used in Cara's operations, and (iii) other changes in Cara's assets and liabilities, which are expected to be completed prior to the Closing, and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined company's future results of operations and financial position.

3. Accounting Policies

During the preparation of the accompanying unaudited pro forma combined financial information, Management was not aware of any material differences between Tvardi's accounting policies and the

accounting policies of Cara. Following the consummation of the Merger, Tvardi will conduct a more detailed review of Cara's accounting policies. As a result, Tvardi may identify differences between the accounting policies of the two companies that, when conformed, could have had a material impact on the accompanying unaudited pro forma combined financial information.

4. Accounting for the Merger

The unaudited pro forma condensed combined financial information gives effect to the Merger, which will be accounted for under GAAP as an in-substance reverse recapitalization of Cara by Tvardi. Under this method of accounting, Tvardi will be considered the accounting acquirer for financial reporting purposes. This determination is based on the expectations that, immediately following the Merger:

- Tvardi stockholders will own a substantial majority of the voting rights of the combined company;
- Tvardi will designate a majority of the initial members of the board of directors of the combined company;
- Tvardi's executive management team will become the management team of the combined company; and
- The combined company will be renamed Tvardi Therapeutics, Inc. and its headquarters will be Tvardi's current headquarters, in Houston, Texas.

As a result of Tvardi being treated as the accounting acquirer, Tvardi's assets and liabilities will be recorded at their pre-combination carrying amounts. Cara's assets will be measured and recognized at their fair values as of the Effective Time, which are expected to approximate the carrying value of the acquired cash and other non-operating assets, with no goodwill or other intangible assets recorded. Any difference between the consideration transferred and the fair value of the assets of Cara following the determination of the actual consideration transferred for Cara will be reflected as an adjustment to additional paid-in capital. For periods prior to the Closing, the historical financial statements of Tvardi shall become the historical financial statements of the combined company.

Preliminary Estimated Consideration Transferred (Purchase Price)

The estimated preliminary purchase price, which represents the consideration transferred to Cara stockholders in the Merger, is calculated based on the fair value of the common stock of the combined company that Cara stockholders will own as of the Closing of the Transaction because, with no active trading market for shares of Tvardi, the fair value of the Cara common stock represents a more reliable measure of the fair value of consideration transferred in the Merger. Accordingly, the accompanying unaudited pro forma combined financial information reflects an estimated preliminary purchase price of approximately \$14.6 million. The following summarizes the preliminary estimate of the purchase price to be paid in the Merger (in thousands, except share and per share amounts):

Common shares of the combined company owned by Cara stockholders ⁽¹⁾	55	5,814,563
Multiplied by the fair value per share of Cara common stock ⁽²⁾	\$	0.26
Total	\$	14,512
Estimated fair value of assumed Cara stock-based awards based on pre-Merger service ⁽³⁾		132
Total estimated purchase price	\$	14,644

(1) The final purchase price was determined based on the number of shares of Cara common stock that Cara stockholders owned immediately prior to the Closing of the Merger. For purposes of this unaudited pro forma combined financial information, the estimated number of shares represents 54,846,639 shares of Cara common stock outstanding as of September 30, 2024 and 967,924 unvested RSUs outstanding as of the date of this proxy statement/prospectus, which will become vested in full upon the Closing.

(2) The estimated preliminary purchase price is based on the closing price on the Nasdaq Capital Market on December 16, 2024.



(3) Reflects the estimated acquisition-date fair value of the assumed Cara equity awards attributable to pre-Merger service expected to be outstanding as of the Effective Time. This is included as an adjustment to the unaudited pro forma condensed combined balance sheet by crediting and debiting additional paid-in capital, resulting in no impact to the unaudited pro forma condensed combined financial information.

The actual purchase price for the assets of Cara will vary based on, among other things, the net cash calculation prior to the Closing, the Exchange Ratio and the Cara share price at the Closing. As such, the estimated purchase price consideration reflected in the unaudited pro forma condensed combined financial information does not purport to represent what the actual purchase price consideration will be when the Merger is completed. The actual purchase price will fluctuate until the Effective Time, and the final valuation of the purchase price consideration could differ significantly from the current estimate.

5. Shares of Cara Common Stock Issued to Tvardi Stockholders upon the Closing of the Merger

At the Closing, (i) all outstanding shares of Tvardi common stock (including shares of Tvardi common stock issued upon conversion of Tvardi convertible preferred stock) will be exchanged for shares of Cara common stock based on the preliminary estimated Exchange Ratio of 4.8997 and (ii) all outstanding Tvardi Convertible Notes, including interest accrued through the anticipated Closing, will be converted into 46,115,173 shares of Cara common stock, determined in accordance with the terms of the Merger Agreement. The estimated number of shares of Cara common stock that Cara expects to issue to Tvardi's stockholders assumes Cara Net Cash at the Closing is \$23.0 million and is determined as follows:

Shares of Tvardi common stock outstanding as of September 30, 2024	19,197,914
Shares of Tvardi common stock issued upon conversion of Tvardi convertible preferred stock, see Note 6(k)	29,555,538
Total Tvardi common stock outstanding prior to the closing of the Merger	48,753,452
Exchange Ratio	4.8997
Shares of Tvardi common stock outstanding before the conversion of Tvardi's Convertible Notes	238,877,881
Shares of Cara common stock issued upon conversion of Tvardi 's Convertible Notes, see Note 6(n)	46,115,173
Shares of Cara common stock issued to Tvardi stockholders upon closing of the Merger	284,993,054

In addition, in connection with the Merger, Cara will assume all of the outstanding options to acquire Tvardi common stock and such stock options will become exercisable for shares of Cara common stock following the Merger.

6. Adjustments to Unaudited Pro Forma Condensed Combined Balance Sheet as of September 30, 2024

The pro forma notes and adjustments, based on preliminary estimates that could change materially as additional information is obtained, are as follows:

Pro forma notes:

- 6(A) Derived from the unaudited condensed consolidated balance sheet of Cara as of September 30, 2024
- 6(B) Derived from the unaudited condensed balance sheet of Tvardi as of September 30, 2024

Pro forma Balance Sheet Transaction Accounting Adjustments:

Transaction Accounting Adjustments — Asset Disposition and Other Adjustments

6(a) To reflect the derecognition of Cara's property and equipment, net of \$3.4 million and operating lease liability of \$3.4 million, all of which were transferred to a third-party on November 1, 2024.

- 6(b) In connection with the transfer of Cara's lease to a third-party, to reflect the release of the \$1.5 million in restricted cash in October 2024, which was previously restricted to serve as collateral for the letter of credit in connection with its lease, to cash and cash equivalents.
- 6(c) To reflect, pursuant to the terms of the APA, the (i) derecognition of Cara's \$40.6 million "liability related to sales of future royalties and milestones, net" as the related obligation will be transferred to a third-party, (ii) the sale of Cara's inventory, and (iii) payment of \$3.0 million to compensate CSL Vifor for the estimated incremental future expenses to be incurred by CSL Vifor as a result of the transfer of the assets to be acquired and the liabilities to be assumed by it in connection with the Asset Disposition. The offset to accumulated deficit primarily reflects a gain related to the extinguishment of Cara's prior obligation.
- 6(d) To reflect the receipt of cash and reduction of receivables of \$1.4 million prior to the Closing of the Merger.
- 6(e) To reflect the derecognition of Cara's prepaid expenses of \$2.4 million, consisting of \$1.7 million of prepaid research and development clinical costs, \$0.5 million of prepaid insurance related to the current Cara's D&O policy that will be fully utilized at the Closing and \$0.2 million of other prepaid costs as these amounts will either be written-off or fully amortized at the Closing.
- 6(f) To reflect the payment of \$6.6 million of Cara's accounts payable and accrued expenses, consisting of \$2.5 million of accounts payable, \$1.5 million of accrued research projects, \$1.2 million of accrued compensation and benefits, and \$1.4 million of accrued professional fees before the Closing of the Merger.

Transaction Accounting Adjustments - Convertible Note Financing

6(g) To reflect, pursuant to the terms of the Convertible Notes, Tvardi's issuance of an aggregate principal of \$28.3 million of Convertible Notes in the fourth quarter of 2024. The Convertible Notes were recorded at their fair value upon issuance of \$28.3 million, which is equivalent to their carrying value. The estimated issuance costs of \$0.1 million are recorded as other expense on the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023.

Transaction Accounting Adjustments - Reverse Merger

- 6(h) To reflect preliminary estimated transaction costs of \$7.9 million, not yet reflected in the historical financial statements of Cara, which are expected to be incurred by Cara in connection with the Merger, such as advisory, legal, accounting, auditing, and other professional fees as an increase in accrued expenses of \$7.9 million and a corresponding increase in accumulated deficit in the unaudited pro forma condensed combined balance sheet. This estimate may change as additional information becomes known.
- 6(i) To reflect preliminary estimated incremental compensation expense of \$3.9 million related to severance, retention, and change-in-control payments resulting from (i) pre-existing employment agreements or severance plan arrangements for executives and (ii) retention agreements for non-executive employees that were agreed upon prior to the Merger that had not yet been paid or fully accrued for as of September 30, 2024. As these costs are expected to be paid prior to the Closing, the \$3.9 million is recorded as decrease to cash and cash equivalents and an increase to accumulated deficit in the unaudited pro forma condensed combined balance sheet as of September 30, 2024.
- 6(j) To reflect (i) preliminary estimated transaction costs of \$4.0 million incurred by Tvardi in connection with the merger, such as advisory, legal and auditor fees as an increase in accrued expenses of \$4.0 million, (ii) the derecognition of the deferred offering costs of \$1.1 million included in the historical financial statements, and (iii) a reduction to additional paid-in capital of \$5.1 million in the unaudited pro forma condensed combined balance sheet. As the merger is accounted for as a reverse recapitalization equivalent to the issuance of equity for the net assets

of Cara, these direct and incremental costs are treated as a reduction of the net proceeds received within additional paid-in capital.

6(k) To reflect the automatic conversion, on a one-to-one basis, of all outstanding shares of Tvardi convertible preferred stock, with a carrying amount of \$85.5 million, into 29,555,538 shares of Tvardi common stock immediately prior to the Merger. Tvardi convertible preferred stock outstanding immediately prior to the Closing was comprised of the following:

Tvardi Convertible Preferred Stock	_
Series A Preferred Stock	9,499,999
Series B Preferred Stock	20,055,539
Total shares of Tvardi convertible preferred stock converted to shares of Tvardi common stock immediately prior to the merger	29,555,538

- 6(1) To reflect the accelerated vesting of 967,924 of Cara's RSUs upon the Closing pursuant to the terms of the Merger Agreement, an increase in compensation expenses of approximately \$0.1 million and a decrease in additional paid-in capital of \$0.1 million.
- 6(m) To reflect the recapitalization of Tvardi, pursuant to the Merger Agreement, through the contribution of 48,753,452 shares of Tvardi common stock (see Note 5), and the issuance of 284,993,054 shares of Cara common stock, reflecting the Exchange Ratio of 4.8997 and including the issuance of common stock upon the conversion of the Convertible Notes, and to reflect the derecognition of the accumulated deficit of Cara which is reversed to additional paid-in capital.

The derecognition of accumulated deficit of Cara of \$724.7 million is determined as follows (in thousands):

Accumulated deficit of Cara as of September 30, 2024	\$(747,933)
Gain in connection with extinguishment of liability related to sales of future royalties and milestones, see Note 6(c)	37,583
Derecognition of prepaid expenses, See Note 6(e)	(2,382)
Transaction costs of Cara, see Note 6(h)	(7,900)
Compensation expense related to change-in-control, severance, and retention payments, see Note 6(i)	(3,899)
Acceleration of Cara's RSUs upon closing of the Merger, see Note 6(1)	(118)
Total adjustment to derecognize the accumulated deficit of Cara	\$(724,649)

6(n) To reflect an (i) incremental fair value adjustment of \$7.3 million on the Convertible Notes, reflecting the 20% discount of the Convertible Notes and accrued interest immediately prior to the conversion and (ii) the issuance of 46,115,173 shares of Cara common stock, pursuant to the terms of the Convertible Notes, described in Note 1. The incremental change in fair value of the Convertible Notes of \$7.3 million is adjusted for pro forma purposes through accumulated deficit as of September 30, 2024.

7. Adjustments to Unaudited Pro Forma Condensed Combined Statement of Operations for the Nine Months Ended September 30, 2024 and for Year Ended December 31, 2023

The pro forma notes and adjustments, based on preliminary estimates that could change materially as additional information is obtained, are as follows:

Pro forma notes:

- 7(A) Derived from the unaudited condensed consolidated statement of operations and comprehensive loss of Cara for the nine months ended September 30, 2024
- 7(B) Derived from the unaudited condensed statement of operations of Tvardi for the nine months ended September 30, 2024

- 7(C) Derived from the audited consolidated statement of operations and comprehensive loss of Cara for year ended December 31, 2023
- 7(D) Derived from the audited statement of operations and comprehensive loss of Tvardi for year ended December 31, 2023

Tvardi and Cara did not record any provision or benefit for income taxes during the nine months ended September 30, 2024 or during the year ended December 31, 2023 because each company expects to incur a pre-tax loss in 2024 and incurred a pre-tax loss in 2023 and each company maintains a full valuation allowance on its deferred tax assets. Accordingly, no pro forma adjustments have an impact on associated income tax.

Pro forma Statement of Operations Transaction Accounting Adjustments:

Transaction Accounting Adjustments — Asset Disposition and Other Adjustments

- 7(a) To reflect the derecognition of Cara's prepaid expenses of \$2.4 million, consisting of \$1.7 million of prepaid research and development clinical costs, \$0.5 million of prepaid insurance related to Cara's current D&O policy that will be fully utilized at the Closing, and \$0.2 million of other prepaid costs, assuming the adjustment made in Note 6(e) was made on January 1, 2023.
- 7(b) To reflect (i) a gain of \$37.6 million representing the transfer of Cara's obligation related to its "liability related to sales of future royalties and milestones, net" to a third-party, CSL Vifor, net of \$3.0 million paid to compensate CSL Vifor for the estimated incremental future expenses to be incurred by CSL Vifor as a result of the transfer of the assets to be acquired and the liabilities to be assumed by it in connection with the Asset Disposition, pursuant to the APA and (ii) the corresponding derecognition of Cara's "non-cash interest expense on liability related to sales of future royalties and milestones," both assuming the adjustment made in Note 6(c) was made on January 1, 2023.

The pro forma adjustment also eliminates Cara's revenue and cost of goods sold recognized in the historical financial statements, assuming that the APA was signed on January 1, 2023, as Cara's revenue and costs of goods sold are directly related to difelikefalin, the rights to which will be sold to a third-party in connection with the APA. Cara's "non-cash interest expense on liability related to sales of future royalties and milestones" is also eliminated in this pro forma adjustment since, as discussed above, the related obligation is being transferred to a third-party.

Transaction Accounting Adjustments — Convertible Note Financing

7(c) To reflect the transaction costs incurred related to the issuance of Tvardi's Convertible Notes, assuming the adjustment made in Note 6(g) was made on January 1, 2023.

Transaction Accounting Adjustments — Reverse Merger

- 7(d) To reflect the preliminary estimated incremental compensation expense of \$3.9 million related to severance, retention, and change-in-control payments recorded in general and administrative expenses, resulting from (i) pre-existing employment agreements or severance plan arrangements for executives and (ii) retention agreements for non-executive employees that were agreed upon prior to the Merger that had not yet been paid or fully accrued for as of September 30, 2024, assuming that the adjustment described in Note 6(i) was made on January 1, 2023.
- 7(e) To reflect Cara's estimated advisory, legal, audit, and other costs related to the Merger, including the estimated D&O tail policy, that were not recorded in its historical financial statements as an increase to general and administrative expenses in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023, assuming that the adjustment described in Note 6(h) was made on January 1, 2023. The D&O tail policy is recorded as an increase to general and administrative expenses in the unaudited pro forma condensed combined statement of operations as most of Cara's directors and officers will not continue as directors and officers in the post-combination entity and therefore the D&O tail policy does not represent any future benefit for the post-combination entity.
- 7(f) To reflect Cara's increase in compensation expense of \$0.1 million due to the accelerated vesting

of 967,924 RSUs in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023, assuming that the adjustment described in 6(1) was made on January 1, 2023.

- 7(g) To reflect the incremental change in fair value related to Tvardi's Convertible Notes that is recorded in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023, assuming that the adjustment described in Note 6(n) was made on January 1, 2023.
- 7(h) The pro forma combined basic and diluted net loss per share has been adjusted to reflect the pro forma net loss for the nine months ended September 30, 2024 and year ended December 31, 2023. In addition, the number of shares used in calculating the pro forma combined basic and diluted net loss per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company for the respective periods. For the nine months ended September 30, 2024 and year ended December 31, 2023, the pro forma weighted-average shares have been calculated as follows:

	September 30, 2024	December 31, 2023
	Basic and Diluted	Basic and Diluted
Historical weighted-average number of Tvardi common stock outstanding	19,192,595	19,134,096
Impact of Tvardi convertible preferred stock assuming conversion as of January 1, 2023, see Note 6(k)	29,555,538	29,555,538
Application of Exchange Ratio to historical Tvardi weighted-average shares outstanding	4.8997	4.8997
Adjusted Tvardi weighted-average number of common stock outstanding	238,851,817	238,565,191
Impact of Convertible Notes assuming consummation of the Merger as of January 1, 2023, see Note 6(n)	46,115,173	46,115,173
Historical weighted-average number of Cara common stock outstanding	54,719,330	54,149,059
Pro forma combined weighted average number of common stock outstanding	339,686,320	338,829,423

TVARDI THERAPEUTICS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Tvardi Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Tvardi Therapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and does not have sufficient cash on hand or available liquidity to fund operations, that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the board of directors and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Prepaid and Accrued Research and Development Expenses — Refer to Notes 2, 4 and 6 to the financial statements

Critical Audit Matter Description

The Company recognizes research and development expense and records accruals for estimated costs of research and development activities conducted by third-party contract research organizations (CROs) service providers. The majority of the Company's service providers invoice in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. The Company records advance payments to service providers as prepaid expenses and other current assets, which are expensed as the contracted services are performed. The Company accrues for these costs based on factors such as the time period over which services will be performed, the enrollment of patients and the level of effort to be expended in each period and in accordance with its agreements with its third party service providers for such services.

Given the significant judgments made by the Company in estimating the progress or stage of completion of the services, auditing the Company's accrued and prepaid research and development expenses related to CROs was especially challenging. Specifically, because the amount of accrued and prepaid research and development expenses is dependent on the Company's receipt of timely and accurate reporting from third-party service providers, the Company's estimates of work completed as of the balance sheet date, and the Company's estimates of the period over which this work will be performed, auditing prepaid and accrued research and development expenses related to CROs required a high degree of auditor judgment and an increased extent of effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to testing the prepaid and accrued research and development expenses included the following, among others:

- We tested the design and implementation of relevant controls over the Company's review of associated journal entries.
- We evaluated the Company's accounting policy for prepaid and accrued research and development liabilities, including the estimation approach for the expenses, for reasonableness.
- We evaluated the Company's judgments, including but not limited to, patient enrollment, using the evidence obtained to determine the prepaid and accrued research and development liabilities.
- For a sample of agreements and contracts, we agreed inputs utilized in the estimate of prepaid and accrued research and development liabilities to the underlying contract, corresponding invoices incurred during the period and evidence of payment to test the Company's disbursements made to third-party service providers.
- We compared invoices received by the Company subsequent to December 31, 2023 to the accrued research and development expenses related to CROs recognized by the Company.

/s/ Deloitte & Touche LLP

Houston, Texas

December 18, 2024 We have served as the Company's auditor since 2022.

Balance Sheets

(Amounts in thousands, except share and per share amounts)

	As of December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,919	\$ 21,489
Short-term investments	_	22,250
Prepaid expenses and other current assets	3,239	370
Total current assets	26,158	44,109
Property and equipment, net	116	147
Intangible assets, net	448	511
Operating lease right-of-use assets	262	313
Other non-current assets	17	17
Total assets	\$ 27,001	\$ 45,097
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,611	\$ 2,409
Accrued expenses	1,577	1,786
Operating lease liabilities, current portion	93	82
Total current liabilities	3,281	4,277
Operating lease liabilities, net of current portion	275	368
Total liabilities	3,556	4,645
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock (Series A, B), \$0.001 par value; 29,723,540 shares authorized as of December 31, 2023 and 2022; 29,555,538 shares issued and outstanding as of December 31, 2023 and 2022; aggregate liquidation preference of \$85,902 as of December 31, 2023 and 2022	85,503	85,503
Stockholders' Deficit:		
Common stock, \$0.001 par value; 58,251,629 shares authorized as of December 31, 2023 and 2022; 19,134,164 and 19,127,914 shares issued and outstanding as of December 31, 2023 and 2022, respectively;	19	19
Additional paid-in capital	762	446
Accumulated other comprehensive loss		(24
Accumulated deficit	(62,839)	(45,492
Total stockholders' deficit	(62,058)	(45,051
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	\$ 27,001	\$ 45,097

The accompanying notes are an integral part of these financial statements.

Statements of Operations and Comprehensive Loss (Amounts in thousands, except share and per share amounts)

	For the Year Ended December 31,			ecember 31,	
		2023		2022	
Operating expenses:					
Research and development	\$	15,866	\$	18,466	
General and administrative		2,799		2,727	
Total operating expenses		18,665		21,193	
Loss from operations		(18,665)		(21,193)	
Other income (expense):					
Interest income		1,318		654	
Interest expense		_		(3)	
Total other income, net		1,318		651	
Net loss	\$	(17,347)	\$	(20,542)	
Net loss per share attributable to common stockholders, basic and diluted	\$	(0.91)	\$	(1.07)	
Weighted-average common shares outstanding, basic and diluted	19	9,134,096		9,116,342	
Comprehensive loss:					
Net loss	\$	(17,347)	\$	(20,542)	
Unrealized loss on short-term investments		_		(24)	
Comprehensive loss	\$	(17,347)	\$	(20,566)	

The accompanying notes are an integral part of these financial statements.

Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit (Amounts in thousands, except share amounts)

	Redeen Conver Prefer Stoo	tible red	Comn Stoo		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	
	Shares	Amount	Shares	Amount		Deficit	Loss	Deficit	
Balances as of January 1, 2022	29,555,538	\$85,503	19,096,873	\$19	\$196	\$(24,950)	\$ —	\$(24,735)	
Exercise of stock options	—	—	31,041	_	4	_	—	4	
Stock-based compensation	_	—	_	—	246	—	—	246	
Unrealized loss on short-term investments	_	_	_	_	_		(24)	(24)	
Net loss	—	—	_	—	_	(20,542)		(20,542)	
Balances as of December 31, 2022	29,555,538	\$85,503	19,127,914	\$19	\$446	\$(45,492)	\$(24)	\$(45,051)	
Exercise of stock options	_	—	6,250	_	2	_	_	2	
Stock-based compensation	_	_	_	—	314	_	_	314	
Maturities of short-term investments	_	—	_	—	_	_	24	24	
Net loss	_	_	_	_	_	(17,347)	_	(17,347)	
Balances as of December 31, 2023	29,555,538	\$85,503	19,134,164	\$19	\$762	\$(62,839)	\$ —	\$(62,058)	

The accompanying notes are an integral part of these financial statements.

Statements of Cash Flows (Amounts in thousands)

	For the Year Ended Decembe		
	2023	2022	
Cash flows from operating activities:			
Net loss	\$(17,347)	\$(20,542	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	95	85	
Stock-based compensation expense	314	246	
Non-cash lease expense	51	34	
Accretion of discounts on short-term investments	(194)	(355)	
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(2,869)	478	
Accounts payable and accrued expenses	(1,008)	2,195	
Operating lease liabilities	(82)	(7	
Net cash used in operating activities	(21,040)	(17,866	
Cash flows from investing activities:			
Purchases of property and equipment		(50	
Purchases of short-term investments	—	(43,995	
Maturities of short-term investments	22,468	22,045	
Net cash provided by (used in) investing activities	22,468	(22,000)	
Cash flows from financing activities:			
Proceeds from exercise of stock options	2	4	
Net cash provided by financing activities	2	4	
Net increase (decrease) in cash and cash equivalents	1,430	(39,862)	
Cash and cash equivalents-beginning of year	21,489	61,351	
Cash and cash equivalents-end of year	\$ 22,919	\$ 21,489	
Non-cash investing and financing activities:			
Leasehold improvements	\$ —	\$ 119	
Supplemental cash flow information:			
Obtaining an operating lease right-of-use asset in exchange for an operating lease liability	\$ —	\$ 347	

The accompanying notes are an integral part of these financial statements.

Notes to Financial Statements

1. Nature of the Business and Basis of Presentation

Tvardi Therapeutics, Inc., or the Company, incorporated on December 20, 2017, is a Delaware Corporation headquartered in Houston, Texas. The Company is a clinical-stage, biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting STAT3 to treat fibrosis-driven diseases with significant unmet need. Based upon its founder's seminal work and deep understanding of the transcription factor, STAT3, the Company has designed an innovative approach to directly inhibit STAT3, a highly validated, yet historically undruggable target. Leveraging this expertise, the Company is developing a pipeline of STAT3 inhibitors with a differentiated mechanism of action and convenient oral dosing. The Company's lead product candidate, TTI-101, is currently in Phase 2 clinical development for the treatment of fibrosis-driven diseases, with an initial focus on idiopathic pulmonary fibrosis, IPF and hepatocellular carcinoma, HCC.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful development of TTI-101 and TTI-109, the development of new technological innovations by competitors, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations and the ability to secure additional capital to fund operations and commercial success of TTI-101 and TTI-109. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be maintained, that any therapeutic products developed will obtain required regulatory approval or that any approved or consumer products will be commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales.

Additionally, the global economy has experienced extreme volatility and disruptions due to the military conflict between Russia and Ukraine and the war between Israel and Hamas. These conditions have impacted, and may continue to impact, the capital and credit markets, which may reduce the Company's ability to raise additional capital through equity, equity-linked instruments or debt financings which could negatively impact the Company's short-term and long-term liquidity. Additionally, the Company's results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to the Company's business, including a reduced ability to raise additional capital when needed on favorable terms, if at all. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Any of the foregoing could harm the Company's business, and it cannot anticipate all of the ways in which the current economic climate and financial market conditions.

Liquidity and Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the year ended December 31, 2023, the Company incurred a net loss of \$17.3 million and used \$21.0 million of cash in operating activities. As of December 31, 2023, the Company had an accumulated deficit of \$62.8 million.

1. Nature of the Business and Basis of Presentation (continued)

To date, the Company has no products approved for marketing and sale and it has not yet recorded any revenue from product sales. The Company's ability to achieve profitability is dependent on its ability to successfully develop its lead compound, conduct clinical trials, obtain regulatory approvals, and support commercialization activities for its product candidates. Any products developed will require approval of the U.S. Food and Drug Administration, or the FDA, or a foreign regulatory authority prior to commercial sale.

Since inception, the Company has relied primarily on sales of redeemable convertible preferred stock and issuance of convertible debt to fund its operations. The Company's product candidates are still in the early stages of development, and substantial additional financing will be needed by the Company to fund its operations and ongoing research and development efforts prior to the commercialization of its product candidates.

The Company's cash and cash equivalents of \$22.9 million as of December 31, 2023 are not sufficient to fund its planned operations for at least one year from the issuance of these financial statements, which raises substantial doubt as to the Company's ability to continue as a going concern.

Significant additional funding is necessary to maintain current operations and to advance the Company's research and development activities. The Company is seeking to complete an initial public offering, or IPO, of its common stock. Alternatively, the Company expects to fund its operations through equity offerings or debt financings, credit or loan facilities, strategic alliances and licensing arrangements. The Company's ability to access capital when and in the amount needed is not assured. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Basis of Presentation

The accompanying financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The accompanying financial statements represent the accounts of the Company. The Company does not maintain ownership in any subsidiaries and therefore does not consolidate any other entities within the presented financial statements.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses as of and during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates. Significant estimates and assumptions reflected within these financial statements include, but are not limited to, prepaid and accrued research and development expenses, including those related to contract research organizations, or CROs, contract development manufacturing organizations, or CDMOs, and other third-party vendors, and the valuation of the Company's common stock and stock-based awards. Changes in estimates are recorded in the period in which they become known.

Concentration of Credit Risk and of Significant Suppliers

The Company's cash, cash equivalents and short-term investments represent potential concentrations of credit risk. The Company deposits its cash and cash equivalents in financial institutions in amounts that may exceed federally insured limits, has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The short-term investments consist of U.S. Treasury Notes which the Company believes represent minimal credit risk.

The following table presents information about the Company's significant suppliers:

		For the Year Ended December 31,		of oer 31,	
	2023	2022	2023	2022	
	-	% of operating expenses		% of accounts payable	
Vendor A	33%	28%	40%	42%	
Vendor B	14%	9%	—	27%	
Vendor C	8%	7%	10%	8%	
Vendor D		_	19%	_	
	55%	44%	69%	77%	

The Company's preclinical studies and clinical trials and testing could be adversely affected by a significant interruption in the supply chain from its significant suppliers.

Cash and Cash Equivalents

The Company considers all highly liquid investments, with an original maturity of three months or less, to be cash equivalents. Cash equivalents include amounts held in money market funds in the amount of \$21.8 million and \$20.4 million as of December 31, 2023 and 2022, respectively.

Short-term Investments

The Company invests excess cash in short-term investments with high credit ratings. These securities consist primarily of U.S. Treasury Notes that are classified as "available-for-sale." The Company classifies any investments as short-term if the maturity date is less than or equal to one year from the balance sheet date or as long-term if the maturity date is in excess of one year from the balance sheet date.

The Company's short-term investments are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income in stockholders' deficit. Realized gains and losses and declines in fair value due to credit-related factors are based on the specific identification method and are included within other income (expense), net in the statements of operations and comprehensive loss. The Company recorded interest income on short-term investments, inclusive of accretion of its discounts on its short-term investments, of \$1.3 million and \$0.7 million during the years ended December 31, 2023 and 2022, respectively, which is classified as interest income in the statements of operations and comprehensive loss.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in other income (expense), net. The Company evaluates whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income (expense), net. The portion that is not credit-related is treated in accordance with other unrealized losses as a component of accumulated other comprehensive income in stockholders' deficit. There have been no impairment or credit losses recognized during any of the periods presented.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholders' deficit as a reduction of additional paid-in-capital generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. The Company did not record any deferred offering costs as of December 31, 2023 and 2022.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The Company's cash equivalents and short-term investments are carried at fair value (Refer to Note 3, *Fair value measurements*).

Property and Equipment

The Company records property and equipment at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Computer equipment	3 years
Office equipment	5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful
	life

Estimated useful lives are periodically assessed to determine if changes are appropriate. Leasehold improvements are amortized using the straight-line method over the lesser of the lease term or its estimated useful life. Lease terms are based upon the initial lease agreement and do not consider potential renewals or extensions until such time that the renewals or extensions are contracted. Expenditures for maintenance and repairs that do not improve or extend the life of the respective assets are expensed as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation

or amortization are eliminated from the balance sheets and any resulting gains or losses are included in the statements of operations and comprehensive loss in the period of disposal.

Depreciation and amortization expense related to property and equipment, net was less than \$0.1 million for each of the years ended December 31, 2023 and 2022.

Intangible Assets

Intangible assets consist of licenses for exclusive use of patent rights owned by a third party, which are amortized using the straight-line method over the estimated periods of benefit, generally the remaining life of the underlying licensed patents.

The Company reviews intangible assets for impairment whenever conditions exist that indicate the carrying value may not be recoverable, such as an economic downturn in the market or a change in the assessment of future operations. No impairment was recorded for the years ended December 31, 2023 and 2022.

Refer to Note 14, Licensing Agreements, for further detail on the Company's licenses.

Impairment of Long-lived Assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value. For the years ended December 31, 2023 and 2022, the Company did not record any impairment losses on long-lived assets.

Operating Leases

The Company determines whether an arrangement is or contains a lease, as defined by Accounting Standards Update, or ASU, 2016-02, *Leases* (Topic 842), or ASC 842, at contract inception by evaluating whether the arrangement conveys the right to use an identified asset and whether the Company obtains substantially all of the economic benefits from and has the ability to direct the use of the asset. If an arrangement is determined to be or contain a lease, the lease is assessed for classification as either an operating or finance lease at the lease commencement date, defined as the date on which the leased asset is made available for use by the Company, based on the economic characteristics of the lease.

ASC 842 includes certain practical expedients that can be elected for new leases that are executed after the adoption of the new requirements. The Company elected the practical expedient to not separate lease and non-lease components. The Company also elected to apply the short-term lease recognition exemption which eliminates the requirement to present on the balance sheets leases with a term of 12 months or less. These two practical expedients were elected for all classes of underlying assets.

At the lease commencement date, the Company recognizes a lease liability and a right-of-use, or ROU, asset representing its right to use the underlying asset over the lease term. The initial measurement of the lease liability is calculated as the present value of the future lease payments in the contract and the ROU asset is measured as the lease liability plus initial direct costs and prepaid lease payments, less lease incentives granted by the lessor. The subsequent measurement of a lease is dependent on whether the lease is classified as an operating lease or a finance lease. Operating lease cost is recognized on a straight-line basis over the lease term in the statements of operations and comprehensive loss.

The Company's lease requires other payments such as costs related to taxes, insurance, maintenance, and other expenses. These costs are generally variable in nature and based on the actual costs incurred and required by the lease. As the Company has elected to not separate lease and non-lease components for all classes of underlying asset, all variable costs associated with the lease are expensed in the period incurred and presented and disclosed as variable lease costs. The Company's lease agreements do not contain any material residual value guarantees or material restrictive financial covenants.

ASC 842 requires that a lessee use the rate implicit in the lease when measuring the lease liability and ROU asset. If the rate implicit in the lease is not readily determinable, the Company is permitted to use its incremental borrowing rate, which is defined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Since the rate implicit in the lease is not readily determinable, the Company uses its incremental borrowing rate when measuring its leases. The incremental borrowing rate is calculated by considering the Company's credit standing, the lease term and other quantitative and qualitative factors.

Most leases include options to renew and, or, terminate the lease, which can impact the lease term. The exercise of these options is at the Company's discretion. Periods covered by an option to extend a lease are not included in the lease term as the Company is not reasonably certain it will exercise this option. Additionally, periods covered by an option to terminate the lease are included in the lease term as it is reasonably certain that the Company will not exercise this option.

Classification of Redeemable Convertible Preferred Stock

The holders of Series A and Series B redeemable convertible preferred stock, or the Preferred Stock, have certain liquidation rights in the event of a liquidation event or a deemed liquidation event that, in certain situations, is not solely within the control of the Company and would call for the redemption of the then outstanding Preferred Stock (see Note 8 *Redeemable Convertible Preferred Stock*, for further detail). Therefore, the Preferred Stock is classified as temporary equity on the accompanying balance sheets.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or CODM, in deciding how to allocate resources and in assessing performance. The Company's CODM, its Chief Executive Officer and Chief Financial Officer, view the Company's operations as a single operating segment, which is the business of discovering and developing novel orally bioavailable, small molecule therapies across a broad range of diseases driven by STAT3 with high unmet need.

All of the Company's long-lived assets are held in the United States.

Research and Development Expenses

Research and development expenses are expensed as incurred. Research and development expenses include wages, associated employee benefits, and stock-based compensation expense of employees engaged in research, amortization of licensed intangible assets, external costs of third-party vendors that conduct research and development and manufacturing activities on behalf of the Company, and other operational costs related to the Company's research and development activities.

Prepaid and Accrued Research and Development Expenses

The Company recognizes research and development expense and records accruals for estimated costs of research and development activities conducted by third-party service providers, which include CROs that conduct research, preclinical studies and clinical trials on the Company's behalf, including in connection with the Company's research and development arrangement, and CDMOs that manufacture the Company's product candidate for use in preclinical studies and clinical trials. The majority of the Company's service providers invoice in arrears for services performed, on a pre-determined schedule or when contractual

milestones are met; however, some require advanced payments. The Company makes estimates of the accrued expenses and includes these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations and comprehensive loss based on facts and circumstances known to the Company at that time. These costs are a significant component of the Company's research and development expenses.

The Company accrues for these costs based on factors such as estimates of the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and in accordance with agreements established with its third-party service providers for such services. The Company makes significant judgments and estimates in determining the accrued research and development liabilities balance at each reporting period. As actual costs become known, the Company adjusts its accrued estimates. To date, there have been no material adjustments to the Company's estimates of accrued research and development expenses. The Company records advance payments to service providers as prepaid expenses and other current assets, which are expensed as the contracted services are performed. If the actual timing of the performance of services varies from the estimate, then the Company adjusts the amount of the accrued expense or the prepaid expense accordingly.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits, including stock-based compensation expense, for employees in operating and finance functions and directors, as applicable; professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include expenses for rent and maintenance of facilities and other operating costs. The Company expenses all general and administrative expenses as incurred.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recoverability of the expenditure. Amounts incurred are classified as general and administrative expenses in the Company's statements of operations and comprehensive loss.

Stock-based Compensation

The Company measures all stock-based awards granted to employees, officers, directors, consultants, and advisors based on the fair value on the date of the grant, and recognizes the resulting fair value over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options granted. The Company has elected to recognize stock-based compensation expense for service-based stock options with graded vesting on a straight-line basis over the requisite service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. The Company classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company measures stock-based compensation costs for employees and non-employees at the grant date based on the estimated fair value of the award, which is reviewed periodically, and recognizes compensation expense on a straight-line basis over the vesting period which approximates the requisite service period. Compensation expense is recognized with an offsetting credit to additional paid-in capital.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources, including unrealized gains and losses on short-term investments held as available-for-sale. There was no difference between net loss and comprehensive loss for the year ended December 31, 2023. For the year ended December 31, 2022, comprehensive loss includes net loss and a net unrealized loss on short-term investments.

Net Loss Per Share

The Company calculated basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for companies with participating securities. The Company's redeemable convertible preferred stock is considered participating as the holders are entitled to receive dividends in preference and priority to the holders of common stock. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period has been distributed. There is no allocation required under the two-class method during periods of loss since the participating securities do not have a contractual obligation to share in the losses of the Company.

Under the two class method, basic net loss per share attributable to common stockholders is computed by dividing net loss attributed to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by (i) adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities and (ii) dividing the diluted net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For purposes of this calculation, redeemable convertible preferred stock and stock options to purchase common stock are considered potential dilutive common shares.

The Company has generated a net loss in all periods presented, and therefore the basic and diluted net loss per share attributable to common stockholders are the same as the inclusion of the potentially dilutive securities would be anti-dilutive.

Income Taxes

The Company provides for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company utilizes a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-02, *Leases*, which requires lessees to recognize most leases on their balance sheet as a ROU asset and a lease liability. The standard, including subsequently issued amendments, collectively referred to as ASC 842, established principles of recognition, measurement, presentation and disclosure of lease arrangements applicable to lessees and lessors in order to enhance the transparency and compatibility of financial reporting related to the arrangements, including with respect to the amount, timing and uncertainty of cash flows arising from a lease. The Company adopted ASU 2016-02 using a modified retrospective transition approach effective January 1, 2022 and it did not have a material impact on the Company's financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740)* — *Simplifying the Accounting for Income Taxes*, or ASU 2019-12, which simplifies the accounting for income taxes by removing certain exceptions to the general principles of ASC 740, *Income Taxes*. The amendments also improve consistent application of and simplify GAAP for other areas of ASC 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for fiscal years and interim periods beginning after December 15, 2020 for public companies and for fiscal years beginning after December 15, 2021 for nonpublic companies, with early adoption permitted. Depending on the amendment, adoption may be applied on a retrospective, modified retrospective, or prospective basis. The Company adopted ASU 2019-12 effective January 1, 2022 and it did not have a material impact on the Company's financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments* — *Credit Losses (Topic 326)*, or ASU 2016-13. The new standard changes the accounting for assets held at amortized costs basis, including short-term investments accounted for as available-for-sale, and trade receivables. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For public entities except smaller reporting companies, the guidance is effective for annual reporting periods beginning after December 15, 2019, and for interim periods within those fiscal years. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments* — *Credit Losses (Topic 326)*, *Derivatives and Hedging (Topic 815)*, *and Leases (Topic 842): Effective Dates*, which deferred the effective date for non-public entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. Early application is allowed. The Company adopted ASU 2016-13 effective January 1, 2023 and it did not have a material impact on its financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company can adopt the new or revised standard at the time non-public companies adopt the new or revised standard at the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, or ASU 2023-07. ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. ASU 2023-07 is effective for public business entities with fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the provisions of this guidance and the potential impact on its financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, or ASU 2023-09. ASU 2023-09 requires public business entities to disclose additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate (the rate reconciliation) for federal, state, and foreign income taxes. It also requires greater detail about individual reconciling items in the rate reconciliation to the extent the impact of those items exceeds a specified threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate). In addition to new disclosures associated with

the rate reconciliation, ASU 2023-09 requires information pertaining to taxes paid (net of refunds received) to be disaggregated for federal, state, and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. The amendments are effective for public business entities for annual periods beginning after December 15, 2024. For entities other than public business entities, the amendments are effective for annual periods beginning after December 15, 2024. For entities other than public business entities, the amendments are effective for annual periods beginning after December 15, 2025. Early adoption is permitted. As of December 31, 2023, the Company has not yet adopted this new ASU however the Company expects no impact to its operations, cash flows, or financial condition upon adoption.

3. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	As of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents:				
Money market funds	\$21,762	\$ —	\$ —	\$21,762
Total financial assets	\$21,762	\$ —	\$ —	\$21,762
	As of December 31, 2022			2
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents:				
Money market funds	\$20,388	\$ —	\$ —	\$20,388
Short-term investments				
U.S. Treasury Notes	22,250	—		22,250
Total financial assets	\$42,638	<u></u>	<u></u>	\$42,638

The Company did not have any Level 3 assets or liabilities at December 31, 2023 or 2022. There were no transfers between Levels during the periods presented.

Short-term investments held as of December 31, 2022 consisted of the following:

	As of December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments				
U.S. Treasury Notes	\$22,274	\$8	\$(32)	\$22,250
Total short-term investments	\$22,274	\$8	\$(32)	\$22,250

The Company had net unrealized losses of approximately \$24,000 during the year ended December 31, 2022. Upon maturity of all of the Company's short-term investments during the year ended December 31, 2023, the Company reversed this loss. The Company did not have short-term investments during the year ended December 31, 2023.

The contractual maturities of the Company's short-term investments in available-for-sale securities held were as follows (in thousands):

	December 31, 2022
Due within one year	\$22,250

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of December 31, 2023 and 2022 (in thousands):

	As of Dece	As of December 31,	
	2023	2022	
Prepaid research and development expenses	\$3,203	\$314	
Other prepaid expenses	36	56	
Total prepaid expenses and other current assets	\$3,239	\$370	

5. Intangible Assets

Intangible assets consisted of the following as of December 31, 2023 and 2022 (in thousands):

	As of Dece	As of December 31,	
	2023	2022	
Licensed patent rights	\$ 826	\$ 826	
Less: accumulated amortization	(378)	\$(315)	
Total intangible assets, net	\$ 448	\$ 511	

As of December 31, 2023, the expected remaining amortization expense is as follows (in thousands):

Year Ended December 31,	Amount
2024	\$ 63
2025	63
2026	63
2027	63
2028	63
Thereafter	133
Total	133 \$448

The Company recognized less than \$0.1 million for amortization expense for each of the years ended December 31, 2023 and 2022, respectively. Amortization expense is included in research and development expense in the statements of operations and comprehensive loss.

6. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2023 and 2022 (in thousands):

	As of December 31,	
	2023	2022
Accrued research and development expenses	\$ 574	\$ 899
Accrued employee compensation and benefits	942	678
Other accrued expenses	61	209
Total accrued expenses	\$1,577	\$1,786

7. Leases

The Company has one operating lease pertaining to 5,969 square feet of corporate office space in Sugar Land, Texas pursuant to a lease agreement that commenced April 1, 2022. As of December 31, 2023 the remaining term of lease was 3.67 years. The lease requires monthly lease payments that are subject to annual increases throughout the lease term.

7. Leases (continued)

The components of lease costs, which are included within general and administrative expenses in the Company's statements of operations and comprehensive loss were as follows (in thousands):

		For the Year Ended December 31,	
	2023	2022	
Lease costs:			
Operating lease cost	\$ 90	\$67	
Variable lease cost	83	25	
Total lease costs	\$173	92	

Supplemental disclosure of cash flow information related to the lease were as follows (in thousands):

		For the Year Ended December 31,	
	2023	2022	
Operating cash flows from operating leases	\$194	\$ 64	
Operating lease right-of-use assets obtained in exchange for new operating lease liabilities	\$ —	\$347	

The weighted-average discount rate and remaining lease term were as follows:

	For the Year Ended December 31,	
	2023	2022
Weighted-average discount rate	9.50%	9.50%
Weighted-average remaining lease term	3.67	4.67

As of December 31, 2023, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year Ended December 31,	Amount
2024	\$123
2025	94
2026	129
2027	88
Total lease payments	434
Less: imputed interest	(66)
Present value of lease liabilities	368
Less: operating lease liabilities, current portion	\$ 93
Operating lease liabilities, net of current portion	\$275

8. Redeemable Convertible Preferred Stock

The Company has issued Series A preferred stock and Series B preferred stock, which are collectively referred to as the Preferred Stock. As of December 31, 2023 and 2022, the Company authorized the issuance of 29,723,540 shares of Preferred Stock, par value of \$0.001 per share, of which 9,499,999 have been designated Series A preferred stock and 20,223,541 have been designated Series B preferred stock.

Series A Preferred Stock

During 2018, the Company entered into the Series A preferred stock purchase agreements for 8,550,340 shares of Series A preferred stock with par value of \$0.001 each at a price \$1.00 per share, or the Series A

8. Redeemable Convertible Preferred Stock (continued)

Original Issue Price, with a group of investors for net proceeds of \$8.4 million, or the Series A Financing. In addition, in connection with the closing of the Series A Financing, then outstanding convertible promissory notes of \$0.4 million were converted into 449,659 shares of Series A preferred stock at the Series A Original Issue Price paid by the Series A Financing investors.

Series B Preferred Stock

In June 2021, the Company entered into the Series B preferred stock purchase agreements for 17,452,411 shares of Series B preferred stock with par value of \$0.001 each at a price \$3.8095 per share, or the Series B Original Issue Price, with a group of investors for net proceeds of \$66.3 million, or the Series B Financing. In addition, in connection with the closing of the Series B Financing, (i) then outstanding convertible promissory notes of \$7.9 million were converted into 2,603,128 shares of Series B preferred stock at 80% of the Series B Original Issue Price paid by the Series B Financing investors and (ii) a then outstanding translational research grant of \$0.5 million was converted into 500,000 shares of Series A Preferred Stock at a conversion price of \$1.00 per share pursuant to the terms of grant agreement, dated as of March 2018.

The following tables summarize the Company's redeemable convertible preferred stock as of December 31, 2023 and 2022:

	Par Value	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A preferred stock	\$0.001	9,499,999	9,499,999	\$ 9,327	\$ 9,500	9,499,999
Series B preferred stock	0.001	20,223,541	20,055,539	76,176	76,402	20,055,539
		29,723,540	29,555,538	\$85,503	\$ 85,902	29,555,538

The key terms of Preferred Stock are as follows:

Dividends

The Company shall not declare, pay or set aside any dividends on shares or any other class or series of capital stock (other than dividends on shares of the Company's common stock payable in shares of common stock) unless first the holders of Series B preferred stock shall first receive, or simultaneously receive, a dividend on each outstanding preferred stock, and second, the holders of the Series A preferred stock shall next receive, or simultaneously receive a dividend on each outstanding preferred stock. If the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of Preferred Stock shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest dividend. There have been no dividends declared by the Company's board of directors, or the Board, as of December 31, 2023 and 2022.

Voting Rights

The holder of each share of Series A and Series B preferred stock shall have the right to one vote for each share of common stock into which such Series A and Series B preferred stock could then be converted.

Right to Elect Directors

Holders of Series A preferred stock are entitled to elect two directors of the Company. The holders of Series B preferred stock are entitled to elect one director of the Company. The holders of the Company's common stock are entitled to elect one director of the Company. The holders of Preferred Stock and Common Stock (voting together as a single class and not as separate series and on as-converted basis) shall be entitled to elect any remaining director of the Company.

Conversion

Each share of Preferred Stock is convertible at the option of the holder, at any time, and without the payment of additional consideration by the holder. In addition, each share of Preferred Stock will be

8. Redeemable Convertible Preferred Stock (continued)

automatically converted into shares of common stock at the applicable conversion ratio then in effect upon either (i) the closing of a firm-commitment underwritten public offering of the Company's common stock at a price of at least \$5.7143 per share resulting in at least \$50.0 million of gross proceeds to the Company, or (ii) the vote or written consent of the holders of a majority of the outstanding shares of Preferred Stock, voting as a single class.

The conversion ratio of Series A and Series B Preferred Stock is determined by dividing the respective original issue price by the applicable conversion price in effect at the time of conversion. The conversion price is \$1.00 and \$3.8095 per share for Series A and Series B preferred stock, respectively. As of December 31, 2023, each outstanding share of Preferred Stock was convertible into the Company's common stock on a one-for-one basis.

Liquidation

In the event of liquidation, dissolution, or winding up of the Company or upon the occurrence of a Deemed Liquidation Event (as defined below), the holders of Series B preferred stock then outstanding are entitled to distribution of the Company's assets or funds, before the holders of Series A preferred stock and common stock, in an amount per share equal to the greater of (i) the Series B Original Issue Price (\$3.8095 per share), plus any dividends declared but unpaid, or (ii) the amount per share that would have been payable had all shares of Series B preferred stock been converted to common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If the assets of the Company are insufficient to pay holders of the Series B Preferred Stock the full amount to which they are entitled, they shall be paid ratably in proportion to the respective amounts they would have received had they been paid in full.

In the event of liquidation, dissolution, or winding up, after the Series B preferred stock holders have been paid in full, the holders of Series A preferred stock are entitled to distribution of the Company's assets or funds, before the common stock, in amount per share equal to the greater of (i) the Series A Original Issue Price (\$1.00 per share), plus any dividends declared but unpaid, or (ii) the amount per share that would have been payable had all shares of Series A preferred stock been converted to common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If the assets or funds of the Company are insufficient to pay holders of the Series A preferred stock the full amount to which they are entitled, they shall be paid ratably in proportion to the respective amounts they would have received had they been paid in full. After payment of all preferential amounts to Series A preferred stock holders, the remaining assets available for distribution shall be distributed to the holders of common stock pro rata based on the number of shares held.

Unless the holders of a majority in voting power of the then outstanding shares of Series B preferred stock elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or sale, lease, transfer, exclusive license or other disposition of all or substantially all of the Company's assets.

Redemption

The holders of the Company's Preferred Stock have no voluntary rights to redeem shares. Upon the occurrence of a Deemed Liquidation Event that are outside of the Company's control, the holders of the Preferred Stock may cause redemption of the Preferred Stock. Accordingly, the Preferred Stock are considered contingently redeemable and are classified as temporary equity on the accompanying balance sheets.

9. Common Stock

As of December 31, 2023 and 2022, the Company's amended and restated certificate of incorporation authorized the issuance of 58,251,629 shares of \$0.001 par value common stock. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights,

9. Common Stock (continued)

powers and preferences of the holders of the Preferred Stock set forth above. As of December 31, 2023 and 2022, there were 19,134,164 shares and 19,127,914 shares of common stock issued and outstanding, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Board, if any, subject to the preferential dividend rights of the Preferred Stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of Preferred Stock equivalent to the dividend amount they would receive if each share of Preferred Stock were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Preferred Stock have been paid in full. As of December 31, 2023 and 2022, no dividends were declared.

As of December 31, 2023 and 2022, the Company had reserved 36,078,703 and 36,084,953 shares of common stock for the conversion of outstanding shares of Preferred Stock (see Note 8, *Redeemable convertible preferred stock*), the exercise of outstanding stock options, and the issuance of stock options remaining available for grant under the Company's 2018 Stock Incentive Plan (see Note 10, *Stock-based compensation*).

10. Stock-based Compensation

Stock Incentive Plan

In March 2018, the Company established the 2018 Stock Incentive Plan, or the 2018 Plan, under which the Company may grant incentive stock options, non-statutory options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock-based awards, collectively referred to as the Awards. Employees, officers, directors, consultants and advisors are eligible to receive awards under the 2018 Plan; however incentive stock options may only be granted to employees.

As of December 31, 2023 and 2022, the total number of shares of common stock reserved for issuance under the 2018 Plan was 6,657,329 shares. Shares of unused common stock underlying any Awards that are forfeited, canceled or reacquired by the Company prior to vesting will again be available for the grant of Awards under the 2018 Plan. Shares underlying any Awards that are forfeited, canceled, or reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated and shares that are withheld upon exercise of an option of settlement of an award to cover the exercise price or tax withholding shall be added back to the shares available for issuance under the 2018 Plan. As of December 31, 2023 and 2022, the Company had 1,013,786 shares and 1,700,915 shares, respectively, remaining available for grant under the 2018 Plan.

The 2018 Plan is administered by the Board. The Board determines the exercise prices for stock options, which may not be less than 100% of the fair market value of the Company's common stock on the date of grant, vesting terms, and other restrictions. The Board also determines the fair value the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. Stock options granted under the 2018 Plan expire ten years after the grant date, unless the Board sets a shorter term, and typically vest over four years.

Fair Value Inputs

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected option term is calculated based on the simplified method for awards with service-based conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to

10. Stock-based Compensation (continued)

develop an estimate based on participant behavior. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock options granted:

	For the Year Ended December 31,		
	2023	2022	
Per share fair value of common stock	\$0.52	\$0.37	
Expected volatility	67.4%	60.4%	
Expected dividends	0%	0%	
Expected term (in years)	6.1	6.0	
Risk-free rate	3.56%	2.11%	

Stock Options

The following table summarizes option activity during the year ended December 31, 2023:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (In Years)	Intrinsic Value (In Thousands)
Outstanding as of January 1, 2023	4,828,500	\$0.37	7.75	\$2,152
Granted	687,129	0.82		
Exercised	(6,250)	0.31		
Outstanding as of December 31, 2023	5,509,379	\$0.43	7.04	\$2,699
Options exercisable as of December 31, 2023	3,658,422	\$0.30	6.35	\$2,264
Vested and expected to vest as of December 31, 2023	5,509,379	\$0.43	7.04	\$2,699

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2023 and 2022 was less than \$0.1 million.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2023 and 2022 was \$0.52 and \$0.37, respectively.

As of December 31, 2023, there was \$0.7 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.19 years.

The following table illustrates the classification of stock-based compensation in the statements of operations and comprehensive loss (in thousands):

	For the Ye Decem	ear Ended Iber 31,
	2023	2022
Research and development	\$111	\$ 37
General and administrative	203	209
Total stock-based compensation	\$314	\$246

11. Income Taxes

During the years ended December 31, 2023 and 2022, the Company did not record a provision for income taxes because it has incurred net operating losses since inception and maintains a full valuation allowance against its deferred tax assets. The Company's entire pre-tax loss for the years ended December 31, 2023 and 2022 were from U.S. operations and resulted in no tax expense or benefit.

A reconciliation of the Company's total tax using the statutory income tax rate to the Company's total tax using their effective income tax rate is as follows (in thousands):

	For the Ye Decem	
	2023	2022
Income tax at U.S. federal statutory rate	\$(3,643)	\$(4,314)
State taxes, net of federal benefit	_	_
Valuation allowance	3,604	4,312
Other	39	2
Total income tax	\$	\$

The Company's significant components of deferred tax assets are as follows (in thousands):

	December 31,		
	2023	2022	
Federal net operating loss carryforwards	\$ 7,235	\$ 5,882	
Capitalized research and development expense	5,665	3,470	
Tax credits	417	\$ 417	
Other	100	43	
Net deferred tax assets before valuation allowance	13,417	9,812	
Valuation allowance	(13,417)	(9,812)	
Net deferred tax assets after valuation allowance	<u>\$ </u>	<u>\$ </u>	

As of December 31, 2023 and 2022, the Company had a federal net operating loss, or NOL, carryforward of \$34.5 million and \$28.0 million, respectively. Of the federal net operating loss carryforwards, \$0.4 million expires in 2037 and \$34.1 million may be carried forward indefinitely.

As of December 31, 2023, the Company also has federal tax credits of \$0.4 million, which begin to expire in 2039.

The future realization of tax benefits from existing temporary differences and tax attributes ultimately depends on the existence of sufficient future taxable income within the carryforward period. In assessing the realization of its deferred tax assets, the Company considered whether it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company considered projected future taxable income, scheduled reversal of deferred tax liabilities, and tax planning strategies in making this assessment. As of December 31, 2023, after consideration of all available evidence, both positive and negative, the Company maintained a full valuation allowance against its net deferred tax assets because it is more likely than not they will not be realized in the future. The change in the valuation allowance between the years ended December 31, 2023 and 2022 was an increase of \$3.6 million.

The future realization of the Company's net operating loss carryforwards and other tax attributes may also be limited by the change in ownership rules under the U.S. Internal Revenue Code Section 382. Under Section 382, if a corporation undergoes an ownership change (as defined), the corporation's ability to utilize its net operating loss carryforwards and other tax attributes to offset income may be limited. The Company has not completed a study to assess whether an ownership changed has occurred or whether there have been multiple ownership changes.

11. Income Taxes (continued)

The Company files income tax returns in the US federal and Texas. Therefore, the Company is subject to tax examination by various US taxing authorities. The Company is not currently under examination, and is not aware of any issues under review that could result in significant payments, accruals or material deviation from its tax positions. As of December 31, 2023, tax years from 2020 to present remain open to examination by the Company's relevant taxing jurisdictions. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period.

The calculation and assessment of the Company's income tax exposures generally involve the uncertainties in the application of complex tax laws and regulations for US federal and state jurisdictions. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation, on the basis of the technical merits. As of December 31, 2023, the Company has not recorded any liabilities or interest and penalties related to uncertain tax positions in its financial statements. The Company recognizes accrued interest and penalties, if any, related to uncertain tax positions in tax expense in its financial statements.

12. Net Loss Per Share

Basis and diluted net loss per share attributable to common stockholders was calculated as follows (dollar amounts in thousands):

	For the Year Ended December 31,		
	2023	2022	
Numerator:			
Net loss attributable to common stockholders	\$ (17,347)	\$ (20,542)	
Denominator:			
Weighted-average common shares outstanding, basic and diluted	19,134,096	19,116,342	
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.91)	\$ (1.07)	

The Company's potentially dilutive securities, which include stock options to purchase common stock and Preferred Stock, have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	For the Ye Decem	
	2023	2022
Preferred stock (as converted to common stock)	29,555,538	29,555,538
Stock options to purchase common stock	5,509,379	4,828,500

13. Commitments and Contingencies

Legal Matters

The Company is subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the balance

13. Commitments and Contingencies (continued)

sheets. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of December 31, 2023 and 2022, the Company was not a party to any material legal proceedings or claims and no liabilities were recorded for loss contingencies.

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts generally provide for termination upon notice and are cancellable without significant penalty or payment, and do not contain any minimum purchase commitments.

Guarantees and Indemnifications

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all members of the Board that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2023 and 2022.

Other Commitments

In addition to our obligation to make potential royalty payments under the BCM First Agreement and BCM Second Agreement (both as discussed and defined in Note 14, *License agreements*), the Company is also obligated to pay royalties to each of its founders in an amount equal to 1% each on the worldwide net sales of TTI-101 and any derivative formulations, or any Royalty Bearing Products. These royalty obligations last, on a country-by-country basis, for the later of (i) the date on which the sale of any Royalty Bearing Products are no longer covered by a Covered Patent (as defined below) in such country, or (ii) 15 years after the first commercial sale of royalty bearing product in such country. The timing of when these royalty payments will actually be made is uncertain as the payments are contingent upon future activities, including the successful development, regulatory approval and commercialization of any Royalty Bearing Products. A Covered Patent means, subject to certain customary exceptions, an issued patent that is owned by the Company or an affiliate, or for which all rights to develop and commercialize pharmaceutical products for the treatment of any human disorder, are exclusively licensed to us or an affiliate by the owner of such patent, with the Company's right or its affiliate's right to grant sublicenses.

14. License Agreements

In July 2012, Stem Med Limited Partnership, or StemMed, entered into a license agreement, or the BCM First Agreement, with Baylor College of Medicine, or BCM, for the exclusive, worldwide, sublicensable license to certain patents and patent applications related to STAT3 inhibitors in oncology and certain non-oncology indications, or the BCM Patent Rights, which are referred to together with certain cell lines, biological materials, compounds, know-how and technologies as the BCM Technology, in all fields of use. Under the license for the BCM First Agreement, the Company is permitted to make, have made, use, market, sell offer to sell, lease and import products, processes or services that incorporate, utilize, or are made with the use of the BCM Patent Rights or BCM Technology, which is referred to together as the BCM1 Licensed Products, in all fields of use.

In June 2015, StemMed entered into a second license agreement with BCM, or the BCM Second Agreement, which is referred to together with the BCM First Agreement as the BCM License Agreements,



14. License Agreements (continued)

for the exclusive, worldwide, sublicensable license to certain patents and patent applications co-owned by BCM and the National Institutes of Health, or NIH, related to methods and compositions for the use of STAT3 inhibitors in certain conditions like anaphylaxis, or the Licensed Patent Rights. Under the license for the Second BCM Agreement, the Company is permitted to make, have made, use, market, sell, offer to sell, lease and import products, processes or services that incorporate, utilize or are made with the use of the Licensed Patent Rights, or the BCM2 Licensed Products, in all fields of use.

StemMed assigned the BCM First Agreement and the BCM Second Agreement to the Company in connection with the transfer of all or substantially all of the assets and businesses to which the BCM License Agreements relate to in January and February 2018.

In accordance with BCM License Agreements, and in consideration for the rights and licenses granted to the Company, the Company agreed to pay BCM the following:

- Annual maintenance fees, ranging from \$30,000 to \$50,000 per year, per license.
- · Milestone payments, up to a low-seven digit figure in the aggregate.
- Royalty fees, set at low-single-digit of net sales of any BSM1 Licensed Products or BSM2 Licensed Products.

Milestones include new drug filings, clinical trial stages, and New Drug Application approval by the FDA.

The Company recorded \$50,000 of annual maintenance fees during each of the years ended December 31, 2023 and 2022. The Company also incurred \$125,000 in milestone payments in each of the years ended December 31, 2023 and 2022, respectively, in relation to the initiation of two Phase 2 clinical trials. To date, no royalty fees have been incurred. All related license costs are expensed as incurred within research and development on the statements of operations and comprehensive loss.

15. Retirement Savings Plan

The Company maintains a 401(k) Plan which is available to all employees. Under the terms of the 401(k) Plan, participants may elect to contribute up to 80% of their compensation or the statutory prescribed limits. The Company does not make any matching contributions to deferrals made by participants.

16. Related-party Transactions

During the years ended December 31, 2023 and 2022, the Company did not have any transactions with related parties. The Company evaluates transactions with counterparties who may be considered related parties, including owners, members of management or affiliates and then discloses the nature and amounts of those transaction in the notes to its financial statements.

17. Subsequent Events

In January of 2024, the Company terminated its Phase 1/b clinical trial for metastatic breast cancer. In connection with the termination, the Company will be responsible for certain costs to close the clinical trial. The Company will recognize these remaining costs to close the clinical trial during 2024 under the Company's expense policy related to clinical trials.

Management has evaluated all other subsequent events through October 4, 2024, which was the date the financial statements were available to be issued and has determined that there are no subsequent events to be reported.



CONDENSED BALANCE SHEETS

(Amounts in thousands, except share and per share amounts)

(Unaudited)

	As of September 30, 2024	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,438	\$ 22,919
Prepaid expenses and other current assets	1,265	3,239
Total current assets	10,703	26,158
Property and equipment, net	92	116
Intangible assets, net	401	448
Operating lease right-of-use assets	218	262
Deferred offering costs	1,083	—
Other non-current assets	17	17
Total assets	\$ 12,514	\$ 27,001
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,978	1,611
Accrued expenses	3,237	1,577
Operating lease liabilities, current portion	92	93
Total current liabilities	5,307	3,281
Operating lease liabilities, net of current portion	207	275
Total liabilities	5,514	3,556
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock (Series A, B), \$0.001 par value; 29,723,540 shares authorized as of September 30, 2024 and December 31, 2023; 29,555,538 shares issued and outstanding as of September 30, 2024 and December 31, 2023; aggregate liquidation preference of \$85,902 as of September 30, 2024 and December 31, 2023	85,503	85,503
Stockholders' Deficit:		
Common stock, \$0.001 par value; 58,251,629 shares authorized as of September 30, 2024 and December 31, 2023; 19,197,914 and 19,134,164 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	19	19
Additional paid-in capital	1,007	762
Accumulated deficit	(79,529)	(62,839)
Total stockholders' deficit	(78,503)	(62,058)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	\$ 12,514	\$ 27,001

The accompanying notes are an integral part of these unaudited condensed financial statements.

CONDENSED STATEMENTS OF OPERATIONS (Amounts in thousands, except share and per share amounts) (Unaudited)

	For the Nine Months Ended September 30,			
		2024	2023	
Operating expenses:				
Research and development	\$	15,047	\$	11,884
General and administrative		2,258		2,117
Total operating expenses		17,305		14,001
Loss from operations		(17,305)		(14,001)
Interest income		615		1,005
Net loss	\$	(16,690)	\$	(12,996)
Net loss per share attributable to common stockholders, basic and diluted	\$	(0.87)	\$	(0.68)
Weighted-average common shares outstanding, basic and diluted	19	9,192,595	19	9,134,072

The accompanying notes are an integral part of these unaudited condensed financial statements.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK

AND STOCKHOLDERS' DEFICIT

(Amounts in thousands, except share amounts)

(Unaudited)

	Redeemable C Preferred		Common	Stock	Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Deficit
Balances as of January 1, 2024	29,555,538	\$85,503	19,134,164	\$19	\$ 762	\$(62,839)	\$ —	\$(62,058)
Exercise of stock options	_	_	63,750		5			5
Stock-based compensation	_	_	_		240	_		240
Net loss	_	_	_		_	(16,690)		(16,690)
Balances as of September 30, 2024	29,555,538	\$85,503	19,197,914	\$19	\$1,007	\$(79,529)	\$ —	\$(78,503)

	Redeemable C Preferred	0			Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Deficit
Balances as of January 1, 2023	29,555,538	\$85,503	19,127,914	\$19	\$446	\$(45,492)	\$(24)	\$(45,051)
Exercise of stock options	_	—	6,250	—	2	_	—	2
Stock-based compensation			_	_	229			229
Maturities of short-term investments	_	_	_	_	_	_	24	24
Net loss				_		(12,996)		(12,996)
Balances as of September 30, 2023	29,555,538	\$85,503	19,134,164	\$19	\$677	\$(58,488)	<u>\$ —</u>	\$(57,792)

The accompanying notes are an integral part of these unaudited condensed financial statements.

CONDENSED STATEMENTS OF CASH FLOWS (Amounts in thousands) (Unaudited)

	For the Nine Months En September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$(16,690)	\$(12,996)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	71	71
Stock-based compensation expense	240	229
Non-cash lease expense	44	38
Accretion of discounts on short-term investments	—	(194)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,974	(3,269)
Accounts payable and accrued expenses	958	890
Operating lease liabilities	(69)	(60)
Net cash used in operating activities	(13,472)	(15,291)
Cash flows from investing activities:		
Maturities of short-term investments		22,468
Net cash provided by investing activities	—	22,468
Cash flows from financing activities:		
Proceeds from exercise of stock options	5	2
Payments of deferred offering costs	(14)	_
Net cash (used in) provided by financing activities	(9)	2
Net (decrease) increase in cash and cash equivalents	(13,481)	7,179
Cash and cash equivalents – beginning of year	22,919	21,489
Cash and cash equivalents - end of year	\$ 9,438	\$ 28,668
Non-cash investing and financing activities		
Deferred offering costs included in accounts payable and accrued expenses	\$ 1,069	\$ —

The accompanying notes are an integral part of these unaudited condensed financial statements.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

1. Nature of the Business and Basis of Presentation

Tvardi Therapeutics, Inc., or the Company, incorporated on December 20, 2017, is a Delaware Corporation headquartered in Houston, Texas. The Company is a clinical-stage, biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting STAT3 to treat fibrosis-driven diseases with significant unmet need. Based upon its founder's seminal work and deep understanding of the transcription factor, STAT3, the Company has designed an innovative approach to directly inhibit STAT3, a highly validated, yet historically undruggable target. Leveraging this expertise, the Company is developing a pipeline of STAT3 inhibitors with a differentiated mechanism of action and convenient oral dosing. The Company's lead product candidate, TTI-101, is currently in Phase 2 clinical development for the treatment of fibrosis-driven diseases, with an initial focus on idiopathic pulmonary fibrosis, IPF and hepatocellular carcinoma, HCC.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful development of TTI-101 and TTI-109, the development of new technological innovations by competitors, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations and the ability to secure additional capital to fund operations and commercial success of TTI-101 and TTI-109. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be maintained, that any therapeutic products developed will obtain required regulatory approval or that any approved or consumer products will be commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales.

Additionally, the global economy has experienced extreme volatility and disruptions due to the military conflict between Russia and Ukraine and the war between Israel and Hamas. These conditions have impacted, and may continue to impact, the capital and credit markets, which may reduce the Company's ability to raise additional capital through equity, equity-linked instruments or debt financings which could negatively impact the Company's short-term and long-term liquidity. Additionally, the Company's results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to the Company's business, including a reduced ability to raise additional capital when needed on favorable terms, if at all. The Federal Reserve has raised interest rates in recent periods in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Any of the foregoing could harm the Company's business, and it cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its business, results of operations, financial condition, or its ability to raise capital.

Liquidity and Going Concern

The accompanying condensed financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the nine months ended September 30, 2024, the Company incurred a net loss of \$16.7 million and used \$13.5 million of cash in operating activities. As of September 30, 2024, the Company had an accumulated deficit of \$79.5 million.

To date, the Company has no products approved for marketing and sale and it has not yet recorded any revenue from product sales. The Company's ability to achieve profitability is dependent on its ability to

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

successfully develop its lead compound, conduct clinical trials, obtain regulatory approvals, and support commercialization activities for its product candidates. Any products developed will require approval of the U.S. Food and Drug Administration, or the FDA, or a foreign regulatory authority prior to commercial sale.

Since inception, the Company has relied primarily on sales of redeemable convertible preferred stock and issuance of convertible debt to fund its operations. The Company's product candidates are still in the early stages of development, and substantial additional financing will be needed by the Company to fund its operations and ongoing research and development efforts prior to the commercialization of its product candidates.

The Company's cash and cash equivalents of \$9.4 million as of September 30, 2024 are not sufficient to fund its planned operations for at least one year from the issuance of these condensed financial statements, which raises substantial doubt as to the Company's ability to continue as a going concern.

Significant additional funding is necessary to maintain current operations and to advance the Company's research and development activities. The Company is seeking to complete a reverse merger transaction or an initial public offering, or IPO, of its common stock. Alternatively, the Company expects to fund its operations through equity offerings or debt financings, credit or loan facilities, strategic alliances and licensing arrangements. The Company's ability to access capital when and in the amount needed is not considered probable. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The accompanying condensed financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Basis of Presentation

The accompanying condensed financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The accompanying condensed financial statements represent the accounts of the Company. The Company does not maintain ownership in any subsidiaries and therefore does not consolidate any other entities within the presented condensed financial statements.

In management's opinion, the unaudited condensed financial statements reflect all adjustments (consisting of normal recurring adjustments) necessary to present fairly the financial position of the Company as of September 30, 2024, and results of operations and cash flows for all periods presented. The interim results presented are not necessarily indicative of results that can be expected for the full year ending December 31, 2024.

2. Summary of Significant Accounting Policies

Other than policies noted below, there have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the "Notes to Financial Statements" in the Company's audited annual financial statements included elsewhere in this proxy statement/prospectus.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses as of and during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

Significant estimates and assumptions reflected within these condensed financial statements include, but are not limited to, prepaid and accrued research and development expenses, including those related to contract research organizations, or CROs, contract development manufacturing organizations, or CDMOs, and other third-party vendors, and the valuation of the Company's common stock and stock- based awards. Changes in estimates are recorded in the period in which they become known.

Concentration of Credit Risk and of Significant Suppliers

The Company's cash and cash equivalents represent potential concentrations of credit risk. The Company deposits its cash and cash equivalents in financial institutions in amounts that may exceed federally insured limits, has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The following table presents information about the Company's significant suppliers:

		For the Nine Months Ended September 30,		As of December 31,	
	2024	2023	2024	2023	
	-	% of operating expenses		counts able	
Vendor A	62%	37%	83%	40%	
Vendor B	—	18%	2%		
Vendor C	2%	11%	_	10%	
Vendor D	—	_	_	19%	
	64%	66%	85%	<u>69</u> %	

The Company's preclinical studies and clinical trials and testing could be adversely affected by a significant interruption in the supply chain from its significant suppliers.

Cash and Cash Equivalents

The Company considers all highly liquid investments, with an original maturity of three months or less, to be cash equivalents. Cash equivalents include amounts held in money market funds in the amount of \$8.8 million and \$21.8 million as of September 30, 2024 and December 31, 2023, respectively.

The Company recorded interest income on its cash equivalents of \$0.6 million for the nine months ended September 30, 2024 on its statements on operations. The Company recorded interest income of \$1.0 million on its cash equivalents and previously outstanding short-term investments during the nine months ended September 30, 2023 on its statements of operations. The \$1.0 million is also inclusive of accretion of its discounts on its short-term investments, which fully matured during fiscal 2023

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in process transactions, such as mergers or equity financings, as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholders' deficit as a reduction of additional paid-in-capital generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations. The Company recorded deferred offering costs of \$1.1 million and \$0 as of September 30, 2024 and December 31, 2023, respectively.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07. ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. ASU 2023-07 is effective for public business entities with fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the provisions of this guidance and the potential impact on its financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, or ASU 2023-09. ASU 2023-09 requires public business entities to disclose additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate (the rate reconciliation) for federal, state, and foreign income taxes. It also requires greater detail about individual reconciling items in the rate reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate). In addition to new disclosures associated with the rate reconciliation, ASU 2023-09 requires information pertaining to taxes paid (net of refunds received) to be disaggregated for federal, state, and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. The amendments are effective for public business entities for annual periods beginning after December 15, 2025. Early adoption is permitted. The Company is currently evaluating the provisions of this guidance and the potential impact on its financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the provisions of this guidance and the potential impact on its financial statements and disclosures.

3. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	As of September 30, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents:				
Money market funds	\$8,827	\$	\$	\$8,827
Total financial assets	\$8,827	\$ —	\$ —	\$8,827

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

	A	As of December 31, 2023			
	Level 1	Level 2	Level 3	Total	
Financial assets:					
Cash equivalents:					
Money market funds	\$21,762	\$ —	\$ —	\$21,762	
Total financial assets	\$21,762	\$ —	\$ —	\$21,762	

The Company did not have any Level 3 assets or liabilities as of September 30, 2024 or December 31, 2023. There were no transfers between Levels during the periods presented.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	As of September 30, 2024	As of December 31, 2023
Prepaid research and development expenses	\$1,212	\$3,203
Other prepaid expenses	53	36
Total prepaid expenses and other current assets	\$1,265	\$3,239

5. Intangible Assets

Intangible assets consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	As of September 30, 2024	As of December 31, 2023
Licensed patent rights	\$ 826	\$ 826
Less: accumulated amortization	(425)	(378)
Total intangible assets, net	\$ 401	\$ 448

As of September 30, 2024, the expected remaining amortization expense is as follows (in thousands):

Year Ended December 31,	Amount
Remainder of 2024	\$ 16
2025	63
2026	63
2027	63
2028	63
Thereafter	133
Total	\$401

The Company recognized less than \$0.1 million for amortization expense for each of the nine months ended September 30, 2024 and 2023. Amortization expense is included in research and development expense in the statements of operations.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

6. Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	As of September 30, 2024	As of December 31, 2023
Accrued research and development expenses	\$1,008	\$ 574
Accrued employee compensation and benefits	1,185	942
Other accrued expenses	1,044	61
Total accrued expenses	\$3,237	\$1,577

7. Leases

The Company has one operating lease pertaining to 5,969 square feet of corporate office space in Sugar Land, Texas, pursuant to a lease agreement that commenced April 1, 2022. As of September 30, 2024, the remaining term of lease was 2.92 years. The lease requires monthly lease payments that are subject to annual increases throughout the lease term.

The components of lease costs, which are included within general and administrative expenses in the Company's statements of operations were as follows (in thousands):

		For the Nine Months Ended September 30,	
	2024	2023	
Lease costs:			
Operating lease cost	\$ 67	\$ 67	
Variable lease cost	59	63	
Total lease costs	\$126	130	

Supplemental disclosure of cash flow information related to the lease were as follows (in thousands):

		For the Nine Months Ended September 30,	
	2024	2023	
Operating cash flows from operating leases	\$148	\$145	

The weighted-average discount rate and remaining lease term were as follows:

	As of September 30, 2024	As of December 31, 2023
Weighted-average discount rate	9.50%	9.50%
Weighted-average remaining lease term	2.92	3.67

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

As of September 30, 2024, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year Ended December 31,	Amount
2024 (remaining three months)	\$ 31
2025	94
2026	129
2027	88
Total lease payments	342
Less: imputed interest	(43)
Present value of lease liabilities	299
Less: operating lease liabilities, current portion	\$ 92
Operating lease liabilities, net of current portion	\$207

8. Redeemable Convertible Preferred Stock

The Company has issued Series A preferred stock and Series B preferred stock, which are collectively referred to as the Preferred Stock. As of September 30, 2024 and December 31, 2023, the Company authorized the issuance of 29,723,540 shares of Preferred Stock, par value of \$0.001 per share, of which 9,499,999 have been designated Series A preferred stock and 20,223,541 have been designated Series B preferred stock.

Series A Preferred Stock

During 2018, the Company entered into the Series A preferred stock purchase agreements for 8,550,340 shares of Series A preferred stock with par value of \$0.001 each at a price \$1.00 per share, or the Series A Original Issue Price, with a group of investors for net proceeds of \$8.4 million, or the Series A Financing. In addition, in connection with the closing of the Series A Financing, then outstanding convertible promissory notes of \$0.4 million were converted into 449,659 shares of Series A preferred stock at the Series A Original Issue Price paid by the Series A Financing investors.

Series B Preferred Stock

In June 2021, the Company entered into the Series B preferred stock purchase agreements for 17,452,411 shares of Series B preferred stock with par value of \$0.001 each at a price \$3.8095 per share, or the Series B Original Issue Price, with a group of investors for net proceeds of \$66.3 million, or the Series B Financing. In addition, in connection with the closing of the Series B Financing, (i) then outstanding convertible promissory notes of \$7.9 million were converted into 2,603,128 shares of Series B preferred stock at 80% of the Series B Original Issue Price paid by the Series B Financing investors and (ii) a then outstanding translational research grant of \$0.5 million was converted into 500,000 shares of Series A Preferred Stock at a conversion price of \$1.00 per share pursuant to the terms of grant agreement, dated as of March 2018.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

The following tables summarize the Company's redeemable convertible preferred stock as of September 30, 2024 and December 31, 2023:

	Par Value	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A preferred stock	\$0.001	9,499,999	9,499,999	\$ 9,327	\$ 9,500	9,499,999
Series B preferred stock	0.001	20,223,541	20,055,539	76,176	76,402	20,055,539
		29,723,540	29,555,538	\$85,503	\$85,902	29,555,538

The key terms of Preferred Stock are as follows:

Dividends

The Company shall not declare, pay or set aside any dividends on shares or any other class or series of capital stock (other than dividends on shares of the Company's common stock payable in shares of common stock) unless first the holders of Series B preferred stock shall first receive, or simultaneously receive, a dividend on each outstanding preferred stock, and second, the holders of the Series A preferred stock shall next receive, or simultaneously receive a dividend on each outstanding preferred stock. If the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of Preferred Stock shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest dividend. There have been no dividends declared by the Company's board of directors, or the Board, as of September 30, 2024 and December 31, 2023.

Voting Rights

The holder of each share of Series A and Series B preferred stock shall have the right to one vote for each share of common stock into which such Series A and Series B preferred stock could then be converted.

Right to Elect Directors

Holders of Series A preferred stock are entitled to elect two directors of the Company. The holders of Series B preferred stock are entitled to elect one director of the Company. The holders of the Company's common stock are entitled to elect one director of the Company. The holders of Preferred Stock and Common Stock (voting together as a single class and not as separate series and on as- converted basis) shall be entitled to elect any remaining director of the Company.

Conversion

Each share of Preferred Stock is convertible at the option of the holder, at any time, and without the payment of additional consideration by the holder. In addition, each share of Preferred Stock will be automatically converted into shares of common stock at the applicable conversion ratio then in effect upon either (i) the closing of a firm-commitment underwritten public offering of the Company's common stock at a price of at least \$5.7143 per share resulting in at least \$50.0 million of gross proceeds to the Company, or (ii) the vote or written consent of the holders of a majority of the outstanding shares of Preferred Stock, voting as a single class.

The conversion ratio of Series A and Series B Preferred Stock is determined by dividing the respective original issue price by the applicable conversion price in effect at the time of conversion. The conversion price is \$1.00 and \$3.8095 per share for Series A and Series B preferred stock, respectively. As of December 31, 2023, each outstanding share of Preferred Stock was convertible into the Company's common stock on a one-for-one basis.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

Liquidation

In the event of liquidation, dissolution, or winding up of the Company or upon the occurrence of a Deemed Liquidation Event (as defined below), the holders of Series B preferred stock then outstanding are entitled to distribution of the Company's assets or funds, before the holders of Series A preferred stock and common stock, in an amount per share equal to the greater of (i) the Series B Original Issue Price (\$3.8095 per share), plus any dividends declared but unpaid, or (ii) the amount per share that would have been payable had all shares of Series B preferred stock been converted to common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If the assets of the Company are insufficient to pay holders of the Series B Preferred Stock the full amount to which they are entitled, they shall be paid ratably in proportion to the respective amounts they would have received had they been paid in full.

In the event of liquidation, dissolution, or winding up, after the Series B preferred stock holders have been paid in full, the holders of Series A preferred stock are entitled to distribution of the Company's assets or funds, before the common stock, in amount per share equal to the greater of (i) the Series A Original Issue Price (\$1.00 per share), plus any dividends declared but unpaid, or (ii) the amount per share that would have been payable had all shares of Series A preferred stock been converted to common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If the assets or funds of the Company are insufficient to pay holders of the Series A preferred stock the full amount to which they are entitled, they shall be paid ratably in proportion to the respective amounts they would have received had they been paid in full. After payment of all preferential amounts to Series A preferred stock holders, the remaining assets available for distribution shall be distributed to the holders of common stock pro rata based on the number of shares held.

Unless the holders of a majority in voting power of the then outstanding shares of Series B preferred stock elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or sale, lease, transfer, exclusive license or other disposition of all or substantially all of the Company's assets.

Redemption

The holders of the Company's Preferred Stock have no voluntary rights to redeem shares. Upon the occurrence of a Deemed Liquidation Event that are outside of the Company's control, the holders of the Preferred Stock may cause redemption of the Preferred Stock. Accordingly, the Preferred Stock are considered contingently redeemable and are classified as temporary equity on the accompanying balance sheets.

9. Common Stock

As of September 30, 2024 and December 31, 2023, the Company's amended and restated certificate of incorporation authorized the issuance of 58,251,629 shares of \$0.001 par value common stock. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above. As of September 30, 2024 and December 31, 2023, there were 19,197,914 shares and 19,134,164 shares of common stock issued and outstanding, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Board, if any, subject to the preferential dividend rights of the Preferred Stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of Preferred Stock equivalent to the dividend amount they would receive if each share of Preferred Stock were converted into common stock. The Company may not pay dividends to common stockholders

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

until all dividends accrued or declared but unpaid on the Preferred Stock have been paid in full. As of September 30, 2024 and December 31, 2023, no dividends were declared.

As of September 30, 2024 and December 31, 2023, the Company had reserved 36,014,953 and 36,078,703 shares of common stock for the conversion of outstanding shares of Preferred Stock (see Note 8, Redeemable convertible preferred stock), the exercise of outstanding stock options, and the issuance of stock options remaining available for grant under the Company's 2018 Stock Incentive Plan (see Note 10, *Stock- based compensation*).

10. Stock-based Compensation

Stock Incentive Plan

In March 2018, the Company established the 2018 Stock Incentive Plan, or the 2018 Plan, under which the Company may grant incentive stock options, non-statutory options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock-based awards, collectively referred to as the Awards. Employees, officers, directors, consultants and advisors are eligible to receive awards under the 2018 Plan; however incentive stock options may only be granted to employees.

As of September 30, 2024 and December 31, 2023, the total number of shares of common stock reserved for issuance under the 2018 Plan was 6,657,329 shares. Shares of unused common stock underlying any Awards that are forfeited, canceled or reacquired by the Company prior to vesting will again be available for the grant of Awards under the 2018 Plan. Shares underlying any Awards that are forfeited, canceled, or reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated and shares that are withheld upon exercise of an option of settlement of an award to cover the exercise price or tax withholding shall be added back to the shares available for issuance under the 2018 Plan. As of September 30, 2024 and December 31, 2023, the Company had 1,008,474 shares and 1,013,786 shares, respectively, remaining available for grant under the 2018 Plan.

The 2018 Plan is administered by the Board. The Board determines the exercise prices for stock options, which may not be less than 100% of the fair market value of the Company's common stock on the date of grant, vesting terms, and other restrictions. The Board also determines the fair value the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. Stock options granted under the 2018 Plan expire ten years after the grant date, unless the Board sets a shorter term, and typically vest over four years.

Fair Value Inputs

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected option term is calculated based on the simplified method for awards with service-based conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant behavior. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock options granted:

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

	For the Nine Months September 30,		
	2024	2023	
Per share fair value of common stock	\$0.62	\$0.52	
Expected volatility	73.8%	67.4%	
Expected dividends	0%	0%	
Expected term (in years)	5.9	6.1	
Risk-free rate	3.93%	3.56%	

Stock Options

The following table summarizes option activity during the nine months ended September 30, 2024:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (In Years)	Intrinsic Value (In Thousands)
Outstanding as of January 1, 2024	5,509,379	\$0.43	7.04	\$2,699
Granted	25,000	0.92		
Exercised	(63,750)	0.08		
Forfeited	(19,688)	0.82		
Outstanding as of September 30, 2024	5,450,941	\$0.44	6.32	\$2,644
Options exercisable as of September 30, 2024	4,382,734	\$0.37	5.97	\$2,413
Vested and expected to vest as of September 30, 2024	5,450,941	\$0.44	6.32	\$2,644

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2024 and 2023 was \$0.62 and \$0.52, respectively.

As of September 30, 2024, there was \$0.4 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 1.55 years.

The following table illustrates the classification of stock-based compensation in the statements of operations (in thousands):

		For the Nine Months Ended September 30,	
	2024	2023	
Research and development	\$ 86	\$ 84	
General and administrative	154	145	
Total stock-based compensation	\$240	\$229	

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

11. Income Taxes

For the three and nine months ended September 30, 2024 and 2023, there was no current or deferred income tax expense or benefit due to the Company's current year losses and full valuation allowance. As of September 30, 2024, the Company evaluated all available evidence and concluded that a valuation allowance is still required against its net deferred tax assets because it is more likely than not they will not be realized in the foreseeable future..

12. Net Loss Per Share

Basis and diluted net loss per share attributable to common stockholders was calculated as follows (dollar amounts in thousands):

	For the Nine Months Ended September 30,		
	2024	2023	
Numerator:			
Net loss attributable to common stockholders	\$ (16,690)	\$ (12,996)	
Denominator:			
Weighted-average common shares outstanding, basic and diluted	19,192,595	19,134,072	
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.87)	\$ (0.68)	

The Company's potentially dilutive securities, which include stock options to purchase common stock and Preferred Stock, have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

		For the Nine Months Ended September 30,		
	2024	2023		
Preferred stock (as converted to common stock)	29,555,538	29,555,538		
Stock options to purchase common stock	5,450,941	5,509,379		

13. Commitments and Contingencies

Legal Matters

The Company is subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the balance sheets. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of September 30, 2024 and December 31, 2023, the Company was not a party to any material legal proceedings or claims and no liabilities were recorded for loss contingencies.

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

generally provide for termination upon notice and are cancellable without significant penalty or payment, and do not contain any minimum purchase commitments.

Guarantees and Indemnifications

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all members of the Board that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of September 30, 2024 and December 31, 2023.

Other Commitments

In addition to our obligation to make potential royalty payments under the BCM First Agreement and BCM Second Agreement (both as discussed and defined in Note 14, *License agreements*), the Company is also obligated to pay royalties to each of its founders in an amount equal to 1% each on the worldwide net sales of TTI-101 and any derivative formulations, or any Royalty Bearing Products. These royalty obligations last, on a country-by-country basis, for the later of (i) the date on which the sale of any Royalty Bearing Products are no longer covered by a Covered Patent (as defined below) in such country, or (ii) 15 years after the first commercial sale of royalty bearing product in such country. The timing of when these royalty payments will actually be made is uncertain as the payments are contingent upon future activities, including the successful development, regulatory approval and commercialization of any Royalty Bearing Products. A Covered Patent means, subject to certain customary exceptions, an issued patent that is owned by the Company or an affiliate, or for which all rights to develop and commercialize pharmaceutical products for the treatment of any human disorder, are exclusively licensed to us or an affiliate by the owner of such patent, with the Company's right or its affiliate's right to grant sublicenses.

14. License Agreements

In July 2012, Stem Med Limited Partnership, or StemMed, entered into a license agreement, or the BCM First Agreement, with Baylor College of Medicine, or BCM, for the exclusive, worldwide, sublicensable license to certain patents and patent applications related to STAT3 inhibitors in oncology and certain non-oncology indications, or the BCM Patent Rights, which are referred to together with certain cell lines, biological materials, compounds, know-how and technologies as the BCM Technology, in all fields of use. Under the license for the BCM First Agreement, the Company is permitted to make, have made, use, market, sell offer to sell, lease and import products, processes or services that incorporate, utilize, or are made with the use of the BCM Patent Rights or BCM Technology, which is referred to together as the BCM1 Licensed Products, in all fields of use.

In June 2015, StemMed entered into a second license agreement with BCM, or the BCM Second Agreement, which is referred to together with the BCM First Agreement as the BCM License Agreements, for the exclusive, worldwide, sublicensable license to certain patents and patent applications co-owned by BCM and the National Institutes of Health, or NIH, related to methods and compositions for the use of STAT3 inhibitors in certain conditions like anaphylaxis, or the Licensed Patent Rights. Under the license for the Second BCM Agreement, the Company is permitted to make, have made, use, market, sell, offer to sell,

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

lease and import products, processes or services that incorporate, utilize or are made with the use of the Licensed Patent Rights, or the BCM2 Licensed Products, in all fields of use.

StemMed assigned the BCM First Agreement and the BCM Second Agreement to the Company in connection with the transfer of all or substantially all of the assets and businesses to which the BCM License Agreements relate to in January and February 2018.

In accordance with BCM License Agreements, and in consideration for the rights and licenses granted to the Company, the Company agreed to pay BCM the following:

- Annual maintenance fees, ranging from \$30,000 to \$50,000 per year, per license.
- Milestone payments, up to a low-seven digit figure in the aggregate.
- Royalty fees, set at low-single-digit of net sales of any BSM1 Licensed Products or BSM2 Licensed Products.

Milestones include new drug filings, clinical trial stages, and New Drug Application approval by the FDA.

The Company recorded \$50,000 of annual maintenance fees during both fiscal 2024 and 2023. No milestone payments were incurred during fiscal 2024 or 2023 in relation to the initiation of two Phase 2 clinical trials. To date, no royalty fees have been incurred. All related license costs are expensed as incurred within research and development on the statements of operations.

15. Retirement Savings Plan

The Company maintains a 401(k) Plan which is available to all employees. Under the terms of the 401(k) Plan, participants may elect to contribute up to 80% of their compensation or the statutory prescribed limits. The Company does not make any matching contributions to deferrals made by participants.

16. Related-party Transactions

During the nine months ended September 30, 2024 and 2023, the Company did not have any transactions with related parties. The Company evaluates transactions with counterparties who may be considered related parties, including owners, members of management or affiliates and then discloses the nature and amounts of those transaction in the notes to its financial statements.

17. Subsequent Events

Management has evaluated all other subsequent events through December 18, 2024, which was the date the financial statements were available to be issued. The Company has concluded that no subsequent events have occurred except as disclosed below.

Convertible Notes

In December 2024, the Company entered into a note purchase agreement to issue and sell convertible promissory notes (the Convertible Notes) with an aggregate principal of \$28.3 million. The Convertible Notes accrue interest at 8% per annum and mature in December 2026.

Merger with Cara

On December 17, 2024, the Company entered into an agreement and plan of merger and reorganization (the Merger Agreement) with Cara Therapeutics, Inc. (Cara), and CT Convergence Merger Sub, Inc., a wholly-owned subsidiary of Cara (Merger Sub), pursuant to which Merger Sub will Merge with and into the Company, with the Company surviving as a wholly-owned subsidiary of Cara (such transaction, the Merger).

TVARDI THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

Upon completion of the Merger, the business of the Company will continue as the business of the surviving corporation. After the completion of the Merger, Cara will change its corporate name to Tvardi Therapeutics, Inc.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the Effective Time), (i) each outstanding share of common stock of Tvardi (including the shares of common stock issuable upon conversion of all shares of preferred stock of Tvardi prior to the Merger), \$0.001 par value per share (Tvardi common stock), will be converted into the right to receive a number shares of common stock of Cara, \$0.001 par value per share (Cara common stock) in the aggregate, based on a ratio calculated in accordance with the Merger Agreement (the Exchange Ratio) (ii) the outstanding Convertible Notes of Tvardi will be converted into shares of Cara common stock, pursuant to the terms of the Convertible Notes and assuming interest on the Convertible Notes is accrued through the anticipated Effective Time. At the Effective Time, subject to the terms and conditions of the Merger Agreement, Cara will assume outstanding and unexercised options to purchase shares of Tvardi common stock, and in connection with the Merger, they will be converted into options to purchase shares of Cara common stock based on the Exchange Ratio. As of the Effective Time, Cara's stockholders will continue to own and hold their then existing shares of Cara common stock, subject to adjustment for a reverse stock split.

The completion of the Merger is subject to customary closing conditions, including, among other things (i) approval by the stockholders of each party of the adoption and approval of the Merger Agreement and the transactions contemplated thereby, (ii) Nasdaq's approval of the listing of shares of Cara common stock to be issued in connection with the Merger, (iii) the effectiveness of a registration statement filed with the SEC in connection with the Merger, and (iv) Cara net cash at the Effective Time of at least \$18.0 million.

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ANNEX A

AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

among:

CARA THERAPEUTICS, INC. a Delaware corporation;

CT CONVERGENCE MERGER SUB, INC., a Delaware corporation; and

TVARDI THERAPEUTICS, INC. a Delaware corporation

Dated as of December 17, 2024

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AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

THIS AGREEMENT AND PLAN OF MERGER AND REORGANIZATION (this "Agreement") is made and entered into as of December 17, 2024, by and among CARA THERAPEUTICS, INC., a Delaware corporation ("Parent"), CT CONVERGENCE MERGER SUB, INC., a Delaware corporation and whollyowned subsidiary of Parent ("Merger Sub"), and TVARDI THERAPEUTICS, INC., a Delaware corporation (the "Company"). Certain capitalized terms used in this Agreement are defined in Exhibit A.

RECITALS

A. Parent and the Company intend to effect a merger of Merger Sub with and into the Company (the "*Merger*") in accordance with this Agreement and the DGCL. Upon consummation of the Merger, Merger Sub will cease to exist and the Company will become a wholly-owned subsidiary of Parent.

B. The Parties intend that the Merger qualify as a "reorganization" within the meaning of Section 368(a) of the Code, and by executing this Agreement, the Parties hereby adopt a "plan of reorganization" within the meaning of Treasury Regulations Sections 1.368-2(g) and 1.368-3(a).

C. The Parent Board has unanimously (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Parent and its stockholders, (ii) authorized, approved and declared advisable this Agreement and the Contemplated Transactions, including the issuance of shares of Parent Common Stock to the stockholders of the Company pursuant to the terms of this Agreement, the change of control of Parent and other actions contemplated by this Agreement, and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of Parent vote to approve the Parent Stockholder Matters.

D. The Merger Sub Board has unanimously (i) determined that the Contemplated Transactions are fair to, advisable, and in the best interests of Merger Sub and its sole stockholder, (ii) authorized, approved and declared advisable this Agreement and the Contemplated Transactions, and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that Parent, as the sole stockholder of Merger Sub votes to adopt this Agreement and thereby approve the Contemplated Transactions.

E. The Company Board has unanimously (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of the Company and its stockholders, (ii) authorized, approved and declared advisable this Agreement and the Contemplated Transactions, and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of the Company vote to approve the Company Stockholder Matters.

F. Concurrently with the execution and delivery of this Agreement and as a condition and inducement to Parent's willingness to enter into this Agreement, (a) the Company Signatories (solely in their capacity as stockholders of the Company), which represent the Required Company Stockholder Vote, are executing support agreements in favor of Parent in substantially the form attached hereto as **Exhibit B-1** (the "Company Stockholder Support Agreement"), and (b) the officers, directors and stockholders of the Company listed in Section A-1 of the Company Disclosure Schedule (the "Company Lock-Up Signatories") (solely in their capacity as stockholders of the Company) are executing lock-up agreements in substantially the form attached hereto as **Exhibit C-1** (the "Company Lock-Up Agreement").

G. Concurrently with the execution and delivery of this Agreement and as a condition and inducement to the Company's willingness to enter into this Agreement, (a) the officers, directors and certain stockholders of Parent listed in Section A-1 of the Parent Disclosure Schedule (solely in their capacity as stockholders of Parent) are executing support agreements in favor of the Company in substantially the form attached hereto as **Exhibit B-2** (the "*Parent Stockholder Support Agreement*"), and (b) the director(s) of Parent listed in Section A-2 of the Parent Disclosure Schedule (solely in their capacity as stockholders of Parent) are executing lock-up agreements in substantially the form attached hereto as **Exhibit C-2** (the "*Parent Lock-Up Agreement*").

H. It is expected that within seven (7) Business Days after the Registration Statement is declared effective by the SEC, stockholders of the Company holding no less than the Required Company Stockholder

Vote will execute and deliver an action by written consent in substantially the form attached hereto as **Exhibit D** (each, a "*Company Stockholder Written Consent*" and collectively, the "*Company Stockholder Written Consent*").

I. Prior to or concurrently with the execution and delivery of this Agreement, certain investors have executed certain convertible notes of the Company (the "*Bridge Notes*").

AGREEMENT

The Parties, intending to be legally bound, agree as follows:

Section 1. DESCRIPTION OF TRANSACTION

1.1 <u>The Merger</u>. Upon the terms and subject to the conditions set forth in this Agreement, at the Effective Time, Merger Sub shall be merged with and into the Company, and the separate existence of Merger Sub shall cease. The Company will continue as the surviving corporation in the Merger (the *"Surviving Corporation"*).

1.2 <u>Effects of the Merger</u>. The Merger shall have the effects set forth in this Agreement, the Certificate of Merger and in the applicable provisions of the DGCL. As a result of the Merger, the Company will become a wholly-owned subsidiary of Parent.

1.3 <u>Closing; Effective Time</u>. Unless this Agreement is earlier terminated pursuant to the provisions of <u>Section 9.1</u>, the consummation of the Merger (the "*Closing*") shall take place remotely on the second (2nd) Business Day following the satisfaction or waiver of the last to be satisfied or waived of the conditions set forth in <u>Sections 6</u>, 7 and <u>8</u> (other than those conditions that by their nature are to be satisfied at or immediately prior to the Closing, but subject to the satisfaction or waiver of each of such conditions), or at such other time, date and place as Parent and the Company may mutually agree in writing. The date on which the Closing actually takes place is referred to as the "*Closing Date*." At the Closing, the Parties shall cause the Merger to be consummated by executing and filing with the Secretary of State of the State of Delaware a certificate of merger with respect to the Merger, satisfying the applicable requirements of the DGCL and in a form reasonably acceptable to Parent and the Company (the "*Certificate of Merger*"). The Merger shall become effective at the time of the filing of such Certificate of Merger with the Secretary of State of Delaware or at such later time as may be specified in such Certificate of Merger with the consent of Parent and the Company (the time as of which the Merger becomes effective being referred to as the "*Effective Time*").

1.4 Certificate of Incorporation and Bylaws; Directors and Officers. At the Effective Time:

(a) the certificate of incorporation of the Surviving Corporation shall be amended and restated in its entirety to read identically to the certificate of incorporation of Merger Sub as in effect immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation; *provided, however*, that at or immediately prior to the Effective Time, the Surviving Corporation shall file an amendment to its certificate of incorporation to change the name of the Surviving Corporation to Tvardi Operating Company, Inc. or such other name as shall be mutually agreed upon by Parent and the Company prior to filing such amendment;

(b) the certificate of incorporation of Parent shall be identical to the certificate of incorporation of Parent immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation; *provided, however*, that at or immediately prior to the Effective Time, Parent shall file an amendment to its certificate of incorporation to (i) change the name of Parent to Tvardi Therapeutics, Inc.; (ii) effect the Nasdaq Reverse Split (to the extent applicable and necessary); and (iii) make such other changes as shall be mutually agreed upon by Parent and the Company prior to filing such amendment;

(c) the bylaws of the Surviving Corporation shall be amended and restated in their entirety to read identically to the bylaws of Merger Sub as in effect immediately prior to the Effective Time



(except that the name of the Surviving Corporation in such bylaws shall reflect the name identified in <u>Section 1.4(a)</u>), until thereafter amended as provided by the DGCL and such bylaws;

(d) the directors and officers of Parent, each to hold office in accordance with the certificate of incorporation and bylaws of Parent, shall be as set forth in <u>Section 5.11</u> after giving effect to the provisions of <u>Section 5.11</u>, or such other persons as shall be mutually agreed upon by Parent and the Company; and

(e) the directors and officers of the Surviving Corporation, each to hold office in accordance with the certificate of incorporation and bylaws of the Surviving Corporation, shall be the directors and officers of Merger Sub.

1.5 Conversion of Shares.

(a) At the Effective Time, by virtue of the Merger and without any further action on the part of Parent, Merger Sub, the Company or any stockholder of the Company or Parent:

(i) any shares of Company Capital Stock held as treasury stock by the Company or held or owned by Parent, Merger Sub or any Subsidiary of Parent or the Company immediately prior to the Effective Time shall be canceled and retired and shall cease to exist, and no consideration shall be delivered in exchange therefor;

(ii) subject to <u>Section 1.5(c)</u>, each share of Company Capital Stock outstanding immediately prior to the Effective Time (excluding shares to be canceled pursuant to <u>Section 1.5(a)(i)</u> and excluding Dissenting Shares), after giving effect to the Preferred Stock Conversion, shall be automatically converted solely into the right to receive a number of shares of Parent Common Stock equal to the Exchange Ratio; and

(iii) subject to <u>Section 1.5(c)</u>, each Bridge Note outstanding immediately prior to the Effective Time shall be automatically converted solely into the right to receive a number of shares of Parent Common Stock in accordance with Section 2(d) of such Bridge Note and calculated in accordance with Schedule I.

(b) If any shares of Company Capital Stock outstanding immediately prior to the Effective Time are unvested or are subject to a repurchase option or a risk of forfeiture under any applicable restricted stock purchase agreement or other similar agreement with the Company, then the shares of Parent Common Stock issued in exchange for such shares of Company Capital Stock at the Effective Time will to the same extent be unvested and subject to the same repurchase option or risk of forfeiture, and such shares of Parent Common Stock shall accordingly be marked with appropriate legends. The Company shall take all actions that may be necessary to ensure that, from and after the Effective Time, Parent is entitled to exercise any such repurchase option or other right set forth in any such restricted stock purchase agreement or other agreement in accordance with its terms.

(c) No fractional shares of Parent Common Stock shall be issued in connection with the Merger, and no certificates or scrip for any such fractional shares shall be issued. Any holder of Company Capital Stock who would otherwise be entitled to receive a fraction of a share of Parent Common Stock (after aggregating all fractional shares of Parent Common Stock issuable to such holder) shall, in lieu of such fraction of a share be paid in cash the dollar amount (rounded to the nearest whole cent), without interest, determined by multiplying such fraction by the Parent Closing Price.

(d) All Company Options outstanding immediately prior to the Effective Time under the Company Plan shall be treated in accordance with Section 5.5(a).

(e) Each share of common stock, \$0.0001 par value per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into and exchanged for one validly-issued, fully-paid and nonassessable share of common stock, \$0.0001 par value per share, of the Surviving Corporation. Each stock certificate or book-entry share of Merger Sub evidencing

ownership of any such shares shall, as of the Effective Time, evidence ownership of such shares of common stock of the Surviving Corporation.

(f) If, between the time of calculating the Exchange Ratio and the Effective Time, the outstanding shares of Company Capital Stock or Parent Common Stock shall have been changed into, or exchanged for, a different number of shares or a different class, by reason of any stock dividend, subdivision, reclassification, recapitalization, split (including the Nasdaq Reverse Split to the extent such split has not been previously taken into account in calculating the Exchange Ratio), combination or exchange of shares or other like change, the Exchange Ratio shall, to the extent necessary, be equitably adjusted to reflect such change to the extent necessary to provide the holders of Company Capital Stock, Parent Common Stock and Company Options with the same economic effect as contemplated by this Agreement prior to such stock dividend, subdivision, reclassification, recapitalization, split (including the Nasdaq Reverse Split), combination or exchange of shares or other like change; *provided, however*, that nothing herein will be construed to permit the Company or Parent to take any action with respect to Company Capital Stock, respectively, that is prohibited or not expressly permitted by the terms of this Agreement.

1.6 Calculation of Parent Net Cash.

(a) For the purposes of this Agreement, the "Anticipated Closing Date" shall be the date, as agreed upon by Parent and the Company at least fifteen (15) calendar days prior to the Parent Stockholders' Meeting, to be the anticipated date for Closing. At least fifteen (15) calendar days prior to the Parent Stockholders' Meeting, Parent shall deliver to the Company a schedule (the "Net Cash Schedule") setting forth Parent's estimated calculation of Parent Net Cash, including each component thereof (the "Net Cash Calculation") as of the Anticipated Closing Date prepared and certified by Parent's Chief Financial Officer (or if there is no Chief Financial Officer, the principal accounting officer of Parent). Parent shall make available to the Company the work papers and back-up materials used or useful in preparing the Net Cash Schedule (including, with respect to Transaction Expenses, estimated final invoices and current accounts receivable from each advisor to Parent) and, as reasonably requested by the Company, Parent's accountants and counsel at reasonable times and upon reasonable notice.

(b) Within three (3) Business Days after delivery of the Net Cash Schedule (the "*Response Date*"), the Company will have the right to dispute any part of the Net Cash Schedule by delivering a written notice to that effect to Parent (a "*Dispute Notice*"). Any Dispute Notice shall identify in reasonable detail the nature of any proposed revisions to the Net Cash Calculation.

(c) If on or prior to the Response Date, the Company (i) notifies Parent in writing that it has no objections to the Net Cash Calculation or (ii) fails to deliver a Dispute Notice as provided in <u>Section 1.6(b)</u> then the Net Cash Calculation as set forth in the Net Cash Schedule shall be deemed to have been finally determined for purposes of this Agreement and to represent Parent Net Cash as of the Anticipated Closing Date for purposes of this Agreement.

(d) If the Company delivers a Dispute Notice on or prior to the Response Date, then Representatives of both Parties shall promptly meet and attempt in good faith to resolve the disputed item(s) and negotiate an agreed-upon determination of Parent Net Cash, which agreed upon Parent Net Cash amount shall be deemed to have been finally determined for purposes of this Agreement and to represent Parent Net Cash as of the Anticipated Closing Date for purposes of this Agreement.

(e) If Parent and the Company are unable to negotiate an agreed-upon determination of Parent Net Cash as of the Anticipated Closing Date pursuant to <u>Section 1.6(d)</u> within three (3) calendar days after delivery of the Dispute Notice (or such other period as Parent and the Company may mutually agree upon), then Parent and the Company shall jointly select an independent auditor of recognized national standing (the "*Accounting Firm*") to resolve any remaining disagreements as to the Net Cash Calculation. Parent shall promptly deliver to the Accounting Firm the work papers and back-up materials used in preparing the Net Cash Schedule, and Parent

and the Company shall use commercially reasonable efforts to cause the Accounting Firm to make its determination within ten (10) calendar days of accepting its selection. The Company and Parent shall be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; provided, however, that no such presentation or discussion shall occur without the presence of a Representative of each of the Company and Parent. The determination of the Accounting Firm shall be limited to the disagreements submitted to the Accounting Firm. The determination of the amount of Parent Net Cash made by the Accounting Firm shall be final and binding upon the Parties and shall be deemed to have been finally determined for purposes of this Agreement and to represent Parent Net Cash as of the Anticipated Closing Date for purposes of this Agreement, and the Parties shall delay the Closing until the resolution of the matters described in this <u>Section 1.6(e)</u>. The fees and expenses of the Accounting Firm shall be allocated between Parent and the Company in the same proportion that the disputed amount of Parent Net Cash that was unsuccessfully disputed by such Party (as finally determined by the Accounting Firm) bears to the total disputed amount of Parent Net Cash. If this Section 1.6(e) applies as to the determination of Parent Net Cash as of the Anticipated Closing Date described in Section 1.6(a), upon resolution of the matter in accordance with this Section 1.6(e), the Parties shall not be required to determine Parent Net Cash again even though the Closing Date may occur later than the Anticipated Closing Date, except that either Party may request a re-determination of Parent Net Cash if the Closing Date is more than five (5) Business Days after the Anticipated Closing Date.

1.7 <u>Closing of the Company's Transfer Books</u>. At the Effective Time: (a) all shares of Company Capital Stock outstanding immediately prior to the Effective Time shall be treated in accordance with <u>Section 1.5(a)</u>, and all holders of certificates or book-entry shares representing shares of Company Capital Stock that were outstanding immediately prior to the Effective Time shall cease to have any rights as stockholders of the Company; and (b) the stock transfer books of the Company shall be closed with respect to all shares of Company Capital Stock outstanding immediately prior to the Effective Time. No further transfer of any such shares of Company Capital Stock shall be made on such stock transfer books after the Effective Time. If, after the Effective Time, a valid certificate previously representing any shares of Company Capital Stock outstanding immediately prior to the Effective Time (including any certificates representing the Company Preferred Stock that were converted or exercised in connection with the conversion of Company Preferred Stock (a "*Company Stock Certificate*")) is presented to the Exchange Agent or to the Surviving Corporation, such Company Stock Certificate shall be exchanged as provided in <u>Sections 1.5</u> and <u>1.8</u>.

1.8 Surrender of Certificates.

(a) Prior to the Closing Date, Parent and the Company shall agree upon and select a reputable bank, transfer agent or trust company to act as exchange agent in the Merger (the "*Exchange Agent*"), and enter into an exchange agent agreement, in a form reasonably acceptable to the Company. At the Effective Time, Parent shall deposit with the Exchange Agent: (i) evidence of book-entry shares representing the Parent Common Stock issuable pursuant to <u>Section 1.5(a)</u>; and (ii) cash sufficient to make payments in lieu of fractional shares in accordance with <u>Section 1.5(c)</u>. The Parent Common Stock and cash amounts so deposited with the Exchange Agent, together with any dividends or distributions received by the Exchange Agent with respect to such shares, are referred to collectively as the "*Exchange Fund*."

(b) Promptly after the Effective Time, the Parties shall cause the Exchange Agent to mail to the Persons who were record holders of shares of Company Capital Stock that were converted into the right to receive the Merger Consideration instructions for effecting the surrender of any Company Stock Certificates, or uncertificated shares of Company Capital Stock, in exchange for shares of Parent Common Stock. Upon surrender of a Company Stock Certificate or other reasonable evidence of the ownership of uncertificated Company Capital Stock to the Exchange Agent for exchange, together with such other documents as may be reasonably required by the Exchange Agent or Parent (including a properly completed IRS Form W-9 or the appropriate version of IRS Form W-8, as applicable): (A) the holder of such Company Capital Stock shall be entitled to receive in exchange therefor book-entry shares representing the Merger Consideration (in a

number of whole shares of Parent Common Stock) that such holder has the right to receive pursuant to the provisions of Section 1.5(a) (and cash in lieu of any fractional share of Parent Common Stock pursuant to the provisions of <u>Section 1.5(c)</u>); and (B) such Company Stock Certificate so surrendered shall be canceled. Until surrendered as contemplated by this Section 1.8(b), each Company Stock Certificate shall be deemed, from and after the Effective Time, to represent only the right to receive book-entry shares of Parent Common Stock representing the Merger Consideration (and cash in lieu of any fractional share of Parent Common Stock). If any Company Stock Certificate shall have been lost, stolen or destroyed, Parent may, in its discretion and as a condition precedent to the delivery of any shares of Parent Common Stock, require the owner of such lost, stolen or destroyed Company Stock Certificate to provide an applicable affidavit with respect to such Company Stock Certificate and post a bond indemnifying Parent against any claim suffered by Parent related to the lost, stolen or destroyed Company Stock Certificate as Parent may reasonably request. In the event of a transfer of ownership of a Company Stock Certificate that is not registered in the transfer records of the Company, payment of the Merger Consideration may be made to a Person other than the Person in whose name such Company Stock Certificate so surrendered is registered if such Company Stock Certificate shall be properly endorsed or otherwise be in proper form for transfer and the Person requesting such payment shall pay any transfer or other Taxes required by reason of the transfer or establish to the satisfaction of Parent that such Taxes have been paid or are not applicable. The Merger Consideration and any dividends or other distributions as are payable pursuant to Section 1.8(c) shall be deemed to have been in full satisfaction of all rights pertaining to Company Capital Stock formerly represented by such Company Stock Certificates.

(c) No dividends or other distributions declared or made with respect to Parent Common Stock with a record date on or after the Effective Time shall be paid to the holder of any unsurrendered Company Stock Certificate with respect to the shares of Parent Common Stock that such holder has the right to receive in the Merger until such holder surrenders such Company Stock Certificate or provides an affidavit of loss, theft or destruction in lieu thereof in accordance with this <u>Section 1.8</u> together with such other documents as may be reasonably required by the Exchange Agent or Parent (at which time (or, if later, on the applicable payment date) such holder shall be entitled, subject to the effect of applicable abandoned property, escheat or similar Laws, to receive all such dividends and distributions, without interest).

(d) Any portion of the Exchange Fund that remains undistributed to holders of Company Capital Stock as of the date that is one (1) year after the Closing Date shall be delivered to Parent upon demand, and any holders of Company Stock Certificates who have not theretofore surrendered their Company Stock Certificates in accordance with this <u>Section 1.8</u> shall thereafter look only to Parent for satisfaction of their claims for Parent Common Stock, cash in lieu of fractional shares of Parent Common Stock and any dividends or distributions with respect to shares of Parent Common Stock.

(e) No Party to this Agreement shall be liable to any holder of any Company Capital Stock or to any other Person with respect to any shares of Parent Common Stock (or dividends or distributions with respect thereto) or for any cash amounts delivered to any public official pursuant to any applicable abandoned property Law, escheat Law or similar Law.

1.9 Appraisal Rights.

(a) Notwithstanding any provision of this Agreement to the contrary, shares of Company Capital Stock that are outstanding immediately prior to the Effective Time and which are held by stockholders who have exercised and perfected appraisal rights for such shares of Company Capital Stock in accordance with the DGCL (collectively, the "*Dissenting Shares*") shall not be converted into or represent the right to receive the Merger Consideration described in <u>Section 1.5</u> attributable to such Dissenting Shares. Such stockholders shall be entitled to receive payment of the appraised value of such shares of Company Capital Stock held by them in accordance with the DGCL, unless and until such stockholders fail to perfect or effectively withdraw or otherwise lose their appraisal rights under the DGCL. All Dissenting Shares held by stockholders who shall have failed to perfect or shall have effectively withdrawn or lost their right to appraisal of such shares of

Company Capital Stock under the DGCL (whether occurring before, at or after the Effective Time) shall thereupon be deemed to be converted into and to have become exchangeable for, as of the Effective Time, the right to receive the Merger Consideration, without interest, attributable to such Dissenting Shares upon their surrender in the manner provided in <u>Sections 1.5</u> and <u>1.8</u>.

(b) The Company shall give Parent prompt written notice of any demands by dissenting stockholders received by the Company, withdrawals of such demands and any other instruments served on the Company and any material correspondence received by the Company in connection with such demands, and Parent shall have the right to participate in all negotiations and proceedings with respect to such demands. The Company shall not, except with Parent's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), make any payment with respect to, or settle or offer to settle, any such demands, or approve any withdrawal of any such demands or agree to do any of the foregoing.

1.10 <u>Further Action</u>. If, at any time after the Effective Time, any further action is determined by the Surviving Corporation to be necessary or desirable to carry out the purposes of this Agreement or to vest the Surviving Corporation with full right, title and possession of and to all rights and property of the Company, then the officers and directors of the Surviving Corporation shall be fully authorized, and shall use their and its commercially reasonable efforts (in the name of the Company, in the name of Merger Sub, in the name of the Surviving Corporation and otherwise) to take such action.

1.11 <u>Withholding</u>. The Parties and the Exchange Agent shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to any holder of Company Capital Stock or any other Person such amounts as such Party or the Exchange Agent reasonably determines it is required to deduct and withhold under the Code or any other Law with respect to the making of such payment. To the extent that amounts are so deducted and withheld and paid to the appropriate Governmental Body, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction and withholding was made.

Section 2. <u>REPRESENTATIONS AND WARRANTIES OF THE COMPANY</u>

Subject to <u>Section 10.13(j)</u>, except as set forth in the disclosure schedule delivered by the Company to Parent concurrently herewith (the "*Company Disclosure Schedule*"), the Company represents and warrants to Parent and Merger Sub as follows:

2.1 Due Organization; Subsidiaries.

(a) The Company is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound, except where the failure to have such power or authority would not reasonably be expected to prevent or materially delay the ability of the Company to consummate the Contemplated Transactions.

(b) The Company is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Company Material Adverse Effect.

(c) The Company does not have, and has never had, any Subsidiaries, and the Company does not own any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or control directly or indirectly, any other Entity.

(d) The Company is not, nor has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. The Company has not

agreed or is obligated to make, or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. The Company has not, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

2.2 <u>Organizational Documents</u>. The Company has made available to Parent accurate and complete copies of the Organizational Documents of the Company in effect as of the date of this Agreement. The Company is not in material breach or violation of its respective Organizational Documents.

2.3 Authority; Binding Nature of Agreement.

(a) The Company has all necessary corporate power and authority to enter into this Agreement and, subject, with respect to the Company, to receipt of the Required Company Stockholder Vote, to perform its obligations under this Agreement and to consummate the Contemplated Transactions. The Company Board (at a meeting duly called and held or by written consent in lieu of a meeting) has unanimously: (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of the Company and its stockholders; (ii) authorized, approved and declared advisable this Agreement and the Contemplated Transactions; and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of the Company vote to approve the Company Stockholder Matters.

(b) This Agreement has been duly executed and delivered by the Company and assuming the due authorization, execution and delivery by Parent and Merger Sub, constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, subject to the Enforceability Exceptions. Prior to the execution of the Company Stockholder Support Agreements, the Company Board approved the Company Stockholder Support Agreements and the transactions contemplated thereby.

2.4 <u>Vote Required</u>. The affirmative vote (or written consent) of the holders of (a) a majority of the then-outstanding shares of Series A Preferred Stock voting as a separate class, (b) a majority of the then-outstanding shares of Series B Preferred Stock voting as a separate class, and (c) a majority of the then-outstanding shares of the capital stock of the Company on an as-converted to Company Common Stock basis (collectively, the "*Required Company Stockholder Vote*"), is the only vote (or written consent) of the holders of any class or series of Company Capital Stock necessary to adopt and approve this Agreement and approve the Contemplated Transactions.

2.5 <u>Non-Contravention; Consents</u>.

(a) Subject to obtaining the Required Company Stockholder Vote and the filing of the Certificate of Merger required by the DGCL, neither (x) the execution, delivery or performance of this Agreement by the Company, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(i) contravene, conflict with or result in a violation of any of the provisions of the Organizational Documents of the Company;

(ii) contravene, conflict with or result in a violation of, or give any Governmental Body or any other Person the right to challenge the Contemplated Transactions or to exercise any remedy or obtain any relief under, any Law or any order, writ, injunction, judgment or decree to which the Company, or any of the assets owned or used by the Company, is subject, except as would not reasonably be expected to be material to the Company or its business;

(iii) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by the Company, except as would not reasonably be expected to be material to the Company or its business;

(iv) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Company Material Contract, or give any Person the right to: (A) declare a default or exercise any remedy under any Company Material Contract; (B) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Company Material Contract; (C) accelerate the maturity or performance of any Company Material Contract; or (D) cancel, terminate or modify any term of any Company Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(v) result in the imposition or creation of any Encumbrance upon or with respect to any asset owned or used by the Company (except for Permitted Encumbrances).

(b) Except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, (ii) the Required Company Stockholder Vote, and (iii) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, the Company is not, nor will it be required to make any filing with or give any notice to, or to obtain any Consent from, any Governmental Body in connection with (x) the execution, delivery or performance of this Agreement, or (y) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of the Company to consummate the Contemplated Transactions.

(c) The Company Board has taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Company Stockholder Support Agreements, the Company Lock-Up Agreements and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, the Company Stockholder Support Agreements, the Company Stockholder Support Agreements, the Company Stockholder Support Agreements, the Company Lock-Up Agreements or any of the Contemplated Transactions.

2.6 Capitalization.

(a) The authorized Company Capital Stock as of the date of this Agreement consists of (i) 58,251,629 shares of Company Common Stock, par value \$0.001 per share, of which 19,197,914 shares have been issued and are outstanding as of the date of this Agreement, and (ii) 29,723,540 shares of preferred stock, par value \$0.001 per share (the "*Company Preferred Stock*"), 9,499,999 shares of which have been designated Series A Preferred Stock (the "*Series A Preferred Stock*"), all of which have been issued and are outstanding as of the date of this Agreement and 20,223,541 shares of which have been designated Series B Preferred Stock (the "*Series B Preferred Stock*"), 20,055,539 shares of which have been issued and are outstanding as of the date of this Agreement. The Company Does not hold any shares of its capital stock in its treasury. Section 2.6(a) of the Company Disclosure Schedule lists, as of the date of this Agreement each record holder of issued and outstanding Company Capital Stock and the number and type of shares of Company Capital Stock held by such holder.

(b) All of the outstanding shares of Company Common Stock and Company Preferred Stock have been duly authorized and validly issued, and are fully paid and nonassessable. Except as set forth in the Investor Agreements, none of the outstanding shares of Company Capital Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Company Capital Stock is subject to any right of first refusal in favor of the Company. Except as contemplated herein and in the Investor Agreements, there is no Company Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Company Capital Stock. The Company is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Company Capital Stock or other securities. Section 2.6(b) of the Company Disclosure Schedule accurately and completely lists all repurchase rights held by the Company with respect to shares of Company Capital Stock (including shares issued pursuant to the exercise of stock options) and specifies which of those repurchase



rights are currently exercisable and whether the holder of such shares of Company Capital Stock timely filed an election with the relevant Governmental Bodies under Section 83(b) of the Code with respect to such shares. Each share of Company Preferred Stock is convertible into one share of Company Common Stock.

(c) Except for the Company's 2018 Stock Incentive Plan (the "Company Plan"), the Company does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the date of this Agreement, the Company has reserved 6,657,329 shares of Company Common Stock for issuance under the Company Plan, of which 5,450,941 shares have been issued and are currently outstanding. Section 2.6(c) of the Company Disclosure Schedule sets forth the following information with respect to each Company Option outstanding as of the date of this Agreement: (i) the name of the optionee; (ii) the number of shares of Company Common Stock subject to such Company Option at the time of grant; (iii) the number of shares of Company Common Stock subject to such Company Option as of the date of this Agreement; (iv) the exercise price of such Company Option; (v) the date on which such Company Option was granted; (vi) the applicable vesting schedule, including the number of vested and unvested Company Options as of the date of this Agreement; (vii) the date on which such Company Option expires; and (viii) whether such Company Option is intended to constitute an "incentive stock option" (as defined in the Code) or a non-qualified stock option. The Company has made available to Parent an accurate and complete copy of the Company Plan and all stock option agreements evidencing outstanding options granted thereunder. Section 2.6(c) of the Company Disclosure Schedule sets forth a list of Company Options that have accelerated vesting in connection with the closing of the Contemplated Transactions.

(d) Except for the Company Options set forth in <u>Section 2.6(c)</u> of the Company Disclosure Schedule, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of the Company; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of the Company; or (iii) condition or circumstance that could be reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of the Company. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to the Company.

(e) All outstanding shares of Company Common Stock, Company Preferred Stock, Company Options and other securities of the Company have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Laws, and (ii) all requirements set forth in applicable Contracts.

2.7 Financial Statements.

(a) Concurrently with the execution hereof, the Company has provided to Parent true and complete copies of (i) the Company's audited balance sheets at December 31, 2023 and 2022, together with related audited consolidated statements of income, stockholders' equity and cash flows, and notes thereto, of the Company for the fiscal years then ended (the "*Company 2023 and 2022 Audited Financial Statements*"), and (ii) the Company Unaudited Interim Balance Sheet, together with the unaudited consolidated statements of income, stockholders' equity and cash flows of the Company for the period reflected in the Company Unaudited Interim Balance Sheet (the "*Company 2024 Interim Financial Statements*," and collectively, the "*Company Financials*"). The Company Financials were prepared in accordance with GAAP applied on a consistent basis throughout the periods covered thereby (except as may be indicated in the notes to such financial statements and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments, none of which are reasonably expected to be material in amount) and fairly present, in all material respects, the financial position and operating results of the Company as of the dates and for the periods indicated therein.

(b) The Company maintains accurate books and records reflecting their assets and liabilities and maintains a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of the financial statements of the Company and to maintain accountability of the Company's assets; (iii) access to the Company's assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for the Company's assets is compared with the existing assets at regular intervals and appropriate action is taken with respect to any differences; and (v) accounts, notes and other receivables and inventory are recorded accurately, and proper and adequate procedures are implemented to effect the collection thereof on a current and timely basis. The Company maintains internal control over financial reporting that provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes.

(c) <u>Section 2.7(c)</u> of the Company Disclosure Schedule lists, and the Company has delivered to Parent accurate and complete copies of the documentation creating or governing, all securitization transactions and "off-balance sheet arrangements" (as described in Instruction 8 to Item 303(b) of Regulation S-K as promulgated under the Securities Act) effected by the Company since January 1, 2021.

(d) Since January 1, 2021, there have been no formal internal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer or general counsel of the Company, the Company Board or any committee thereof. Since January 1, 2021, neither the Company nor its independent auditors have identified (i) any significant deficiency or material weakness in the design or operation of the system of internal accounting controls utilized by the Company, (ii) any fraud, whether or not material, that involves the Company, the Company's management or other employees who have a role in the preparation of financial statements or the internal accounting controls utilized by the Company, or (iii) any claim or allegation regarding any of the foregoing.

2.8 Absence of Changes.

(a) Between the date of the Company Unaudited Interim Balance Sheet and the date of this Agreement, the Company has conducted its business only in the Ordinary Course of Business (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto, including the Contemplated Transactions).

(b) Between the date of the Company Unaudited Interim Balance Sheet and the date of this Agreement, there has not been any Company Material Adverse Effect.

(c) Between the date of the Company Unaudited Interim Balance Sheet and the date of this Agreement, there has not been any action, event or occurrence that would have required the consent of Parent pursuant to <u>Section 4.2(b)</u> had such action, event or occurrence taken place after the execution and delivery of this Agreement.

2.9 Absence of Undisclosed Liabilities. As of the date of this Agreement, the Company does not have any liability, indebtedness, obligation or expense of any kind, whether accrued, absolute, contingent, matured or unmatured (whether or not required to be reflected in the financial statements in accordance with GAAP) (each a "*Liability*"), individually or in the aggregate, of a type required to be recorded or reflected on a balance sheet or disclosed in the footnotes thereto under GAAP except for: (a) Liabilities disclosed, reflected or reserved against in the Company Unaudited Interim Balance Sheet; (b) Liabilities that have been incurred by the Company since the date of the Company Unaudited Interim Balance Sheet in the Ordinary Course of Business; (c) Liabilities for performance of obligations of the Company under Company Material Contracts which have not resulted from a breach of such Company Material Contracts, breach of warranty, tort, infringement or violation of Law; (d) Liabilities incurred in connection with the Contemplated Transactions; and (e) Liabilities which would not, individually or in the aggregate, reasonably be expected to be material to the Company.

2.10 <u>Title to Assets</u>. The Company owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it, including: (a) all tangible assets reflected on the Company Unaudited Interim Balance Sheet; and (b) all other tangible assets reflected in the books and records of the Company as being owned by the Company. All of such assets are owned or, in the case of leased assets, leased by the Company free and clear of any Encumbrances, other than Permitted Encumbrances.

2.11 <u>Real Property; Leasehold</u>. The Company does not own and has never owned any real property. The Company has made available to Parent (a) an accurate and complete list of all real properties with respect to which the Company directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by the Company, and (b) copies of all leases under which any such real property is possessed (the "*Company Real Estate Leases*"), each of which is in full force and effect, with no existing material default thereunder. The Company's use and operation of each such leased property conforms to all applicable Laws in all material respects, and the Company has exclusive possession of each such leased property and has not granted any occupancy rights to tenants or licensees with respect to such leased property. In addition, each such leased property is free and clear of all Encumbrances other than Permitted Encumbrances.

2.12 Intellectual Property.

(a) Section 2.12(a) of the Company Disclosure Schedule accurately identifies (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the application or registration number and (iv) any other co-owners, for each item of Registered IP owned in whole or in part by the Company (the "Company Owned Registered IP"). Each of the patents and patent applications included in the Company Owned Registered IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. To the Company's Knowledge, (A) the Company Owned Registered IP is valid, enforceable and subsisting, and in full force and effect, (B) none of the Company Owned Registered IP has been misused, withdrawn, cancelled, expired, or abandoned, and (C) all application, registration, issuance, renewal and maintenance fees due for the Company Owned Registered IP having a due date on or before the date of this Agreement have been paid in full and are current. To the Company's Knowledge, with respect to each item of Company Owned Registered IP and each patent application from which such Company Owned Registered IP claims priority, all statements made and information presented to the applicable patent office by or on behalf of the Company or any inventor thereof, or their respective patent counsel, during the prosecution thereof are accurate and complete and comply with 37 CFR 1.56. As of the date of this Agreement, no interference, opposition, reissue, reexamination, derivation, inter partes review, or other proceeding of any nature (other than initial examination proceedings and other than in the ordinary course of prosecution and maintenance) is pending or, to the Company's Knowledge, threatened in writing, in which the scope, validity, enforceability, or ownership of any Company Owned Registered IP is being or has been contested or challenged.

(b) The Company owns or co-owns all right, title and interest in and to all Company IP, free and clear of all Encumbrances other than Permitted Encumbrances and, to the Company's Knowledge, has the right, pursuant to a Company In-bound License to use all other material Intellectual Property Rights used by the Company in its businesses as currently conducted. The Company IP and the Intellectual Property Rights licensed to the Company pursuant to a Company In-bound License (the "*Company In-Licensed IP*") are all the Intellectual Property Rights necessary to operate the business of the Company as currently conducted and as proposed to be conducted as of the date of this Agreement. No Company Associate owns or has any claim, right (whether or not currently exercisable) or interest to or in any Company IP, and each Company Associate involved in the creation or development of any material Company IP, pursuant to such Company Associate's activities on behalf of the Company, has signed or has the obligation to sign a valid, enforceable written agreement containing a present assignment of all of such Company Associate's rights in such Company IP to the Company (without further payment being owed to any such Company Associate and without any restrictions or obligations on the Company's ownership

or use thereof (except for the obligation to pay service fee pursuant to the terms of the applicable service agreements that is not based on the revenues or profits of the Company)) and confidentiality provisions protecting the Company IP, which, to the Company's Knowledge, has not been breached by such Company Associate. Without limiting the foregoing, the Company has taken commercially reasonable steps to protect, maintain and enforce all Company IP and Company In-Licensed IP, including the secrecy, confidentiality and value of trade secrets and other confidential information therein, and to the Company's Knowledge there have been no authorized disclosures of any Company IP or Company In-Licensed IP. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will conflict with, alter or impair any of the Company's or, following the Closing, Parent's, rights in or to any Company IP or Company IP or cause any payments of any kind to be due or payable to any Person.

(c) To the Company's Knowledge, no funding, facilities or personnel of any Governmental Body or any university, college, research institute or other educational or academic institution has been used, in whole or in part, to create any Company IP or any Company In-Licensed IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership or other rights (including any "march in" rights or a right to direct the location of manufacturing of products) to such Company IP or Company In-Licensed IP or the right to receive royalties or other consideration for the practice of such Company IP or Company In-Licensed IP. To the Company's Knowledge, no Company Associate who was involved in, or who contributed to, the creation or development of any Company IP or any Company In-Licensed IP, has performed services for a Governmental Body or any university, college, research institute or other educational or academic institution in a manner that would affect the Company's interest in Company IP or any Company In-Licensed IP.

(d) Section 2.12(d) of the Company Disclosure Schedule sets forth each license agreement pursuant to which the Company (i) is granted a license under any Intellectual Property Right owned by any third party (each a "Company In-bound License"), or (ii) grants to any third party a license, option, covenant not to sue or other right under any Company IP or any Company In-Licensed IP (each a "Company Out-bound License") (provided, that, Company In-bound Licenses shall not include material transfer agreements, clinical trial agreements, services agreements, nondisclosure agreements, commercially-available Software-as-a-Service offerings, off-the-shelf software licenses or generally-available patent license agreements, in each case entered into in the Ordinary Course of Business on a non-exclusive basis and where the license is incidental to the primary purpose of the relevant Contracts; and Company Out-bound Licenses shall not include material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, or non-exclusive outbound licenses, in each case entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of the Company). To the Company's Knowledge, no other party to any Company Inbound License or Company Out-bound License has breached or is in breach of any of its obligations under any Company In-bound License or Company Out-bound License.

(e) To the Company's Knowledge: (i) the operation of the businesses of the Company as currently conducted or as proposed to be conducted as of the date of this Agreement does not infringe or misappropriate or otherwise violate any Intellectual Property Right owned by any other Person; and (ii) no other Person is infringing, misappropriating or otherwise violating any Company IP or any Company In-Licensed IP. As of the date of this Agreement, no Legal Proceeding is pending (or, to the Company's Knowledge, is threatened in writing) (A) against the Company alleging that the operation of the businesses of the Company infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by the Company alleging that another Person has infringed, misappropriated or otherwise violated any of the Company IP or any Company In-Licensed IP. Since January 1, 2021, the Company has not received any written notice or other written communication alleging that the operation of any Intellectual Property Right of another Person.

(f) None of the Company IP or, to the Company's Knowledge, any Company In-Licensed IP is subject to any pending or outstanding injunction, directive, order, decree, settlement, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by the Company of any such Company IP or Company In-Licensed IP or otherwise would reasonably be expected to adversely affect the validity, scope, use, registrability, or enforceability of any Company IP or Company In-Licensed IP.

(g) Except as would not reasonably be expected to have, individually or in the aggregate, a Company Material Adverse Effect, the Company and the operation of the Company's businesses are in substantial compliance with all applicable Laws pertaining to data privacy and data security of any personally identifiable information and sensitive business information (collectively, "*Sensitive Data*") in the Company's possession, custody, or control. Since January 1, 2021, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of the Company, (ii) no violations of any security policy of the Company regarding any such Sensitive Data, (iii) no unauthorized access to or unauthorized use of any Sensitive Data used in the business of the Company, and (iv) no unintended or improper disclosure of any personally identifiable information in the possession, custody or control of the Company, or a contractor or agent acting on behalf of the Company, in each case of clauses (i) through (iv), except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect.

(h) The Company is not now nor has ever been a member or promoter of, or a contributor to, any industry standards body or any similar organization that would reasonably be expected to require or obligate any of the Company to grant or offer to any other Person any license or right to any Company IP or Company In-Licensed IP.

(i) Solely with respect to Intellectual Property Rights for which the Company controls the filing, prosecution, or maintenance and to the Company's Knowledge: (i) all information to the Knowledge of Company relating to the subject matter of the claims of the Company IP or Company In-Licensed IP has been disclosed to the United States Patent and Trademark Office ("USPTO") to the extent required by 37 C.F.R. § 1.56 or any applicable patent office in any other jurisdiction to the extent required by the applicable rules and regulations in such jurisdiction; (ii) all material information submitted to the USPTO and any applicable patent office in any other jurisdiction in connection with the Company IP or Company In-Licensed IP, and in connection with the prosecution thereof, was accurate in all material respects at the time it was submitted; (iii) the Company, with respect to any of the Company IP or Company In-Licensed IP, has not made any material misrepresentation or concealed any material information from the USPTO in violation of 37 C.F.R. Section § 1.56 or from any applicable patent office in any other jurisdiction in violation of the applicable rules and regulations in such jurisdiction, and (iv) each item of Company IP or Company In-Licensed IP is valid, subsisting, enforceable and in full force and effect and has not been cancelled, expired, or abandoned.

2.13 Agreements, Contracts and Commitments.

(a) <u>Section 2.13(a)</u> of the Company Disclosure Schedule lists the following Company Contracts in effect as of the date of this Agreement (other than any Company Benefit Plans) (each, a "*Company Material Contract*" and collectively, the "*Company Material Contracts*"):

(i) each Company Contract that would be a material contract as defined in Item 601(b)
 (10) of Regulation S-K as promulgated under the Securities Act (for purposes of this provision, assuming the Company was subject to the public reporting requirements of the Exchange Act);

(ii) each Company Contract relating to any agreement of indemnification or guaranty not entered into in the Ordinary Course of Business;

(iii) each Company Contract containing (A) any covenant limiting the freedom of the Company or the Surviving Corporation to engage in any line of business or compete with any Person, (B) any "most-favored nations" pricing provision or marketing or distribution rights

related to any products or territory, (C) any exclusivity provision, (D) any agreement to purchase minimum quantity of goods or services, or (E) any material non-solicitation provision applicable to the Company;

(iv) each Company Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of \$200,000 pursuant to its express terms and not cancelable without penalty;

(v) each Company Contract relating to the disposition or acquisition of material assets or any ownership interest in any Entity;

(vi) each Company Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit in excess of \$50,000 or creating any material Encumbrances with respect to any assets of the Company or any loans or debt obligations with officers or directors of the Company;

(vii) each Company Contract requiring payment by or to the Company after the date of this Agreement in excess of \$300,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of the Company; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, collaboration, development or other agreement currently in force under which the Company has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which the Company has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by the Company; or (D) any Contract to license any third party to manufacture or produce any product, service or service of the Company or any Contract to sell, distribute or commercialize any products or service of the Company, in each case, except for Contracts entered into in the Ordinary Course of Business;

(viii) each Company Contract with any Person, including any financial advisor, broker, finder, investment banker or other Person, providing advisory services to the Company in connection with the Contemplated Transactions;

- (ix) each Company Real Estate Lease;
- (x) each Company Contract with any Governmental Body;
- (xi) each Company Out-bound License and Company In-bound License;

(xii) each Company Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of the Company; or

(xiii) any other Company Contract that is not terminable at will (with no penalty or payment) by the Company, as applicable, and (A) which involves payment or receipt by the Company after the date of this Agreement under any such Company Contract of more than \$300,000 in the aggregate, or obligations after the date of this Agreement in excess of \$300,000 in the aggregate, or (B) that is material to the business or operations of the Company.

(b) The Company has delivered or made available to Parent accurate and complete copies of all Company Material Contracts, including all amendments thereto. There are no Company Material Contracts that are not in written form. The Company has not, nor, to the Company's Knowledge, has any other party to a Company Material Contract, breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of, or Laws applicable to, any Company Material Contract in such manner as would permit any other party to cancel or terminate any such Company Material Contract, or would permit any other party to seek damages or pursue other legal remedies which would reasonably be expected to be material to the Company or its business or operations. As to the Company, each Company Material Contract is valid, binding, enforceable and in full force and effect, subject to the Enforceability

Exceptions. No Person is renegotiating, or has a right pursuant to the terms of any Company Material Contract to change, any material amount paid or payable to the Company under any Company Material Contract or any other material term or provision of any Company Material Contract.

2.14 Compliance; Permits; Restrictions.

(a) The Company is, and since January 1, 2021, has been, in compliance in all material respects with all applicable Laws, including applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), the U.S. Food and Drug Administration ("FDA") regulations adopted thereunder, the Public Health Service Act ("PHSA") and any other similar Law administered or promulgated by the FDA or other comparable Governmental Body responsible for regulation of the development, nonclinical and clinical testing, manufacturing, sale, marketing, distribution and importation or exportation of drug and biopharmaceutical products (each, a "Drug Regulatory Agency"), except for any noncompliance, either individually or in the aggregate, which would not be material to the Company. No claim, suit, proceeding, audit or, to the Company's Knowledge, investigation or other action by any Governmental Body is pending or, to the Company's Knowledge, threatened against the Company. There is no agreement, judgment, injunction, order or decree binding upon the Company which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of the Company, any acquisition of material property by the Company or the conduct of business by the Company as currently conducted, (ii) is reasonably likely to have an adverse effect on the Company's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions.

(b) The Company holds all required Governmental Authorizations that are material to the operation of the business of the Company as currently conducted (the "*Company Permits*"). <u>Section 2.14(b)</u> of the Company Disclosure Schedule identifies each Company Permit. The Company holds all right, title and interest in and to all Company Permits free and clear of any Encumbrance. The Company is in material compliance with the terms of the Company Permits. No Legal Proceeding is pending or, to the Company's Knowledge, threatened, which seeks to revoke, limit, suspend, or materially modify any Company Permit. The rights and benefits of each Company Permit will be available to the Surviving Corporation, as applicable, immediately after the Effective Time on terms substantially identical to those enjoyed by the Company as of the date of this Agreement and immediately prior to the Effective Time.

(c) There are no proceedings pending or, to the Company's Knowledge, threatened with respect to an alleged material violation by the Company of the FDCA, FDA regulations adopted thereunder, the PHSA or any other similar Law administered or promulgated by any Drug Regulatory Agency. The Company is not currently conducting or addressing, and, to the Company's Knowledge, there is no basis to expect that it will be required to conduct or address, any corrective actions, including product recalls or clinical holds.

(d) All clinical, nonclinical and other studies and tests conducted by or on behalf of, or sponsored by, the Company, or in which the Company or its current product candidates have participated, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and in compliance in all material respects with the applicable regulations of any applicable Drug Regulatory Agency and other applicable Law, including 21 C.F.R. Parts 50, 54, 58 and 312. Since January 1, 2021, the Company has not received any notices, correspondence, or other communications from any Drug Regulatory Agency requiring or threatening to initiate the termination or suspension of any clinical studies conducted by or on behalf of, or sponsored by, the Company or in which the Company or its current product candidates have participated. The Company has made available to Parent true and complete copies of all material notices, correspondence or other communications received by the Company from any Drug Regulatory Agency.

(e) The Company is not the subject of any pending or, to the Company's Knowledge, threatened investigation by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. To the Company's Knowledge, the Company has not committed any acts, made any statement, or failed to make any statement, in each case in respect of its business or products, that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. Neither the Company nor any of its respective officers, employees or agents has been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion (i) under 21 U.S.C. Section 335a or (ii) under 42 U.S.C. §§ 1320a-7 or 1320a-7a or any similar applicable Law. No debarment or exclusionary claims, actions, proceedings or investigations in respect of its business or products are pending or, to the Company's Knowledge, threatened against the Company or any of its respective officers, employees, or to the Company's Knowledge, agents.

2.15 Legal Proceedings; Orders.

(a) As of the date of this Agreement, there is no pending Legal Proceeding and, to the Company's Knowledge, no Person has threatened to commence any Legal Proceeding: (i) that involves (A) the Company, (B) any Company Associate (in his or her capacity as such) or (C) any of the material assets owned or used by the Company; or (ii) that challenges, or that would reasonably be expected to have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Since January 1, 2021, no Legal Proceeding has been pending against the Company that resulted in material liability to the Company.

(c) There is no order, writ, injunction, judgment or decree to which the Company, or any of the material assets owned or used by the Company, is subject. To the Company's Knowledge, no officer or employee of the Company is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of the Company or to any material assets owned or used by the Company.

2.16 Tax Matters.

(a) The Company has timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No written claim has ever been made by any Governmental Body in any jurisdiction where the Company does not file a particular Tax Return or pay a particular Tax that the Company or such Subsidiary is subject to taxation by that jurisdiction.

(b) All income and other material Taxes due and owing by the Company on or before the date of this Agreement (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of the Company did not, as of the date of the Company Unaudited Interim Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Company Unaudited Interim Balance Sheet. Since the date of the Company Unaudited Interim Balance Sheet, the Company has not incurred any material Liability for Taxes outside the Ordinary Course of Business.

(c) All Taxes that the Company are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, equityholders, lenders, customers or other third parties, and have been timely paid to the proper Governmental Body or other Person or properly set aside in accounts for this purpose.

(d) There are no Encumbrances for material Taxes (other than Taxes not yet due and payable) upon any of the assets of the Company.



(e) No deficiencies for income or other material Taxes with respect to the Company have been claimed, proposed or assessed by any Governmental Body in writing. There are no pending or ongoing, and, to the Company's Knowledge, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of the Company. The Company (nor any of its predecessors) has not waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) The Company has not been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) The Company is not a party to any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) Neither Parent nor the Company will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes made on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) intercompany transaction or excess loss account described in Treasury Regulations under Section 1502 of the Code (or any similar provision of state, local or foreign Law) entered into on or prior to the Closing Date; (v) installment sale or open transaction disposition made on or prior to the Closing Date; (vi) prepaid amount received or deferred revenue accrued on or prior to the Closing Date; (vii) application of Section 367(d) of the Code to any transfer of intangible property on or prior to the Closing Date; (viii) application of Sections 951 or 951A of the Code (or any similar provision of state, local or foreign Law) to any income received or accrued on or prior to the Closing Date; or (ix) election under Section 108(i) of the Code (or any similar provision of state, local or foreign Law) made on or prior to the Closing Date. The Company has not made any election under Section 965(h) of the Code.

(i) The Company has never been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is the Company) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. The Company has no Liability for any material Taxes of any Person (other than the Company) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) The Company (i) is not a "controlled foreign corporation" as defined in Section 957 of the Code, (ii) is not a "passive foreign investment company" within the meaning of Section 1297 of the Code, or (iii) and has never had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized.

(k) The Company has not participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a "listed transaction" that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(1) The Company has not taken any action, nor to the Company's Knowledge is there any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

(m) The Company has not availed itself of any Tax relief pursuant to any Pandemic Response Laws that could reasonably be expected to materially impact the Tax payment or Tax reporting obligations of Parent and its Affiliates (including the Company) after the Closing Date.

(n) No material claim has been made in writing by any Governmental Body in a jurisdiction where the Company or any of its Subsidiaries do not currently file or have filed a Tax Return that the Company or any of its Subsidiaries are or may be subject to taxation by such jurisdiction.

(o) The Company is a corporation for U.S. federal income Tax purposes under Section 7701 of the Code.

(p) The Company has not distributed stock of another Person, nor had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 of the Code or Section 361 of the Code.

(q) To the Company's Knowledge, the Company has not been, is not, and immediately prior to the Closing Date will not be, treated as an "investment company" within the meaning of Section 368(a)(2)(F) of the Code.

For purposes of this <u>Section 2.16</u>, each reference to the Company shall be deemed to include any Person that was liquidated into, merged with, or otherwise a predecessor to, the Company.

2.17 Employee and Labor Matters; Benefit Plans.

(a) Section 2.17(a) of the Company Disclosure Schedule lists, as of the date of this Agreement, all Company Benefit Plans, including each Company Benefit Plan that provides for retirement, change in control, stay or retention, deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits. "Company Benefit Plan" means the following, but in all events exclusive of any arrangement maintained by a professional employer organization or other third-party employer: each (i) "employee benefit plan" as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based, phantom equity, employment, consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (other than regular salary or wages) (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen or terminated), in either case, maintained, contributed to, or required to be contributed to, by the Company or Company ERISA Affiliates for the benefit of any current or former employee, director, officer or independent contractor of the Company or under which the Company has any actual or contingent liability (including as to the result of it being treated as a single employer under Section 414 of the Code with any other person).

(b) As applicable with respect to each material Company Benefit Plan, the Company has made available to Parent, true and complete copies of (i) each material Company Benefit Plan, including all amendments thereto, and in the case of an unwritten material Company Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the three (3) most recently filed annual reports on Form 5500 and all schedules thereto, (v) the most recent IRS determination, opinion or advisory letter, (vi) the three (3) most recent nondiscrimination testing reports, actuarial reports, financial statements, (vii) all records, notices and filings concerning IRS or United States Department of Labor or other Governmental Body audits or investigations since January 1, 2021, (viii) each written report constituting a valuation of the Company's capital stock for purposes of Sections 409A or 422 of the Code, whether prepared internally by the Company or by an outside, third-party valuation firm, and (ix) all material written materials provided to employees or participants relating to the amendment, termination, establishment, or increase or decrease in benefits under any Company Benefit Plan.

(c) Each Company Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other applicable Laws.

(d) The Company Benefit Plans which are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and, to the Company's Knowledge, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Company Benefit Plan or the tax exempt status of the related trust.

(e) None of the Company nor any Company ERISA Affiliate sponsors, maintains, contributes to, is required to contribute to, or has any liability with respect to, or has within the past six (6) years sponsored, maintained, contributed to, or been required to contribute to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA), (iii) any "multiple employer plan" (within the meaning of Section 413 of the Code), or (iv) any "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA), and none of the Company or any of its respective ERISA Affiliates has, within the preceding six (6) years, incurred a complete or partial withdrawal from any "multiemployer plan" or otherwise incurred any liability under Section 4202 of ERISA.

(f) There are no pending audits or investigations by any Governmental Body involving any Company Benefit Plan, and no pending or, to the Company's Knowledge, threatened claims (except for individual claims for benefits payable in the normal operation of the Company Benefit Plans), suits or proceedings involving any Company Benefit Plan, any fiduciary thereof or service provider thereto. All contributions and premium payments required to have been made under any of the Company Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made and neither the Company nor any Company Benefit Plan (other than contributions which may continue to be accrued in the Ordinary Course of Business).

(g) Neither the Company or Company ERISA Affiliates, nor, to the Company's Knowledge, any fiduciary, trustee or administrator of any Company Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Company Benefit Plan which would subject any such Company Benefit Plan, the Company or Company ERISA Affiliates or Parent to a Tax, penalty or liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Company Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement, other than coverage mandated by Law.

(i) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions will, either alone or in connection with any other event(s), (i) result in any payment becoming due to any current or former employee, director, officer, independent contractor or other service provider of the Company or any Subsidiary thereof, (ii) increase any amount of compensation or benefits otherwise payable to any current or former employee, director, officer, independent contractor or other service provider of the Company or any Subsidiary thereof, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Company Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Company Benefit Plan, or (v) limit the right to merge, amend or terminate any Company Benefit Plan.

(j) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including a termination of employment) will result in the receipt or retention by any person who is a "disqualified individual" (within the meaning of Section 280G of the Code) with respect to the Company of any payment or benefit that is or could be characterized as a "parachute payment" (within the

meaning of Section 280G of the Code), determined without regard to the application of Section 280G(b)(5) of the Code.

(k) To the Company's Knowledge, each Company Benefit Plan providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder.

(1) No Person has any "gross up" agreements with the Company or other assurance of reimbursement or compensation by the Company for any Taxes imposed under Section 409A or Section 4999 of the Code.

(m) The Company does not have any Company Benefit Plan that is maintained for service providers located outside of the United States.

(n) The Company is not a party to, bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union or labor organization representing any of its employees, and there is no labor union or labor organization representing or, to the Company's Knowledge, purporting to represent or seeking to represent any employees of the Company, including through the filing of a petition for representation election.

(o) The Company is, and since January 1, 2021, has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including worker classification, discrimination, wrongful termination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, wages (including overtime wages), unemployment and workers' compensation, leaves of absence, and hours of work. Except as would not be reasonably likely to result in a material liability to the Company, with respect to employees of the Company, the Company, since January 1, 2021: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, demands, lawsuits, investigations, audits, administrative matters or other Legal Proceedings pending or, to the Company's Knowledge, threatened against the Company relating to any current or former employee, applicant for employment, consultant, employment agreement or Company Benefit Plan (other than routine claims for benefits). All employees of the Company are employed "at will" and their employment can be terminated without advance notice or payment of severance.

(p) Except as would not be reasonably likely to result in a material liability to the Company, with respect to each individual who currently renders services to the Company, the Company has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, the Company has accurately classified him or her as overtime eligible or overtime ineligible under all applicable Laws. The Company does not have any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt from overtime wages.

(q) There is not and has not been since January 1, 2021, nor is there or has there been since January 1, 2021, any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to the Company's Knowledge, any union organizing activity, against the Company. No event has occurred, and, to the Company's

Knowledge, no condition or circumstance exists, that might directly or indirectly give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute.

2.18 Environmental Matters. The Company is in compliance, and since January 1, 2021, have complied, with all applicable Environmental Laws, which compliance includes the possession by the Company of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to the Company or its business. The Company has not received since January 1, 2021 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Body or other Person, that alleges that the Company is not in compliance with or has liability pursuant to any Environmental Law and, to the Company's Knowledge, there are no circumstances that would reasonably be expected to prevent or interfere with the Company's compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to the Company or its business. No current or (during the time a prior property was leased or controlled by the Company) prior property leased or controlled by the Company has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of the Company pursuant to any applicable Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Body is required by any applicable Environmental Laws in connection with the execution and delivery of this Agreement or the consummation of the Contemplated Transactions.

2.19 <u>Insurance</u>. The Company has delivered or made available to Parent accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of the Company. Each of such insurance policies is in full force and effect and the Company is in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2021, the Company has not received any notice or other communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. The Company has provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against the Company for which the Company has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding, or informed the Company of its intent to do so.

2.20 <u>No Financial Advisors</u>. Except as set forth on <u>Schedule 2.20</u>, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of the Company.

2.21 Disclosure. The information to be supplied by or on behalf of the Company for inclusion or incorporation by reference in the Registration Statement, or to be included or supplied by or on behalf of the Company for inclusion in any filing pursuant to Rule 165 and Rule 425 under the Securities Act or Rule 14a-12 under the Exchange Act (each a "Regulation M-A Filing"), shall not at the time the Registration Statement or any such Regulation M-A Filing is filed with the SEC, at any time it is amended or supplemented or at the time the Registration Statement is declared effective by the SEC contain any statement that, at such time and in light of the circumstances under which it shall be made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements therein not false or misleading, or omit to state any material fact necessary to correct any statement therein that has become false or misleading. The information supplied by or on behalf of the Company for inclusion or incorporation by reference in the Proxy Statement, which information shall be deemed to include all information about or related to the Company or the Company Stockholder Matters, shall not, on the date the Proxy Statement is first mailed to Parent's stockholders, or at the time of the Parent Stockholders' Meeting or as of the Effective Time, contain any statement that, at such time and in light of the circumstances under which it shall be made, is false or misleading

with respect to any material fact, or omit to state any material fact necessary in order to make the statements made in the Proxy Statement not false or misleading, or omit to state any material fact necessary to correct any statement in any earlier communication with respect to the solicitation of proxies for the Parent Stockholders' Meeting that has become false or misleading.

2.22 Transactions with Affiliates.

(a) There are no material transactions or relationships, since January 1, 2021, between, on one hand, the Company and, on the other hand, any (i) executive officer or director of the Company or, to the Company's Knowledge, any of such executive officer's or director's immediate family members, (ii) owner of more than 5% of the voting power of the outstanding Company Capital Stock or (iii) to the Company's Knowledge, any "related person" (within the meaning of Item 404 of Regulation S-K as promulgated under the Securities Act) of any such executive officer, director or equityholder (other than the Company) in the case of each of (i), (ii) or (iii) that is of the type that would be required to be disclosed under Item 404 of Regulation S-K as promulgated under the Securities Act (assuming the Company was subject to the public reporting requirements of the Exchange Act).

(b) <u>Section 2.22(b)</u> of the Company Disclosure Schedule lists each stockholders' agreement, voting agreement, registration rights agreement, co-sale agreement or other similar Contract between the Company and any holders of Company Capital Stock, including any such Contract granting any Person investor rights, rights of first refusal, rights of first offer, registration rights, director designation rights or similar rights (collectively, the "*Investor Agreements*").

2.23 <u>Anti-Bribery</u>. Neither the Company nor any of its respective directors, officers, employees or, to the Company's Knowledge, agents or any other Person acting on its behalf has, directly or indirectly, made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action, in violation of the Foreign Corrupt Practices Act of 1977, the UK Bribery Act of 2010 or any other anti-bribery or anti-corruption Law (collectively, the "*Anti-Bribery Laws*"). The Company is not, nor has it been the subject of any investigation or inquiry by any Governmental Body with respect to potential violations of Anti-Bribery Laws.

2.24 <u>Disclaimer of Other Representations or Warranties</u>. Except as previously set forth in this <u>Section 2</u> or in any certificate delivered by the Company to Parent or Merger Sub pursuant to this Agreement, the Company makes no representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and any such other representations or warranties are hereby expressly disclaimed. The Company hereby acknowledges and agrees that, except as set forth in <u>Section 3</u> or in any certificate delivered by Parent or Merger Sub to the Company pursuant to this Agreement, none of Parent or Merger Sub makes any representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and the Company has not relied on any representation or warranty except as set forth in <u>Section 3</u> or in any certificate delivered by Parent to this Agreement, and any such other representations or warranties are hereby expressive to it or except as set forth in <u>Section 3</u> or in any certificate delivered by Parent or Merger Sub to the Company pursuant to this Agreement, and any such other representations or warranties are hereby expressly disclaimed.

Section 3. REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Subject to <u>Section 10.13(j)</u>, except (a) as set forth in the disclosure schedule delivered by Parent to the Company concurrently herewith (the "*Parent Disclosure Schedule*") or (b) as disclosed in the Parent SEC Documents filed with, or furnished to, the SEC prior to the date of this Agreement and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system (but (i) without giving effect to any amendment thereof filed with, or furnished to, the SEC on or after the date of this Agreement and (ii) excluding any disclosures contained under the heading "Risk Factors" and any disclosure of risks included in any "forward-looking statements" disclaimer or in any other section to the extent they are forward-looking statements or cautionary, predictive or forward-looking in nature), Parent and Merger Sub represent and warrant to the Company as follows:

3.1 Due Organization; Subsidiaries.

(a) Each of Parent and Merger Sub is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware, and has all necessary corporate power

and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound, except where the failure to have such power or authority would not reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions. Since the date of its incorporation, Merger Sub has not engaged in any activities other than activities incident to its formation or in connection with or as contemplated by this Agreement.

(b) Parent is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Parent Material Adverse Effect.

(c) Parent has no Subsidiaries, except for the Entities identified in Section 3.1(c) of the Parent Disclosure Schedule; and neither Parent nor any of the Entities identified in Section 3.1(c) of the Parent Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls directly or indirectly, any other Entity other than the Entities identified in Section 3.1(c) of the Parent Disclosure Schedule. Each of Parent's Subsidiaries is a corporation or other legal entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the failure to have such power or authority would not be reasonably expected to have a Parent Material Adverse Effect.

(d) Neither Parent nor any of its Subsidiaries is or has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Neither Parent nor any of its Subsidiaries has agreed or is obligated to make, or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. Neither Parent nor any of its Subsidiaries has agreed partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

3.2 <u>Organizational Documents</u>. Parent has made available to the Company accurate and complete copies of the Organizational Documents of Parent and each of its Subsidiaries in effect as of the date of this Agreement. Neither Parent nor any of its Subsidiaries is in material breach or violation of its respective Organizational Documents.

3.3 Authority; Binding Nature of Agreement.

(a) Each of Parent and Merger Sub has all necessary corporate power and authority to enter into this Agreement and subject, with respect to Parent, to receipt of the Required Parent Stockholder Vote and, with respect to Merger Sub, the adoption of this Agreement by Parent in its capacity as sole stockholder of Merger Sub, to perform its obligations under this Agreement and to consummate the Contemplated Transactions. The Parent Board (at a meeting duly called and held or by written consent in lieu of a meeting) has unanimously: (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Parent and its stockholders; (ii) authorized, approved and declared advisable this Agreement and the Contemplated Transactions, including the issuance of shares of Parent Common Stock to the stockholders of the Company pursuant to the terms of this Agreement, the change of control of Parent and other actions contemplated by this Agreement; and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of Parent vote to approve the Parent Stockholder Matters. The Merger Sub Board (by unanimous written consent) has: (x) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Merger Sub and its sole stockholder; (y) authorized, approved and declared advisable

this Agreement and the Contemplated Transactions; and (z) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the sole stockholder of Merger Sub vote to approve this Agreement and the Contemplated Transactions.

(b) This Agreement has been duly executed and delivered by Parent and Merger Sub and, assuming the due authorization, execution and delivery by the Company, constitutes the legal, valid and binding obligation of Parent and Merger Sub, enforceable against each of Parent and Merger Sub in accordance with its terms, subject to the Enforceability Exceptions. Prior to the execution of the Parent Stockholder Support Agreements, the Parent Board approved the Parent Stockholder Support Agreements and the transactions contemplated thereby.

3.4 <u>Vote Required</u>. The affirmative vote of a majority of the votes cast is the only vote of the holders of any class or series of Parent's capital stock necessary to approve the proposals in <u>Section 5.3(a)(i)</u>, <u>Section 5.3(a)(ii)</u> and <u>Section 5.3(a)(iii)</u> (the "*Required Parent Stockholder Vote*").

3.5 Non-Contravention; Consents.

(a) Subject to obtaining the Required Parent Stockholder Vote, except as set forth on Section 3.5(a) of the Parent Disclosure Schedule, the adoption of this Agreement (effective immediately following the execution of this Agreement) by Parent as the sole stockholder of Merger Sub and the filing of the Certificate of Merger required by the DGCL, neither (x) the execution, delivery or performance of this Agreement by Parent or Merger Sub, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(i) contravene, conflict with or result in a violation of any of the provisions of the Organizational Documents of Parent or any of its Subsidiaries;

(ii) contravene, conflict with or result in a violation of, or give any Governmental Body or other Person the right to challenge the Contemplated Transactions or to exercise any remedy or obtain any relief under, any Law or any order, writ, injunction, judgment or decree to which Parent or any of its Subsidiaries, or any of the assets owned or used by Parent or any of its Subsidiaries, is subject, except as would not reasonably be expected to be material to Parent or its business;

(iii) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Parent or its Subsidiaries, except as would not reasonably be expected to be material to Parent or its business;

(iv) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Parent Material Contract, or give any Person the right to: (A) declare a default or exercise any remedy under any Parent Material Contract; (B) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Parent Material Contract; (C) accelerate the maturity or performance of any Parent Material Contract; or (D) cancel, terminate or modify any term of any Parent Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(v) require any change-in-control or similar payment obligations to become due or payable;

(vi) result in the imposition or creation of any Encumbrance upon or with respect to any asset owned or used by Parent or any of its Subsidiaries (except for Permitted Encumbrances).

(b) Except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, (ii) the Required Parent Stockholder Vote, and (iii) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, neither Parent nor any of its Subsidiaries is or will be required to make any filing with or give any notice to, or to obtain any

Consent from, any Governmental Body in connection with (x) the execution, delivery or performance of this Agreement, or (y) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions.

(c) The Parent Board and the Merger Sub Board have taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Parent Stockholder Support Agreements and the Parent Lock-Up Agreements and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, the Parent Stockholder Support Agreements or any of the Contemplated Transactions.

3.6 Capitalization.

(a) The authorized capital stock of Parent as of the date of this Agreement consists of (i) 200,000,000 shares of Parent Common Stock, par value \$0.001 per share, of which 54,855,514 shares have been issued and are outstanding as of the close of business on the Reference Date and (ii) 5,000,000 shares of preferred stock of Parent, par value \$0.001 per share, of which no shares have been issued and are outstanding as of the date of this Agreement. Parent does not hold any shares of its capital stock in its treasury.

(b) All of the outstanding shares of Parent Common Stock have been duly authorized and validly issued, and are fully paid and nonassessable. None of the outstanding shares of Parent Common Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Parent Common Stock is subject to any right of first refusal in favor of Parent. Except as contemplated herein and as set forth in Section 3.6(b)(i) of the Parent Disclosure Schedule, there is no Parent Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Parent Common Stock. Except as set forth in Section 3.6(b)(i) of the Parent Disclosure Schedule, parent Disclosure Schedule, to repurchase, redeem or otherwise acquire any outstanding shares of Parent Common Stock or other securities.

(c) Except for the Parent Equity Incentive Plans, Parent does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the close of business on the Reference Date, Parent has (i) reserved 10,976,425 shares of Parent Common Stock for issuance under the Parent 2014 Plan, of which 0 shares are subject to Parent's right of repurchase, 4,086,079 shares have been reserved for issuance upon exercise of Parent Options previously granted and currently outstanding under the Parent 2014 Plan, 959,049 shares have been reserved for issuance upon the settlement of Parent RSUs granted under the Parent 2014 Plan that are outstanding as of the close of business on the Reference Date, and 5,931,297 shares remain available for future issuance pursuant to the Parent 2014 Plan; and (ii) reserved 300,000 shares of Parent Common Stock for issuance under the Parent 2019 Plan, of which 0 shares have been issued and are currently outstanding, of which 0 shares are subject to Parent's right of repurchase, 0 shares have been reserved for issuance upon exercise of Parent Options previously granted and currently outstanding under the Parent 2019 Plan, 0 shares have been reserved for issuance upon the settlement of Parent RSUs granted under the Parent 2019 Plan that are outstanding as of the close of business on the Reference Date, and 300,000 shares remain available for future issuance pursuant to the Parent 2019 Plan.

(d) Except for the Parent Options and the Parent RSUs, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of Parent or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any

shares of the capital stock or other securities of Parent or any of its Subsidiaries; or (iii) condition or circumstance that could be reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of Parent or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Parent or any of its Subsidiaries.

(e) All outstanding shares of Parent Common Stock, Parent Options, Parent RSUs and other securities of Parent have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Laws, and (ii) all requirements set forth in applicable Contracts.

3.7 SEC Filings; Financial Statements.

(a) Other than such documents that can be obtained on the SEC's website at <u>www.sec.gov</u>, Parent has delivered or made available to the Company accurate and complete copies of all registration statements, proxy statements, Certifications and other statements, reports, schedules, forms and other documents filed by Parent with the SEC since January 1, 2021 (the "Parent SEC Documents"). All material statements, reports, schedules, forms and other documents required to have been filed by Parent or its officers with the SEC have been so filed on a timely basis. As of the time it was filed with the SEC (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), each of the Parent SEC Documents complied in all material respects with the applicable requirements of the Securities Act or the Exchange Act (as the case may be) and, as of the time they were filed, none of the Parent SEC Documents contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Parent SEC Documents (collectively, the "Certifications") are accurate and complete and comply as to form and content with all applicable Laws. As used in this Section 3.7, the term "file" and variations thereof shall be broadly construed to include any manner in which a document or information is furnished, supplied or otherwise made available to the SEC.

(b) The financial statements (including any related notes) contained or incorporated by reference in the Parent SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements or, in the case of unaudited financial statements, except as permitted by the SEC on Form 10-Q under the Exchange Act, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments) applied on a consistent basis unless otherwise noted therein throughout the periods indicated; and (iii) fairly present, in all material respects, the financial position of Parent and its consolidated Subsidiaries as of the respective dates thereof and the results of operations and cash flows of Parent and its consolidated Subsidiaries for the periods covered thereby. Other than as expressly disclosed in the Parent SEC Documents filed prior to the date of this Agreement, there has been no material change in Parent's accounting methods or principles that would be required to be disclosed in Parent's financial statements in accordance with GAAP. The books of account and other financial records of Parent and each of its Subsidiaries are true and complete in all material respects.

(c) Except as set forth on Section 3.7(c) of the Parent Disclosure Schedule, as of the date of this Agreement, Parent is in compliance in all material respects with the applicable provisions of the Sarbanes-Oxley Act and the applicable current listing and governance rules and regulations of Nasdaq.

(d) Parent maintains a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and to provide reasonable assurance (i) that

transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, (ii) that receipts and expenditures are made only in accordance with authorizations of management and the Parent Board, and (iii) regarding prevention or timely detection of the unauthorized acquisition, use or disposition of Parent's assets that could have a material effect on Parent's financial statements. Parent has evaluated the effectiveness of Parent's internal control over financial reporting as of December 31, 2023, and, to the extent required by applicable Law, presented in any applicable Parent SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation. Parent has disclosed, based on its most recent evaluation of internal control over financial reporting, to Parent's auditors and audit committee (and made available to the Company a summary of the significant aspects of such disclosure) (A) all significant deficiencies, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect Parent's ability to record, process, summarize and report financial information, and (B) any known fraud that involves management or other employees who have a significant role in Parent's internal control over financial reporting. Parent has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of Parent's internal control over financial reporting.

(e) Parent maintains "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are reasonably designed to ensure that information required to be disclosed by Parent in the periodic reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods, and that all such information is accumulated and communicated to Parent's management as appropriate to allow timely decisions regarding required disclosure and to make the Certifications.

(f) To the Knowledge of Parent, Parent's auditor has at all times since the date of enactment of the Sarbanes-Oxley Act been: (i) a registered public accounting firm (as defined in Section 2(a) (12) of the Sarbanes-Oxley Act); (ii) with respect to Parent, "independent" with respect to Parent within the meaning of Regulation S-X under the Exchange Act; and (iii) to the Knowledge of Parent, in compliance with subsections (g) through (l) of Section 10A of the Exchange Act and the rules and regulations promulgated by the SEC and the Public Company Accounting Oversight Board thereunder.

(g) Except as set forth in <u>Section 3.7(g)</u> of the Parent Disclosure Schedule, since January 1, 2021, Parent has not received any comment letter from the SEC or the Staff thereof or any correspondence from Nasdaq or the staff thereof relating to the delisting or maintenance of listing of the Parent Common Stock on Nasdaq that has not been disclosed in the Parent SEC Documents. Parent has not disclosed any unresolved comments.

(h) Since January 1, 2021, there have been no formal internal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer, or general counsel of Parent, the Parent Board or any committee thereof, other than ordinary course audits or reviews of accounting policies and practices or internal controls required by the Sarbanes-Oxley Act.

(i) <u>Schedule II</u> sets forth a true, complete and correct document containing the components of Parent Net Cash, with the calculations set forth therein assuming the date hereof as the Anticipated Closing Date.

3.8 Absence of Changes.

(a) Between the date of the Parent Balance Sheet and the date of this Agreement, Parent has conducted its business only in the Ordinary Course of Business (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto, including the Contemplated Transactions).

(b) Between the date of the Parent Balance Sheet and the date of this Agreement, there has not been any Parent Material Adverse Effect.

(c) Between the date of the Parent Balance Sheet and the date of this Agreement, there has not been any action, event or occurrence that would have required the consent of the Company pursuant to Section 4.1(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

3.9 <u>Absence of Undisclosed Liabilities</u>. As of the date of this Agreement, neither Parent nor any of its Subsidiaries has any Liability, individually or in the aggregate, of a type required to be recorded or reflected on Parent's balance sheet or disclosed in the footnotes thereto under GAAP except for: (a) Liabilities disclosed, reflected or reserved against in the Parent Balance Sheet; (b) Liabilities that have been incurred by Parent or any of its Subsidiaries since the date of the Parent Balance Sheet in the Ordinary Course of Business; (c) Liabilities for performance of obligations of Parent or any of its Subsidiaries under Parent Material Contracts which have not resulted from a breach of such Parent Material Contracts, breach of warranty, tort, infringement or violation of Law; (d) Liabilities incurred in connection with the Contemplated Transactions; and (e) Liabilities which would not, individually or in the aggregate, reasonably be expected to be material to Parent.

3.10 <u>Title to Assets</u>. Parent and each of its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it, including: (a) all tangible assets reflected on the Parent Balance Sheet; and (b) all other tangible assets reflected in the books and records of Parent or any of its Subsidiaries as being owned by Parent or such Subsidiary. All of such assets are owned or, in the case of leased assets, leased by Parent or its applicable Subsidiary free and clear of any Encumbrances, other than Permitted Encumbrances.

3.11 <u>Real Property; Leasehold</u>. Neither Parent nor any of its Subsidiaries owns any real property. Parent has terminated, with no remaining Liability to Parent or any of its Subsidiaries, all leasehold interest for any real property it has ever held, directly or indirectly, and neither Parent nor any of its Subsidiaries has any Liability with respect to, and has no real estate that is in the possession of or leased by Parent or any of its Subsidiaries.

3.12 Intellectual Property.

(a) <u>Section 3.12(a)</u> of the Parent Disclosure Schedule accurately identifies (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the application or registration number and (iv) any other co-owners, for each item of Registered IP owned in whole or in part by Parent or its Subsidiaries ("Parent Owned Registered IP"). To Parent's Knowledge, each of the patents and patent applications included in the Parent Owned Registered IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. To Parent's Knowledge, (A) the Parent Owned Registered IP is valid, enforceable and subsisting, and in full force and effect, (B) none of the Parent Owned Registered IP has been misused, withdrawn, cancelled, expired, or abandoned, and (C) all application, registration, issuance, renewal and maintenance fees due for the Parent Owned Registered IP and each patent application from which such Parent Owned Registered IP claims priority, all statements made and information presented to the applicable patent office by or on behalf of the Parent or any inventor thereof, or its respective patent counsel during the prosecution thereof are accurate and complete and comply with 37 CFR 1.56. As of the date of this Agreement, no interference, opposition, reissue, reexamination, derivation, inter partes review, or other proceeding of any nature (other than initial examination proceedings and other than in the ordinary course of prosecution and maintenance) is pending or, to Parent's Knowledge, threatened in writing, in which the scope, validity, enforceability or ownership of any Parent Owned Registered IP is being or has been contested or challenged.

(b) Except as set forth on <u>Section 3.12(b)</u> of the Parent Disclosure Schedule, Parent or its Subsidiaries owns or co-owns all right, title and interest in and to all Parent IP, free and clear of all Encumbrances other than Permitted Encumbrances. To Parent's Knowledge, each Parent Associate has the right, pursuant to a Parent In-bound License to use all other material Intellectual Property Rights used by the Company in its businesses as currently conducted. The Parent IP

and the Intellectual Property Rights licensed to Parent or its Subsidiaries pursuant to a Parent Inbound License (the "Parent In-Licensed IP") are all the Intellectual Property Rights necessary to operate the business of Parent or its Subsidiaries as currently conducted and as proposed to be conducted as of the date of this Agreement. No Parent Associate owns or has any claim, right (whether or not currently exercisable) or interest to or in any Parent IP, and each Parent Associate involved in the creation or development of any material Parent IP, pursuant to such Parent Associate's activities on behalf of Parent or its Subsidiaries, has signed or has an obligation to sign a valid, enforceable written agreement containing a present assignment of all such Parent Associate's rights in such material Parent IP to Parent or its Subsidiaries (without further payment being owed to any such Parent Associate and without any restrictions or obligations on Parent's or its Subsidiaries' ownership or use thereof (except for the obligation to pay service fee pursuant to the terms of the applicable service agreements that is not based on the revenues or profits of Parent or any of its Subsidiaries)) and confidentiality provisions protecting the Parent IP, which, to Parent's Knowledge, has not been materially breached by such Parent Associate. Without limiting the foregoing, Parent and its Subsidiaries have taken commercially reasonable steps to protect, maintain and enforce all Parent IP and Parent In-Licensed IP, including the secrecy, confidentiality and value of trade secrets and other confidential information therein, and to Parent's Knowledge there have been no authorized disclosures of any Parent IP or Parent In-Licensed IP. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will conflict with, alter or impair any of Parent's or, following the Closing, the Company's, rights in or to any Parent IP or Parent In-Licensed IP or cause any payments of any kind to be due or payable to any Person.

(c) To Parent's Knowledge, no funding, facilities or personnel of any Governmental Body or any university, college, research institute or other educational or academic institution has been used, in whole or in part, to create any Parent IP or Parent In-Licensed IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership or other rights (including any "march in" rights or a right to direct the location of manufacturing of products) to such Parent IP or Parent In-Licensed IP or the right to receive royalties or other consideration for the practice of such Parent IP or Parent In-Licensed IP. To the Parent's Knowledge, no Parent Associate who was involved in, or who contributed to, the creation or development of any Parent IP or any Parent In-Licensed IP, has performed services for a Governmental Body or any university, college, research institute or other educational or academic institution in a manner that would affect Parent's interest in the Parent IP or any Parent In-Licensed IP.

(d) <u>Section 3.12(d)</u> of Parent Disclosure Schedule sets forth each license agreement pursuant to which Parent or any of its Subsidiaries (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by Parent or any of its Subsidiaries in its business as currently conducted (each a "Parent In-bound License") or (ii) grants to any third party a license, option, covenant not to sue or other right under any Parent IP or any Parent In-Licensed IP (each a "Parent Out-bound License") (provided, that, Parent In-bound Licenses shall not include material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, commercially-available Software-as-a-Service offerings, off-the-shelf software licenses or generally-available patent license agreements entered into in the Ordinary Course of Business on a non-exclusive basis and where the license is incidental to the primary purpose of the relevant Contracts; and Parent Out-bound Licenses shall not include material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, or non-exclusive outbound licenses entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of Parent or any of its Subsidiaries). Neither Parent nor its Subsidiaries nor, to Parent's Knowledge, any other party to any Parent In-bound License or Parent Out-bound License has breached or is in breach of any of its obligations under any Parent In-bound License or Parent Out-bound License.

(e) To Parent's Knowledge: (i) the operation of the businesses of Parent and its Subsidiaries as currently conducted does not infringe or misappropriate or otherwise violate any Intellectual Property Right owned by any other Person; and (ii) no other Person is infringing, misappropriating

or otherwise violating any Parent IP or Parent In-Licensed IP. No Legal Proceeding is pending (or, to Parent's Knowledge, is threatened) (A) against Parent or any of its Subsidiaries alleging that the operation of the businesses of Parent or its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by Parent or any of its Subsidiaries alleging that another Person has infringed, misappropriated or otherwise violated any of Parent IP or any Parent In-Licensed IP. Since January 1, 2021, neither Parent nor any of its Subsidiaries has received any written notice or other written communication alleging that the operation of the businesses of Parent or any of its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person.

(f) None of the Parent IP or, to Parent's Knowledge, any Parent In-Licensed IP is subject to any pending or outstanding injunction, directive, order, decree, settlement, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by Parent or any of its Subsidiaries of any such Parent IP or Parent In-Licensed IP or otherwise would reasonably be expected to adversely affect the validity, scope, use, registrability, or enforceability of any Parent IP or Parent In-Licensed IP.

(g) Except as would not reasonably be expected to have, individually or in the aggregate, a Parent Material Adverse Effect, Parent and its Subsidiaries and the operation of Parent's and its Subsidiaries' businesses are in substantial compliance with all applicable Laws pertaining to data privacy and data security of Sensitive Data. To Parent's Knowledge, since January 1, 2021, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of Parent or its Subsidiaries, (ii) no violations of any security policy of Parent or its Subsidiaries regarding any such Sensitive Data, (iii) no unauthorized access or unauthorized use of any Sensitive Data used in the business of Parent or its Subsidiaries, and (iv) no unintended or improper disclosure of any personally identifiable information in the possession, custody or control of Parent or its Subsidiaries or a contractor or agent acting on behalf of Parent or its Subsidiaries, in each case of clauses (i) through (iv), except as would not reasonably be expected to, individually or in the aggregate, have a Parent Material Adverse Effect.

(h) None of Parent or its Subsidiaries is now or has ever been a member or promoter of, or a contributor to, any industry standards body or any similar organization that would reasonably be expected to require or obligate Parent or any of its Subsidiaries to grant or offer to any other Person any license or right to any Parent IP or Parent In-Licensed IP.

(i) Solely with respect to Intellectual Property Rights for which Parent or any of its Subsidiaries controls the filing, prosecution, or maintenance and to Parent's Knowledge: (i) all information to the Knowledge of Parent and its subsidiaries relating to the subject matter of the claims of the Parent IP or Parent In-Licensed IP has been disclosed to the United States Patent and Trademark Office ("USPTO") to the extent required by 37 C.F.R. § 1.56 or any applicable patent office in any other jurisdiction to the extent required by the applicable rules and regulations in such jurisdiction; (ii) all material information submitted to the USPTO and any applicable patent office in any other jurisdiction in connection with the Parent IP or Parent In-Licensed IP, and in connection with the prosecution thereof, was accurate in all material respects at the time it was submitted; (iv) parent and its subsidiaries, with respect to any of the Parent IP or Parent In-Licensed IP, has not made any material misrepresentation or concealed any material information from the USPTO in violation of 37 C.F.R. Section § 1.56 or from any applicable patent office in any other jurisdiction in violation of the applicable rules and regulations in such jurisdiction; and (iv) each item of Parent IP or Parent In-Licensed IP is valid, subsisting, enforceable and in full force and effect; and has not been cancelled, expired, or abandoned.

3.13 Agreements, Contracts and Commitments.

(a) <u>Section 3.13</u> of the Parent Disclosure Schedule lists the following Parent Contracts in effect as of the date of this Agreement (other than any Parent Benefit Plan) (each, a "*Parent Material Contract*" and collectively, the "*Parent Material Contracts*"):

(i) Each Parent Contract that would be a material contract as defined in Item 601(b)(10) of Regulation S-K as promulgated under the Securities Act;

(ii) each Parent Contract relating to any agreement of indemnification or guaranty not entered into in the Ordinary Course of Business;

(iii) each Parent Contract containing (A) any covenant limiting the freedom of Parent or any of its Subsidiaries to engage in any line of business or compete with any Person, (B) any "most-favored nations" pricing provision or marketing or distribution rights related to any products or territory, (C) any exclusivity provision, (D) any agreement to purchase minimum quantity of goods or services, or (E) any material non-solicitation provision applicable to Parent or any of its Subsidiaries;

(iv) each Parent Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of \$50,000 pursuant to its express terms and not cancelable without penalty;

(v) each Parent Contract relating to the disposition or acquisition of material assets or any ownership interest in any Entity;

(vi) each Parent Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit or creating any material Encumbrances with respect to any assets of Parent or any of its Subsidiaries or any loans or debt obligations with officers or directors of Parent or any of its Subsidiaries;

(vii) each Parent Contract requiring payment by or to Parent or any of its Subsidiaries after the date of this Agreement in excess of \$50,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of Parent or any of its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Parent or any of its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Parent or any of its Subsidiaries to develop any Intellectual Property Rights that will not be owned, in whole or in part, by Parent or any of its Subsidiaries; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of Parent or any of its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of Parent or any of its Subsidiaries, in each case, except for Contracts entered into in the Ordinary Course of Business;

(viii) each Parent Contract with any Person, including any financial advisor, broker, finder, investment banker or other Person, providing advisory services to Parent in connection with the Contemplated Transactions;

- (ix) each Parent Contract with any Governmental Body;
- (x) each Parent Out-bound License and Parent In-bound License;

(xi) each Parent Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of Parent or any of its Subsidiaries; or

(xii) any other Parent Contract that is not terminable at will (with no penalty or payment) by Parent or its Subsidiaries, as applicable, and (A) which involves payment or receipt by Parent or its Subsidiaries after the date of this Agreement under any such Parent Contract of more than \$50,000 in the aggregate or obligations after the date of this Agreement in excess of \$50,000 in the aggregate, or (B) that is material to the business or operations of Parent and its Subsidiaries, taken as a whole.

(b) Parent has delivered or made available to the Company accurate and complete copies of all Parent Material Contracts, including all amendments thereto. There are no Parent Material Contracts that are not in written form. None of Parent, any of its Subsidiaries nor, to Parent's Knowledge, any other party to a Parent Material Contract, has breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of, or Laws applicable to, any Parent Material Contract in such manner as would permit any other party to cancel or terminate any such Parent Material Contract, or would permit any other party to seek damages or pursue other legal remedies which would reasonably be expected to be material to Parent or its business or operations. As to Parent and its Subsidiaries, each Parent Material Contract is valid, binding, enforceable and in full force and effect, subject to the Enforceability Exceptions. No Person is renegotiating, or has a right pursuant to the terms of any Parent Material Contract to change, any material amount paid or payable to Parent or any of its Subsidiaries under any Parent Material Contract or any other material term or provision of any Parent Material Contract.

3.14 Compliance; Permits; Restrictions.

(a) Parent and each of its Subsidiaries are, and since January 1, 2021, have been, in compliance in all material respects with all applicable Laws, including applicable provisions of the FDCA, the FDA regulations adopted thereunder, the PHSA and any other similar Law administered or promulgated by the FDA or other Drug Regulatory Agency, except for any noncompliance, either individually or in the aggregate, which would not be material to Parent. No investigation, claim, suit, proceeding, audit or, to Parent's Knowledge, investigation or other action by any Governmental Body is pending or, to Parent's Knowledge, threatened against Parent or any of its Subsidiaries. There is no agreement, judgment, injunction, order or decree binding upon Parent or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of Parent or any of its Subsidiaries or the conduct of business by Parent or any of its Subsidiaries as currently conducted, (ii) is reasonably likely to have an adverse effect on Parent's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of proventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions.

(b) Parent and its Subsidiaries hold all required Governmental Authorizations that are material to the operation of the business of Parent and its Subsidiaries as currently conducted (the "*Parent Permits*"). Section 3.14(b) of the Parent Disclosure Schedule identifies each Parent Permit. Parent and its Subsidiaries hold all right, title and interest in and to all Parent Permits free and clear of any Encumbrance. Parent and each of its Subsidiaries is in material compliance with the terms of the Parent Permits. No Legal Proceeding is pending or, to Parent's Knowledge, threatened, which seeks to revoke, limit, suspend, or materially modify any Parent Permit.

(c) There are no proceedings pending or, to Parent's Knowledge, threatened with respect to an alleged material violation by Parent or any of its Subsidiaries of the FDCA, the FDA regulations adopted thereunder, the PHSA or any other similar Law administered or promulgated by any Drug Regulatory Agency. Neither Parent nor any of its Subsidiaries is currently conducting or addressing, and, to Parent's Knowledge, there is no basis to expect that it will be required to conduct or address, any corrective actions, including product recalls or clinical holds.

(d) All clinical, nonclinical and other studies and tests conducted by or on behalf of, or sponsored by, Parent or any of its Subsidiaries, or in which Parent or any of its Subsidiaries or their respective current products or product candidates have participated, were and, if still pending, are being conducted in compliance in all material respects with the applicable regulations of any applicable Drug Regulatory Agency and other applicable Law, including 21 C.F.R. Parts 50, 54, 58 and 312. Since January 1, 2021, neither Parent nor any of its Subsidiaries has received any notices, correspondence, or other communications from any Drug Regulatory Agency requiring or, threatening to initiate the termination or suspension of any clinical studies conducted by or on behalf of, or sponsored by, Parent or any of its Subsidiaries or in which Parent or any of its Subsidiaries or their respective current product candidates have participated.

(e) Neither Parent nor any of its Subsidiaries is the subject of any pending or to Parent's Knowledge, threatened investigation in respect of its business or products by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. To Parent's Knowledge, neither Parent nor any of its Subsidiaries has committed any acts, made any statement, or failed to make any statement, in each case in respect of its business or products that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. None of Parent, any of its Subsidiaries or any of their respective officers, employees or agents has been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion (i) under 21 U.S.C. Section 335a or (ii) under 42 U.S.C. §§ 1320a-7 or 1320a-7a or any similar applicable Law. No debarment or exclusionary claims, actions, proceedings or investigations in respect of their business or products are pending, or to Parent's Knowledge, threatened against Parent, any of its Subsidiaries or any of their respective officers, employees or, to the Parent's Knowledge, agents.

3.15 Legal Proceedings; Orders.

(a) There is no pending Legal Proceeding and, to Parent's Knowledge, no Person has threatened to commence any Legal Proceeding: (i) that involves (A) Parent, (B) any of its Subsidiaries, (C) any Parent Associate (in his or her capacity as such), or (D) any of the material assets owned or used by Parent or its Subsidiaries; or (ii) that challenges, or that would reasonably be expected to have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Since January 1, 2021, no Legal Proceeding has been pending against Parent or any of its Subsidiaries that resulted in material liability to Parent or any of its Subsidiaries.

(c) There is no order, writ, injunction, judgment or decree to which Parent or any of its Subsidiaries, or any of the material assets owned or used by Parent or any of its Subsidiaries, is subject. To Parent's Knowledge, no officer or employee of Parent or any of its Subsidiaries is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of Parent or any of its Subsidiaries or to any material assets owned or used by Parent or any of its Subsidiaries.

3.16 Tax Matters.

(a) Parent and each of its Subsidiaries have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No written claim has ever been made by any Governmental Body in any jurisdiction where Parent or any of its Subsidiaries does not file a particular Tax Return or pay a particular Tax that Parent or such Subsidiary is subject to taxation by that jurisdiction.

(b) All income and other material Taxes due and owing by Parent or any of its Subsidiaries on or before the date of this Agreement (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of Parent and its Subsidiaries did not, as of the date of the Parent Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Parent Balance Sheet. Since the date of the Parent Balance Sheet, neither Parent nor or any of its Subsidiaries has incurred any material Liability for Taxes outside the Ordinary Course of Business.

(c) All Taxes that Parent or any of its Subsidiaries are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, equityholders, lenders, customers or other third-parties, and have been timely paid to the proper Governmental Body or other Person or properly set aside in accounts for this purpose. (d) There are no Encumbrances for material Taxes (other than Taxes not yet due and payable) upon any of the assets of Parent or any of its Subsidiaries.

(e) No deficiencies for income or other material Taxes with respect to Parent or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Body in writing. There are no pending or ongoing, and, to Parent's Knowledge, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of Parent or any of its Subsidiaries. Neither Parent nor any of its Subsidiaries (or any of their predecessors) has waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) Neither Parent nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(i) of the Code.

(g) Neither Parent nor any of its Subsidiaries is a party to any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) Neither Parent nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes made on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) intercompany transaction or excess loss account described in Treasury Regulations under Section 1502 of the Code (or any similar provision of state, local or foreign Law) entered into on or prior to the Closing Date; (v) installment sale or open transaction disposition made on or prior to the Closing Date; (vi) prepaid amount received or deferred revenue accrued on or prior to the Closing Date; (vii) application of Section 367(d) of the Code to any transfer of intangible property on or prior to the Closing Date; (viii) application of Sections 951 or 951A of the Code (or any similar provision of state, local or foreign Law) to any income received or accrued on or prior to the Closing Date; or (ix) election under Section 108(i) of the Code (or any similar provision of state, local or foreign Law) made on or prior to the Closing Date. Parent has not made any election under Section 965(h) of the Code.

(i) Neither Parent nor any of its Subsidiaries has ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is Parent) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither Parent nor any of its Subsidiaries has any Liability for any material Taxes of any Person (other than Parent and any of its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) Neither Parent nor any of its Subsidiaries (i) is a "controlled foreign corporation" as defined in Section 957 of the Code; (ii) is a "passive foreign investment company" within the meaning of Section 1297 of the Code; or (iii) has ever had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized.

(k) Neither Parent nor any of its Subsidiaries has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a "listed transaction" that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(1) Neither Parent nor any of its Subsidiaries has taken any action or knows of any fact that would reasonably be expected to prevent the Contemplated Transactions from qualifying for the Intended Tax Treatment.

(m) Neither Parent nor any of its Subsidiaries has availed itself of any Tax relief pursuant to any Pandemic Response Laws that could reasonably be expected to materially impact the Tax payment or Tax reporting obligations of Parent and its Affiliates (including the Company) after the Closing Date.

(n) No material claim has been made in writing by any Governmental Body in a jurisdiction where the Parent or any of its Subsidiaries do not currently file or have filed a Tax Return that the Parent or any of its Subsidiaries are or may be subject to taxation by such jurisdiction.

(o) The Parent is a corporation for U.S. federal income Tax purposes under Section 7701 of the Code.

(p) The Parent has not distributed stock of another Person, nor had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 of the Code or Section 361 of the Code.

(q) To the Parent's Knowledge, the Parent has not been, is not, and immediately prior to the Closing Date will not be, treated as an "investment company" within the meaning of Section 368(a)(2)(F) of the Code.

For purposes of this <u>Section 3.16</u>, each reference to Parent or any of its Subsidiaries shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, Parent of any of its Subsidiaries.

3.17 Employee and Labor Matters; Benefit Plans.

(a) <u>Section 3.17(a)</u> of the Parent Disclosure Schedule lists, as of the date of this Agreement, all Parent Benefit Plans, including each Parent Benefit Plan that provides for retirement, change in control, stay or retention deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits. "*Parent Benefit Plan*" means each (i) "employee benefit plan" as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based, phantom equity, employment, consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (other than regular salary or wages) (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen or terminated), in any case, maintained, contributed to, or required to be contributed to, by Parent, any of its Subsidiaries or Parent ERISA Affiliates for the benefit of any current or former employee, director, officer or independent contractor of Parent or any of its Subsidiaries or under which Parent or any of its Subsidiaries has any actual or contingent liability (including as to the result of it being treated as a single employer under Section 414 of the Code with any other person).

(b) As applicable with respect to each material Parent Benefit Plan, Parent has made available to the Company, true and complete copies of (i) each material Parent Benefit Plan, including all amendments thereto, and in the case of an unwritten material Parent Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the three (3) most recently filed annual reports with any on Form 5500 and all schedules thereto, (v) the most recent IRS determination, opinion or advisory letter, (vi) the three (3) most recent, nondiscrimination testing reports, actuarial reports and financial statements, (vii) all records, notices and filings concerning IRS or United States Department of Labor or other Governmental Body audits or investigations since January 1, 2021, and (viii) all material written materials provided to employees or participants relating to the amendment, termination, establishment, or increase or decrease in benefits under any Parent Benefit Plan.

(c) Each Parent Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other applicable Laws.

(d) The Parent Benefit Plans which are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and, to Parent's Knowledge, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Parent Benefit Plan or the tax exempt status of the related trust.

(e) None of Parent, any of its Subsidiaries nor any Parent ERISA Affiliate sponsors, maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to or has within the past six (6) years sponsored, maintained, contributed to, or been required to contribute to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA), (iii) any "multiple employer plan" (within the meaning of Section 3(40) of ERISA), and none of the Parent, any of its Subsidiaries or any of their respective ERISA Affiliates has, within the preceding six (6) years, incurred a complete or partial withdrawal from any "multiemployer plan" or otherwise incurred any liability under Section 420 of ERISA.

(f) There are no pending audits or investigations by any Governmental Body involving any Parent Benefit Plan, and no pending or, to Parent's Knowledge, threatened claims (except for individual claims for benefits payable in the normal operation of the Parent Benefit Plans), suits or proceedings involving any Parent Benefit Plan, any fiduciary thereof or service provider thereto. All contributions and premium payments required to have been made under any of the Parent Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made and neither Parent nor any Parent ERISA Affiliate has any liability for any unpaid contributions with respect to any Parent Benefit Plan (other than contributions which may continue to be accrued in the Ordinary Course of Business).

(g) None of Parent, any of its Subsidiaries nor any Parent ERISA Affiliates, nor, to Parent's Knowledge, any fiduciary, trustee or administrator of any Parent Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Parent Benefit Plan which would subject any such Parent Benefit Plan, Parent, any of its Subsidiaries or Parent ERISA Affiliates or the Company to a Tax, penalty or liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) Except as set forth on <u>Section 3.17(h)</u> of the Parent Disclosure Schedule, no Parent Benefit Plan provides (i) death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement, other than coverage mandated by Law or (ii) death or retirement benefits under a Parent Benefit Plan qualified under Section 401(a) of the Code, and none of Parent, any of its Subsidiaries or any Parent ERISA Affiliates has made a written or oral representation promising the same.

(i) Except as set forth on <u>Section 3.17(i)</u> of the Parent Disclosure Schedule, neither the execution of this Agreement, nor the consummation of the Contemplated Transactions will either alone or in connection with any other event(s) (i) result in any payment becoming due to any current or former employee, director, officer, independent contractor or other service provider of Parent or any of its Subsidiaries, (ii) increase any amount of compensation or benefits otherwise payable to any current or former employee, director, officer, independent contractor or other service provider of Parent or any of its Subsidiaries, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Parent Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Parent Benefit Plan or (v) limit the right to merge, amend or terminate any Parent Benefit Plan.

(j) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including a

termination of employment) will result in the receipt or retention by any person who is a "disqualified individual" (within the meaning of Section 280G of the Code) with respect to Parent and its Subsidiaries of any payment or benefit that is or could be characterized as a "parachute payment" (within the meaning of Section 280G of the Code), determined without regard to the application of Section 280G(b)(5) of the Code.

(k) To Parent's Knowledge, each Parent Benefit Plan providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder.

(1) No Person has any "gross up" agreements with Parent or any of its Subsidiaries or other assurance of reimbursement or compensation by Parent or any of its Subsidiaries for any Taxes imposed under Section 409A or Section 4999 of the Code.

(m) Parent does not have any Parent Benefit Plan that is maintained for service providers located outside of the United States.

(n) Neither Parent nor any of its Subsidiaries is a party to or bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union or labor organization representing any of its employees, and there is no labor union or labor organization representing or, to Parent's Knowledge, purporting to represent or seeking to represent any employees of Parent or its Subsidiaries, including through the filing of a petition for representation election.

(o) Parent and each of its Subsidiaries is, and since January 1, 2021 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including worker classification, discrimination, wrongful termination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, wages (including overtime wages), unemployment and workers' compensation, leaves of absence, and hours of work. Except as would not be reasonably likely to result in a material liability to Parent or any of its Subsidiaries, with respect to employees of Parent or any of its Subsidiaries, each of Parent and its Subsidiaries, since January 1, 2021: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, demands, lawsuits, investigations, audits, administrative matters or other Legal Proceedings pending or, to Parent's Knowledge, threatened against Parent or any of its Subsidiaries relating to any current or former employee, applicant for employment, consultant, employment agreement or Parent Benefit Plan (other than routine claims for benefits). Except as set forth on Section 3.18(o) of the Parent Disclosure Schedule, all employees of Parent and its Subsidiaries are employed "at will" and their employment can be terminated without advance notice or payment of severance.

(p) Except as would not be reasonably likely to result in a material liability to Parent or any of its Subsidiaries, with respect to each individual who currently renders services to Parent or any of its Subsidiaries, Parent and each of its Subsidiaries has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, Parent has accurately classified him or her as overtime eligible or overtime ineligible under all applicable Laws. Neither Parent nor any of its Subsidiaries has any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt from overtime wages.

(q) There is not and has not been since January 1, 2021, nor is there or has there been since January 1, 2021, any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to Parent's Knowledge, any union organizing activity, against Parent or any of its Subsidiaries. No event has occurred, and, to Parent's Knowledge, no condition or circumstance exists, that might directly or indirectly be likely to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute.

(r) Each Contract entered into by and between Parent and its Affiliates and any professional employer organization is terminable at will without triggering any liquidation charges, surrender charges or other fees.

3.18 Environmental Matters. Parent and each of its Subsidiaries are in compliance, and since January 1, 2021, have complied, with all applicable Environmental Laws, which compliance includes the possession by Parent and its Subsidiaries of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to Parent or its business. Neither Parent nor any of its Subsidiaries has received since January 1, 2021 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Body or other Person, that alleges that Parent or any of its Subsidiaries is not in compliance with or has liability pursuant to any Environmental Law and, to Parent's Knowledge, there are no circumstances that would reasonably be expected to prevent or interfere with Parent's or any of its Subsidiaries' compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to Parent or its business. To the Parent's Knowledge, no current or (during the time a prior property was leased or controlled by Parent or any of its Subsidiaries) prior property leased or controlled by Parent or any of its Subsidiaries has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of Parent or any of its Subsidiaries pursuant to any applicable Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Body is required by any applicable Environmental Laws in connection with the execution and delivery of this Agreement or the consummation of the Contemplated Transactions. Prior to the date of this Agreement, Parent has provided or otherwise made available to the Company true and correct copies of all material environmental reports, assessments, studies and audits in the possession or control of Parent or any of its Subsidiaries with respect to any property leased or controlled by Parent or any of its Subsidiaries or any business operated by them.

3.19 <u>Transactions with Affiliates</u>. Since the date of Parent's proxy statement filed in 2024 with the SEC, no event has occurred that would be required to be reported by Parent pursuant to Item 404 of Regulation S-K as promulgated under the Securities Act.

3.20 Insurance. Parent has delivered or made available to the Company accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of Parent and each of its Subsidiaries, as of the date of this Agreement. Each of such insurance policies is in full force and effect and Parent and each of its Subsidiaries are in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2021, neither Parent nor any of its Subsidiaries has received any notice or other communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. Parent and each of its Subsidiaries have provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against Parent or any of its Subsidiaries for which Parent or such Subsidiary has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding, or informed Parent or any of its Subsidiaries of its intent to do so.

3.21 <u>No Financial Advisors</u>. Except for Piper Sandler & Co., no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Parent or any of its Subsidiaries.

3.22 <u>Disclosure</u>. The information supplied by or on behalf of Parent and each of its Subsidiaries for inclusion or incorporation by reference in the Registration Statement, or to be included or supplied by or on behalf of Parent and each of its Subsidiaries for inclusion in any Regulation M-A Filing, shall not at the time the Registration Statement or any such Regulation M-A Filing is filed with the SEC, at any time it is amended or supplemented or at the time the Registration Statement is declared effective by the SEC contain any statement that, at such time and in light of the circumstances under which it shall be made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements therein not false or misleading, or omit to state any material fact necessary to correct any statement therein that has become false or misleading. The information supplied by or on behalf of Parent and each of its Subsidiaries for inclusion or incorporation by reference in the Proxy Statement, which information shall be deemed to include all information about or related to Parent and each of its Subsidiaries, the Parent Stockholder Matters and the Parent Stockholder Meeting, shall not, on the date the Proxy Statement is first mailed to Parent's stockholders, or at the time of the Parent Stockholders' Meeting or as of the Effective Time, contain any statement that, at such time and in light of the circumstances under which it shall be made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements made in the Proxy Statement not false or misleading, or omit to state any material fact necessary to correct any statement in any earlier communication with respect to the solicitation of proxies for the Parent Stockholders' Meeting that has become false or misleading.

3.23 <u>Anti-Bribery</u>. None of Parent, any of its Subsidiaries nor any of their respective directors, officers, employees or, to Parent's Knowledge, agents or any other Person acting on its behalf has directly or indirectly made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action, in violation of Anti-Bribery Laws. Neither Parent nor any of its Subsidiaries is or has been the subject of any investigation or inquiry by any Governmental Body with respect to potential violations of Anti-Bribery Laws.

3.24 <u>Valid Issuance</u>. The Parent Common Stock to be issued in the Merger will, when issued in accordance with the provisions of this Agreement, be validly issued, fully paid and nonassessable.

3.25 <u>Opinion of Financial Advisor</u>. The Parent Board has received an opinion of Piper Sandler & Co. to the effect that, as of December 17, 2024, and subject to the assumptions, qualifications, limitations and other matters set forth therein, the Exchange Ratio (without giving effect to the Nasdaq Reverse Split) is fair, from a financial point of view, to Parent. It is agreed and understood that such opinion is for the benefit of the Parent Board and may not be relied upon by the Company.

3.26 <u>Disclaimer of Other Representations or Warranties</u>. Except as previously set forth in this <u>Section 3</u> or in any certificate delivered by Parent or Merger Sub to the Company pursuant to this Agreement, neither Parent nor Merger Sub makes any representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and any such other representations or warranties are hereby expressly disclaimed. Parent and Merger Sub each hereby acknowledges and agrees that, except as previously set forth in <u>Section 2</u> or in any certificate delivered by the Company to Parent or Merger Sub pursuant to this Agreement, the Company makes no representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and neither Parent nor Merger Sub has relied on any representation or warranty except as set forth in <u>Section 2</u> or in any certificate delivered by the Company to Parent or Merger Sub has relied on any representation or warranty except as set forth in <u>Section 2</u> or in any certificate delivered by the Company to Parent or Merger Sub has relied on any representation or warranty except as set forth in <u>Section 2</u> or in any certificate delivered by the Company to Parent or Merger Sub pursuant to this Agreement and any such other representations or warranties are hereby expressly disclaimed.

Section 4. CERTAIN COVENANTS OF THE PARTIES

4.1 Operation of Parent's Business.

(a) Except (i) as set forth on <u>Section 4.1(a)</u> of the Parent Disclosure Schedule, (ii) as expressly permitted by or required in accordance with this Agreement including in connection

with the Asset Dispositions pursuant to <u>Section 4.7</u>, (iii) as required by applicable Law, or (iv) as may be consented to in writing by the Company (which consent shall not be unreasonably withheld, conditioned or delayed), during the period commencing on the date of this Agreement and continuing until the earlier to occur of the termination of this Agreement pursuant to <u>Section 9</u> and the Effective Time (the "*Pre-Closing Period*"): each of Parent and its Subsidiaries shall (A) conduct its business and operations in the Ordinary Course of Business and in compliance in all material respects with all applicable Laws and the requirements of all Contracts that constitute Parent Material Contracts, and (B) continue to pay material outstanding accounts payable and other material current Liabilities (including payroll) in the Ordinary Course of Business.

(b) Except (i) as expressly permitted by this Agreement, (ii) as set forth on Section 4.1(b) of the Parent Disclosure Schedule, (iii) as required by applicable Law, (iv) in connection with the Asset Dispositions pursuant to Section 4.7 or the winding down of Parent's prior research and development activities (including the termination of ongoing contractual obligations related to Parent's current products or product candidates), or (v) with the prior written consent of the Company (which consent shall not be unreasonably withheld, conditioned or delayed), at all times during the Pre-Closing Period, Parent shall not, nor shall it cause or permit any of its Subsidiaries to, do any of the following:

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Parent or in connection with the payment of the exercise price or withholding Taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the Parent Equity Incentive Plans in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Parent or any of its Subsidiaries (except for shares of Parent Common Stock issued upon the valid exercise of Parent Options or upon settlement of Parent RSUs); (B) any option, warrant or right to acquire any capital stock or any other security; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Parent or any of its Subsidiaries;

(iii) (A) amend the terms of any outstanding Parent Options to extend the exercise period or the exercise price of any such Parent Option or (B) permit the net settlement of any Parent Options in any manner in which cash of Parent is to be remitted or paid by Parent rather than the relevant holder of any such Parent Options;

(iv) except as required to give effect to anything in contemplation of the Closing, amend any of its or its Subsidiaries' Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;

(v) form any Subsidiary or acquire any equity interest or other interest in any other Entity or enter into a joint venture with any other Entity;

(vi) (A) lend money to any Person, (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, (D) other than the incurrence or payment of Transaction Expenses, make any capital expenditure in excess of \$5,000, or (E) forgive any loans to any Persons, including Parent's employees, officers, directors or Affiliates;

(vii) other than as required by applicable Law or the terms of any Parent Benefit Plan as in effect on the date of this Agreement or as set forth on <u>Schedule 4.1(b)(vii)</u>: (A) adopt, terminate, establish or enter into any Parent Benefit Plan; (B) cause or permit any Parent Benefit Plan to be amended; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, fringe benefits, commissions, bonus, or other

compensation or benefits payable to any of its directors, officers, consultants, or employees; (D) hire any (x) officer or (y) employee (1) whose annual base salary is or is expected to be more than \$200,000 per year, (2) who is entitled to severance benefits, or (3) who is not hired on an at-will basis; (E) increase the severance or change-of-control benefits offered to any current or new employees, directors or consultants (other than acceleration of Parent Options or Parent RSUs as contemplated by this Agreement), or (F) grant any new, or increase any existing, severance, retention benefits, change in control award, or similar compensation or benefit to any Person;

(viii) recognize any labor union or labor organization;

(ix) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Encumbrance with respect to such material assets or properties;

(x) sell, assign, transfer, license, sublicense or otherwise dispose of any Parent IP or any Parent In-Licensed IP;

(xi) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability or submit any voluntary disclosure application, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than seven (7) months), or adopt or change any material accounting method in respect of Taxes;

(xii) enter into, materially amend or terminate any Parent Material Contract or Contract that would be deemed a Parent Material Contract if entered into prior to the date hereof;

(xiii) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xiv) initiate or settle any Legal Proceeding;

(xv) (A) fail to maintain any material insurance policies in full force and effect prior to the renewal period of any such material insurance policies or (B) fail to use commercially reasonable efforts to renew any such material insurance policies following the applicable expiration or acquire substantially similar insurance policies;

(xvi) enter into or amend a Contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions;

(xvii) enter into a new line of business or start to conduct a line of business; or

(xviii) agree, resolve or commit to do any of the foregoing.

(c) Nothing contained in this Agreement shall give the Company, directly or indirectly, the right to control or direct the operations of Parent prior to the Effective Time. Prior to the Effective Time, Parent shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over its business operations.

4.2 Operation of the Company's Business.

(a) Except (i) as set forth on <u>Schedule 4.2(a)</u>, (ii) as expressly permitted by or required in accordance this Agreement, (iii) as required by applicable Law, or (iv) as may be consented to in

writing by Parent (which consent shall not be unreasonably withheld, conditioned or delayed), during the Pre-Closing Period: the Company shall (A) conduct its business and operations in the Ordinary Course of Business and in compliance in all material respects with all applicable Laws and the requirements of all Contracts that constitute Company Material Contracts, and (B) continue to pay material outstanding accounts payable and other material current Liabilities (including payroll) in the Ordinary Course of Business.

(b) Except (i) as expressly permitted by this Agreement, (ii) as set forth on <u>Schedule 4.2(b)</u>, (iii) as required by applicable Law or (iv) with the prior written consent of Parent (which consent shall not be unreasonably withheld, conditioned or delayed), at all times during the Pre-Closing Period, the Company shall not do any of the following:

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of the Company or in connection with the payment of the exercise price or withholding Taxes incurred upon the exercise, settlement or vesting of any award granted under the Company Plan in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of the Company (except for shares of Company Common Stock issued upon the valid exercise of Company Options);
(B) any option, warrant or right to acquire any capital stock or any other security, other than stock options or restricted stock unit awards granted to employees and service providers in the Ordinary Course of Business which are included in the calculation of the Company Outstanding Shares; or (C) any instrument convertible into or exchangeable for any capital stock or other security of the Company;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of its Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other Entity or enter into a joint venture with any other Entity;

(v) (A) lend money to any Person (except for the advancement of reasonable and customary expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of Transaction Expenses, make any capital expenditure in excess of \$250,000 of the budgeted capital expenditure amounts set forth in the Company operating budget delivered to Parent concurrently with the execution of this Agreement (the "*Company Budget*") or (E) forgive any loans to any Persons, including the Company's employees, officers, directors or Affiliates;

(vi) other than as required by applicable Law or the terms of any Company Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Company Benefit Plan; (B) cause or permit any Company Benefit Plan to be amended in any material respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business consistent with past practice; (D) increase the severance or change-of-control benefits offered to any current or new employees, directors or consultants or (E) terminate or give notice of termination to any officer other than for cause;

(vii) recognize any labor union or labor organization;

(viii) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Encumbrance with respect to such material assets or properties, except in the Ordinary Course of Business;

(ix) sell, assign, transfer, license, sublicense or otherwise dispose of any Company IP (other than pursuant to non-exclusive licenses in the Ordinary Course of Business) or any Company In-Licensed IP;

(x) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability or submit any voluntary disclosure application, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than seven (7) months), or adopt or change any material accounting method in respect of Taxes;

(xi) enter into, materially amend or terminate any Company Material Contract or Contract that would be deemed a Company Material Contract if entered into prior to the date hereof (other than in connection with the Ordinary Course of Business);

(xii) except as otherwise set forth in the Company Budget and the incurrence or payment of any Transaction Expenses, make any expenditures or discharge or satisfy any Liabilities, in each case, in amounts that exceed the aggregate amount anticipated in the Company Budget by \$1,500,000;

(xiii) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xiv) initiate or settle any Legal Proceeding;

(xv) (A) fail to maintain any material insurance policies in full force and effect prior to the renewal period of any such material insurance policies or (B) fail to use commercially reasonable efforts to renew any such material insurance policies following the applicable expiration or acquire substantially similar insurance policies;

(xvi) enter into or amend a Contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions;

(xvii) enter into a new line of business in a new geographic area where it was not previously conducted; or

(xviii) agree, resolve or commit to do any of the foregoing.

(c) Nothing contained in this Agreement shall give Parent, directly or indirectly, the right to control or direct the operations of the Company prior to the Effective Time. Prior to the Effective Time, the Company shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over its business operations.

4.3 Access and Investigation.

(a) Subject to the terms of the Confidentiality Agreement, which the Parties agree will continue in full force following the date of this Agreement, during the Pre-Closing Period, upon reasonable notice, Parent, on the one hand, and the Company, on the other hand, shall and shall use commercially reasonable efforts to cause such Party's Representatives to: (a) provide the other Party and such other Party's Representatives with reasonable access during normal business hours

to such Party's Representatives, personnel, property and assets and to all existing books, records, Tax Returns, work papers and other documents and information relating to such Party and its Subsidiaries; (b) provide the other Party and such other Party's Representatives with such copies of the existing books, records, Tax Returns, work papers, product data, and other documents and information relating to such Party and its Subsidiaries, and with such additional financial, operating and other data and information regarding such Party and its Subsidiaries as the other Party may reasonably request; (c) permit the other Party's officers and other employees to meet, upon reasonable notice and during normal business hours, with the chief financial officer and other officers and managers of such Party responsible for such Party's financial statements and the internal controls of such Party to discuss such matters as the other Party may reasonably deem necessary or appropriate; and (d) make available to the other Party copies of unaudited financial statements, material operating and financial reports prepared for senior management or the board of directors of such Party, and any material notice, report or other document filed with or sent to or received from any Governmental Body in connection with the Contemplated Transactions. Any investigation conducted by either Parent or the Company pursuant to this Section 4.3 shall be conducted in such manner as not to interfere unreasonably with the conduct of the business of the other Party.

(b) Notwithstanding the foregoing, any Party may restrict the foregoing access to the extent that any Law applicable to such Party requires such Party to restrict or prohibit access to any such properties or information or may redact any of the foregoing documents or reports to the extent necessary to preserve the attorney-client privilege under any circumstances in which such privilege may be jeopardized by such access or the disclosure of such document or report.

4.4 Parent Non-Solicitation.

(a) Parent agrees that, during the Pre-Closing Period, neither it nor any of its Subsidiaries shall, nor shall it or any of its Subsidiaries authorize any of their respective Representatives to, directly or indirectly, other than relating to communicating, discussing, negotiating or consummating the Asset Dispositions: (i) solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnish any non-public information regarding Parent or any of its Subsidiaries to any Person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engage in discussions (other than to inform any Person of the existence of the provisions in this Section 4.4) or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approve, endorse or recommend any Acquisition Proposal (subject to Section 5.3); (v) execute or enter into any letter of intent or any Contract contemplating or otherwise relating to any Acquisition Transaction (other than a confidentiality agreement permitted under this Section 4.4(a)); or (vi) publicly propose to do any of the foregoing; provided, however, that, notwithstanding anything contained in this Section 4.4 and subject to compliance with this Section 4.4, prior to obtaining the Required Parent Stockholder Vote, Parent and its Subsidiaries may furnish non-public information regarding Parent or any of its Subsidiaries to, and enter into discussions or negotiations with, any Person in response to a bona fide Acquisition Proposal by such Person, which the Parent Board determines in good faith, after consultation with Parent's outside financial advisors and outside legal counsel, constitutes, or is reasonably likely to result in, a Superior Offer (and is not withdrawn) if: (A) none of Parent, any of its Subsidiaries or any of their respective Representatives shall have breached this Section 4.4 in any material respect, (B) the Parent Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action would be inconsistent with the fiduciary duties of the Parent Board under applicable Law; (C) Parent receives from such Person an executed confidentiality agreement containing provisions (including nondisclosure provisions, use restrictions, non-solicitation provisions, no hire and "standstill" provisions), in the aggregate, at least as favorable to Parent as those contained in the Confidentiality Agreement; and (D) substantially contemporaneously with furnishing any such non-public information to such Person, Parent gives the Company notice of Parent's intention to furnish nonpublic information to, or enter into discussions with, such Person and furnishes such non-public information to the Company (to the

extent such information has not been previously furnished by Parent to the Company). Without limiting the generality of the foregoing, Parent acknowledges and agrees that, in the event any Representative of Parent or any of its Subsidiaries (whether or not such Representative is purporting to act on behalf of Parent or any of its Subsidiaries) takes any action that, if taken by Parent or any of its Subsidiaries, would constitute a breach of this <u>Section 4.4</u>, the taking of such action by such Representative shall be deemed to constitute a breach of this <u>Section 4.4</u> by Parent for purposes of this Agreement.

(b) If Parent, any of its Subsidiaries or any of their respective Representatives receives an Acquisition Proposal or Acquisition Inquiry at any time during the Pre-Closing Period, then Parent shall promptly (and in no event later than one (1) Business Day after Parent becomes aware of such Acquisition Proposal or Acquisition Inquiry) (i) advise the Company orally and in writing of such Acquisition Proposal or Acquisition Inquiry (including the identity of the Person making or submitting such Acquisition Proposal or Acquisition Inquiry), (ii) in the case of a written Acquisition Proposal or Acquisition Inquiry, furnish any written documentation and correspondence to or from Parent, any of its Subsidiaries or any of their respective Representatives, including any subsequent modifications or amendments, and (iii) in the case of an oral Acquisition Proposal or Acquisition Inquiry, provide a written summary of the terms thereof. Parent shall keep the Company reasonably and promptly informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry, any material modification, amendment or proposed material modification thereto (including any revision in the amount, form or mix of consideration) and of all verbal or written communications related thereto, together with copies of new written documentation and correspondence to or from Parent, any of its Subsidiaries or any of their respective Representatives as well as written summaries of any material oral communications).

(c) Parent shall immediately cease and cause to be terminated any existing discussions, negotiations and communications with any Person that relate to any Acquisition Proposal or Acquisition Inquiry (other than any Asset Disposition) that has not already been terminated as of the date of this Agreement, immediately terminate access to any non-public information of Parent provided to such Person via an electronic or physical data room and within three (3) Business Days after the date of this Agreement, request the destruction or return of any non-public information of Parent or any of its Subsidiaries provided to such Person as soon as practicable after the date of this Agreement.

4.5 Company Non-Solicitation.

(a) The Company agrees that, during the Pre-Closing Period, it shall not, nor shall it authorize any of their respective Representatives to, directly or indirectly: (i) solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnish any non-public information regarding the Company to any Person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engage in discussions (other than to inform any Person of the existence of the provisions in this Section 4.5) or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approve, endorse or recommend any Acquisition Proposal; (v) execute or enter into any letter of intent or any Contract contemplating or otherwise relating to any Acquisition Transaction; or (vi) publicly propose to do any of the foregoing. Without limiting the generality of the foregoing, the Company acknowledges and agrees that, in the event any Representative of the Company (whether or not such Representative is purporting to act on behalf of the Company) takes any action that, if taken by the Company, would constitute a breach of this <u>Section 4.5</u>, the taking of such action by such Representative shall be deemed to constitute a breach of this Section 4.5 by the Company for purposes of this Agreement.

(b) If the Company or any of their respective Representatives receives an Acquisition Proposal or Acquisition Inquiry at any time during the Pre-Closing Period, then the Company shall promptly (and in no event later than one (1) Business Day after the Company becomes aware of such Acquisition Proposal or Acquisition Inquiry) (i) advise Parent orally and in writing of

such Acquisition Proposal or Acquisition Inquiry (including the identity of the Person making or submitting such Acquisition Proposal or Acquisition Inquiry), (ii) in the case of a written Acquisition Proposal or Acquisition Inquiry, furnish any written documentation and correspondence to or from the Company or any of its Representatives, including any subsequent modifications or amendments, and (iii) in the case of an oral Acquisition Proposal or Acquisition Inquiry, provide a written summary of the terms thereof). The Company shall keep Parent reasonably and promptly informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry, any material modification, amendment or proposed material modification thereto (including any revision in the amount, form or mix of consideration) and of all verbal or written communications related thereto, together with copies of new written documentation and correspondence to or from the Company or any of its respective Representatives as well as written summaries of any material oral communications).

(c) The Company shall immediately cease and cause to be terminated any existing discussions, negotiations and communications with any Person that relate to any Acquisition Proposal or Acquisition Inquiry that has not already been terminated as of the date of this Agreement, immediately terminate access to any non-public information of the Company provided to such Person via an electronic or physical data room and within three (3) Business Days after the date of this Agreement, request the destruction or return of any non-public information of the Company provided to such Person as soon as practicable after the date of this Agreement.

4.6 Notification of Certain Matters.

(a) During the Pre-Closing Period, the Company shall promptly (and in no event later than two (2) Business Days after the Company becomes aware of the same) notify Parent (and, if in writing, furnish copies of any relevant documents) if any of the following occurs: (i) any notice or other communication is received from any Person alleging that the Consent of such Person is or may be required in connection with any of the Contemplated Transactions; (ii) any Legal Proceeding against or involving or otherwise affecting the Company is commenced, or, to the Company's Knowledge, threatened against the Company or, to the Company's Knowledge, any director or officer of the Company; (iii) the Company becomes aware of any inaccuracy in any representation or warranty made by it in this Agreement; or (iv) the failure of the Company to comply with any covenant or obligation of the Company; in each case of clauses (i) through (iv), that could reasonably be expected to make the timely satisfaction of any of the conditions set forth in <u>Sections 6</u> or <u>7</u>, as applicable, impossible or materially less likely. No notification given to Parent pursuant to this <u>Section 4.6(a)</u> shall change, limit or otherwise affect any of the representations, warranties, covenants or obligations of the Company contained in this Agreement or the Company Disclosure Schedule for purposes of <u>Sections 6</u> and <u>7</u>, as applicable.

(b) During the Pre-Closing Period, Parent shall promptly (and in no event later than two (2) Business Days after Parent becomes aware of the same) notify the Company (and, if in writing, furnish copies of any relevant documents) if any of the following occurs: (i) any notice or other communication is received from any Person alleging that the Consent of such Person is or may be required in connection with any of the Contemplated Transactions; (ii) any Legal Proceeding against or involving or otherwise affecting Parent or any of its Subsidiaries is commenced, or, to Parent's Knowledge, threatened against Parent or any of its Subsidiaries or, to Parent's Knowledge, any director or officer of Parent or any of its Subsidiaries; (iii) Parent becomes aware of any inaccuracy in any representation or warranty made by it in this Agreement; or (iv) the failure of Parent to comply with any covenant or obligation of Parent or Merger Sub; in each case of clauses (i) through (iv), that could reasonably be expected to make the timely satisfaction of any of the conditions set forth in Sections 6 or 8, as applicable, impossible or materially less likely. No notification given to the Company pursuant to this Section 4.6(b) shall change, limit or otherwise affect any of the representations, warranties, covenants or obligations of Parent or any of its Subsidiaries contained in this Agreement or the Parent Disclosure Schedule for purposes of Sections 6 and 8, as applicable.

4.7 <u>Potentially Transferable Assets</u>. Parent shall use commercially reasonable efforts to sell, transfer, license, assign or otherwise divest the Potentially Transferable Assets to one or more third parties in one or a series of transactions concurrently with, or immediately following the Closing (each an "Asset Disposition" and collectively, the "Asset Dispositions"); provided, that any such Asset Disposition shall require, to the extent consistent with applicable Laws, the prior written consent of the Company (which consent shall be in the sole discretion of the Company) if such Asset Disposition would create any post-disposition Liabilities or indemnity obligations for Parent following the Closing; provided, however, that the prior written consent of the Company shall not be required in connection with any Asset Disposition if Parent agrees that the maximum aggregate dollar value of any postdisposition Liabilities or indemnity obligation shall be considered as a reduction to Parent Net Cash as set forth in this Agreement. Notwithstanding anything herein to the contrary, in no event shall Parent enter into any Asset Disposition that would result in excess of \$100,000 of indemnity obligations or post-disposition Liabilities to, or obligations of, Parent following the Closing; provided, however, that the Parties acknowledge and agree that the CSL Asset Purchase Agreement shall not require consent by the Company (to the extent not amended by the parties thereto after the date hereof other than as set forth on Section 4.7 of the Parent Disclosure Schedules).

Section 5. ADDITIONAL AGREEMENTS OF THE PARTIES

5.1 Registration Statement; Proxy Statement.

(a) As promptly as practicable after the date of this Agreement, the Parties shall prepare, and Parent shall cause to be filed with the SEC, the Registration Statement, in which the Proxy Statement will be included as a prospectus. Parent covenants and agrees that the Registration Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith) will not, at the time that the Proxy Statement or any amendments or supplements thereto are filed with the SEC, at the time the Proxy Statement or any amendments or supplements thereto are first mailed to Parent's stockholders and at the time of the Parent Stockholder Meeting, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Company covenants and agrees that the information provided by or on behalf of the Company or their respective Representatives to Parent for inclusion in the Registration Statement (including the Company Audited Financial Statements or the Company Interim Financial Statements, as the case may be) will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make such information not misleading. Parent makes no covenant, representation or warranty with respect to statements made in the Registration Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, based on information provided by or on behalf of the Company or any of its Representatives for inclusion therein, and the Company makes no covenant, representation or warranty with respect to statements made in the Registration Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, other than with respect to the information provided by or on behalf of the Company, or any of its Representatives for inclusion therein. The Company and its legal counsel shall be given reasonable opportunity to review and comment on the Registration Statement, including all amendments and supplements thereto, prior to the filing thereof with the SEC, and on the response to any comments of the SEC on the Registration Statement, prior to the filing thereof with the SEC. Parent shall provide the Company with copies of any written comments, and shall inform the Company of any oral comments, that Parent receives from the SEC or its staff with respect to the Registration Statement promptly after the receipt of such comments. Parent shall use commercially reasonable efforts to respond promptly to any comments of the SEC or its staff and to have the Registration Statement declared effective under the Securities Act as promptly as practicable after it is filed with the SEC. Each of the Parties shall use commercially reasonable efforts to cause the Proxy Statement to be mailed to Parent's stockholders as promptly as practicable after the Registration Statement is declared effective under the Securities Act. Each Party shall promptly furnish to the other Party all information concerning such Party and such Party's Affiliates and such Party's stockholders that may be required or reasonably requested in connection with any action contemplated by this Section 5.1. If Parent, Merger Sub or the Company

become aware of any event or information that, pursuant to the Securities Act or the Exchange Act, should be disclosed in an amendment or supplement to the Registration Statement or Proxy Statement, as the case may be, then such Party, as the case may be, shall promptly inform the other Parties thereof and shall cooperate with such other Parties in filing such amendment or supplement with the SEC and, if appropriate, in mailing such amendment or supplement to Parent's stockholders. The Company and Parent shall each use commercially reasonable efforts to cause the Registration Statement and the Proxy Statement to comply with the applicable rules and regulations promulgated by the SEC and applicable federal and state securities Laws requirements.

(b) The Parties shall reasonably cooperate with each other and provide, and require their respective Representatives to provide, the other Party and its Representatives, with all true, correct and complete information regarding such Party or its Subsidiaries that is required by Law to be included in the Registration Statement and the Proxy Statement or reasonably requested by the other Party to be included in the Registration Statement and the Proxy Statement.

(c) If, in connection with the preparation and filing of the Registration Statement, the SEC requests or requires that a tax opinion be prepared and submitted regarding the Intended Tax Treatment ("*Tax Opinion*") (i) each of Parent and the Company shall deliver to Cooley LLP and Mintz, Cohn, Ferris, Glovsky and Popeo, P.C., respectively, customary tax representation letters satisfactory to its counsel, dated and executed as of the date the Registration Statement that shall have been declared effective by the SEC and such other date(s) as determined reasonably necessary by such counsel in connection with the preparation and filing of the Registration Statement, which counsel shall be entitled to rely upon in rendering the Tax Opinion, and (ii) the Company and Parent shall each use its reasonable best efforts to cause Cooley LLP and Mintz, Cohn, Ferris, Glovsky and Popeo, P.C. to furnish a Tax Opinion with respect to the Intended Tax Treatment. For the avoidance of doubt, in no event shall any such Tax Opinion be a condition to Closing.

5.2 Company Information Statement; Stockholder Written Consent.

(a) Promptly after the Registration Statement shall have been declared effective under the Securities Act, and in any event no later than three (3) Business Days thereafter, the Company shall prepare, with the cooperation of Parent, and cause to be mailed to its stockholders an information statement, which shall include a copy of the Proxy Statement (the "Information Statement"), to solicit the approval by written consent from the Company Signatories (within seven (7) Business Days after the Registration Statement shall have been declared effective), including the Company stockholders sufficient for the Required Company Stockholder Vote in lieu of a meeting pursuant to Section 228 of the DGCL, for purposes of: (i) adopting and approving this Agreement and the Contemplated Transactions, (ii) acknowledging that the approval given thereby is irrevocable and that such stockholder is aware of its rights to demand appraisal for its shares of Company Capital Stock pursuant to Section 262 of the DGCL, a true and correct copy of which will be attached thereto, and that such stockholder has received and read a copy of Section 262 of the DGCL, (iii) acknowledging that by its approval of the Merger it is not entitled to appraisal rights with respect to its shares of Company Capital Stock in connection with the Merger and thereby waives any rights to receive payment of the fair value of its shares of Company Capital Stock under the DGCL, and (iv) electing an automatic conversion of each share of Company Preferred Stock into shares of Company Common Stock immediately prior to the Effective Time in accordance with the relevant provisions of the Company's Organizational Documents (the "Preferred Stock Conversion") (collectively, the "Company Stockholder Matters"). Under no circumstances shall the Company assert that any approval or consent other than the Required Company Stockholder Vote is necessary for its stockholders or otherwise to approve this Agreement and the Contemplated Transactions. All materials (including any amendments thereto) submitted to the stockholders of the Company in accordance with this Section 5.2(a) shall be subject to Parent's advance review and reasonable approval. The Parties shall reasonably cooperate with each other and provide, and require their respective Representatives to provide, the other Party and its Representatives with all true, correct and complete information regarding

such Party or its Subsidiaries that is required by applicable Law to be included in the Information Statement or reasonably requested by the other Party to be included in the Information Statement.

(b) The Company covenants and agrees that the Information Statement, including any pro forma financial statements included therein (and the letter to stockholders and form of Company Stockholder Written Consent included therewith), will not, at the time that the Information Statement or any amendment or supplement thereto is first mailed, distributed or otherwise made available to the stockholders of the Company, at the time of receipt of the Required Company Stockholder Vote and at the Effective Time, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. Notwithstanding the foregoing, the Company makes no covenant, representation or warranty with respect to statements made in the Information Statement (and the letter to the stockholders and form of Company Stockholder Written Consent included therewith), if any, based on information furnished in writing by Parent or any of its Representatives specifically for inclusion therein. Each of the Parties shall use commercially reasonable efforts to cause the Information Statement to comply with the applicable rules and regulations promulgated by the SEC and applicable federal and state securities Laws requirements.

(c) Promptly following receipt of the Required Company Stockholder Vote, the Company shall prepare and mail a notice (the "*Stockholder Notice*") to every stockholder of the Company that did not execute the Company Stockholder Written Consent. The Stockholder Notice shall (i) be a statement to the effect that the Company Board determined that the Merger is advisable in accordance with Section 251(b) of the DGCL and in the best interests of the stockholders of the Company and authorized, approved and adopted this Agreement, the Merger and the other Contemplated Transactions, (ii) provide the stockholder Written Consent, including the adoption and approval of this Agreement, the Merger and the other Contemplated Transactions in accordance with Section 228(e) of the DGCL and the Organizational Documents of the Company, and (iii) include a description of the appraisal rights of the Company's stockholders available under the DGCL, along with such other information as is required thereunder and pursuant to applicable Law. All materials (including any amendments thereto) submitted to the stockholders of the Company in accordance with this <u>Section 5.2(c)</u> shall be subject to Parent's advance review and reasonable approval.

(d) The Company agrees that: (i) the Company Board shall recommend that the Company's stockholders vote to approve the Company Stockholder Matters and shall use reasonable best efforts to solicit such approval from the Company's stockholders within the time set forth in <u>Section 5.2(a)</u> (the recommendation of the Company Board that the Company's stockholders vote to adopt and approve the Company Stockholder Matters being referred to as the "*Company Board Recommendation*"); and (ii)(1) the Company Board Recommendation shall not be withdrawn or modified, (2) the Company Board shall not publicly propose to withdraw or modify the Company Board Recommendation and (3) no resolution by the Company Board or any committee thereof to withdraw or modify the Company Board Recommendation or to adopt, approve or recommend) any Acquisition Proposal shall be adopted or proposed (the actions set forth in the foregoing clause (ii), if taken, shall constitute, in each case, a "*Company Board Adverse Recommendation Change*").

(e) The Company's obligation to solicit the consent of its stockholders to sign the Company Stockholder Written Consent in accordance with <u>Section 5.2(a)</u> and <u>Section 5.2(d)</u> shall not be limited or otherwise affected by the commencement, disclosure, announcement or submission of any Superior Offer or other Acquisition Proposal.

5.3 Parent Stockholders' Meeting.

(a) Promptly after the Registration Statement has been declared effective by the SEC under the Securities Act, Parent shall take all action necessary under applicable Law to call, give notice

of and hold a meeting of the holders of Parent Common Stock for the purpose of seeking approval of this Agreement and the Contemplated Transactions, including:

(i) (A) the issuance of Parent Common Stock or other securities of Parent that represent (or are convertible into) more than twenty percent (20%) of the shares of Parent Common Stock outstanding immediately prior to the Merger to the holders of Company Capital Stock and Company Options in connection with the Contemplated Transactions pursuant to the Nasdaq rules (the "*Parent Share Issuance*") and (B) the change of control of Parent resulting from the Merger pursuant to the Nasdaq rules;

(ii) the amendment of Parent's certificate of incorporation to effect the Nasdaq Reverse Split;

(iii) the amendment of Parent's certificate of incorporate to effect the Authorized Share Increase;

(iv) the Equity Plan Proposals; and

(v) any other proposals the Parties deem necessary or desirable to consummate the Contemplated Transactions.

(the matters contemplated by <u>Section 5.3(a)(i)</u> through <u>Section 5.3(a)(iii)</u> are referred to as the "*Parent Stockholder Matters*," and such meeting, the "*Parent Stockholders' Meeting*").

(b) The Parent Stockholders' Meeting shall be held as promptly as practicable after the Registration Statement is declared effective under the Securities Act and, in any event, no later than forty-five (45) calendar days after the effective date of the Registration Statement. Parent shall take reasonable measures to ensure that all proxies solicited in connection with the Parent Stockholders' Meeting are solicited in compliance with all applicable Laws. Notwithstanding anything to the contrary contained herein, if on the date of the Parent Stockholders' Meeting, or a date preceding the date on which the Parent Stockholders' Meeting is scheduled, Parent reasonably believes that (i) it will not receive proxies sufficient to obtain the Required Parent Stockholder Vote, whether or not a quorum would be present, or (ii) it will not have sufficient shares of Parent Common Stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Parent Stockholders' Meeting, Parent may postpone or adjourn, or make one or more successive postponements or adjournments of, the Parent Stockholders' Meeting as long as the date of the Parent Stockholders' Meeting is not postponed or adjourned more than an aggregate of thirty (30) calendar days in connection with any postponements or adjournments.

(c) Parent agrees that, subject to <u>Section 5.3(d)</u>: (i) the Parent Board shall recommend that the holders of Parent Common Stock vote to approve the Parent Stockholder Matters and the Equity Plan Proposals and shall use commercially reasonable efforts to solicit such approval within the timeframe set forth in <u>Section 5.3(b)</u> above; (ii) the Proxy Statement shall include a statement to the effect that the Parent Board recommends that Parent's stockholders vote to approve the Parent Stockholder Matters and the Equity Plan Proposals (the recommendation of the Parent Board with respect to the Parent Stockholder Matters being referred to as the "*Parent Board Recommendation*"); and (iii)(1) the Parent Board Recommendation shall not be withheld, amended, withdrawn or modified, (2) the Parent Board Recommendation, (3) no resolution by the Parent Board or any committee thereof to withdraw or modify the Parent Board Recommendation or to adopt, approve or recommend (or publicly propose to adopt, approve or recommend) any Acquisition Proposal shall be adopted or proposed, and (4) the Parent Board shall not publicly announce an intention or resolution to effect any of the foregoing (the actions set forth in the foregoing clause (iii), if taken, shall constitute, in each case, a "*Parent Board Adverse Recommendation Change*").

(d) Notwithstanding anything to the contrary contained in this Agreement, and subject to compliance with Section 4.4 and this Section 5.3(d), if at any time prior to the approval of the Parent Stockholder Matters at the Parent Stockholders' Meeting by the Required Parent Stockholder Vote:

(i) If Parent has received a *bona fide* Acquisition Proposal (which Acquisition Proposal did not arise out of a material breach of Section 4.4) from any Person that has not been withdrawn and after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer, the Parent Board may make a Parent Board Adverse Recommendation Change if and only if: (A) the Parent Board determines in good faith, after consultation with Parent's outside legal counsel and financial advisor, that the failure to do so would be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law: (B) Parent shall have given the Company prior written notice of its intention to consider making a Parent Board Adverse Recommendation Change at least four (4) Business Days prior to making any such Parent Board Adverse Recommendation Change (a "Determination Notice"; and such period the "Parent Notice Period") (which notice shall not constitute a Parent Board Adverse Recommendation Change); and (C)(1) Parent shall have provided to the Company a description in reasonable detail of the reasons for such Parent Board Adverse Recommendation Change, the identity of the party making the Acquisition Proposal, a summary of the material terms and conditions of the Acquisition Proposal and written copies of any relevant proposed transaction documents (including with respect to financing arrangements), in accordance with Section 4.4(b), (2) Parent shall have given the Company the three (3) Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make another proposal and shall have made its Representatives reasonably available to negotiate in good faith with the Company (to the extent the Company desires to negotiate) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by the Company, if any, after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer and that the failure to make the Parent Board Adverse Recommendation Change would be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law; provided during any Parent Notice Period, the Company shall be entitled to deliver to Parent one or more counterproposals to such Acquisition Proposal and Parent will, and cause its Representatives to, negotiate with the Company in good faith (to the extent the Company desires to negotiate) to enable the Company to propose in writing an offer binding on the Company to effect such adjustments to the terms and conditions of this Agreement so that the applicable Acquisition Proposal ceases to constitute a Superior Offer. For the avoidance of doubt, the provisions of this Section 5.3(d)(i) shall also apply to any material change to the facts and circumstances relating to such Acquisition Proposal or any amendment to such Acquisition Proposal (including any revision in the amount, form or mix of consideration), and require a new Determination Notice and Parent shall be required to provide the Company with notice of such material change or amendment, except that the references to four (4) Business Days shall be deemed to be two (2) Business Days.

(ii) Other than in connection with an Acquisition Proposal, the Parent Board may make a Parent Board Adverse Recommendation Change in response to a Parent Change in Circumstance, if and only if: (A) the Parent Board determines in good faith, after consultation with Parent's outside legal counsel, that the failure to do so would be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law; (B) Parent shall have given the Company a Determination Notice at least four (4) Business Days prior to making any such Parent Board Adverse Recommendation Change; and (C)(1) Parent shall have specified the Parent Change in Circumstance in reasonable detail, including the material facts and circumstances related to the applicable Parent Change in Circumstance, (2) Parent shall have given the Company the four (4) Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make another proposal, and shall have made its Representatives reasonably available to negotiate in good faith with the Company (to

the extent the Company desires to do so) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by the Company, if any, after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that the failure to make the Parent Board Adverse Recommendation Change in response to such Parent Change in Circumstance would be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law. For the avoidance of doubt, the provisions of this Section 5.3(d)(ii) shall also apply to any material change to the facts and circumstances relating to such Parent Change in Circumstance, and require a new Determination Notice and Parent shall be required to provide the Company with notice of such material change, except that the references to four (4) Business Days shall be deemed to be two (2) Business Days.

(e) Nothing contained in this Agreement shall prohibit Parent or the Parent Board from (i) complying with Rules 14d-9 and 14e-2(a) promulgated under the Exchange Act, (ii) issuing a "stop, look and listen" communication or similar communication of the type contemplated by Section 14d-9(f) under the Exchange Act or (iii) otherwise making any disclosure to Parent's stockholders; *provided however*, that, in the case of the foregoing clause (iii), the Parent Board determines in good faith, after consultation with its outside legal counsel, that failure to make such disclosure would be inconsistent with applicable Law, including its fiduciary duties under applicable Law.

(f) Unless this Agreement is otherwise terminated pursuant to Section 9.1, Parent's obligation to call, give notice of and hold the Parent Stockholders' Meeting in accordance with Section 5.3(b) shall not be limited or otherwise affected by the commencement, disclosure, announcement or submission of any Acquisition Proposal or by any Parent Board Adverse Recommendation Change.

5.4 <u>Regulatory Approvals</u>. Each Party shall use reasonable best efforts to file or otherwise submit, as soon as practicable after the date of this Agreement, all applications, notices, reports, filings and other documents required to be filed by such Party with or otherwise submitted by such Party to any Governmental Body with respect to the Contemplated Transactions, to submit promptly any additional information requested by any such Governmental Body, and to keep the other Party promptly informed of any communication from or to any Governmental Body.

5.5 Company Options.

(a) At the Effective Time, each Company Option that is outstanding and unexercised immediately prior to the Effective Time under the Company Plan, whether or not vested, shall be converted into and become an option to purchase Parent Common Stock, and Parent shall assume the Company Plan and each such Company Option in accordance with the terms (as in effect as of the date of this Agreement) of the Company Plan and the terms of the stock option agreement by which such Company Option is evidenced (but with changes to such documents as Parent in good faith determines are appropriate to reflect the substitution of the Company Options by Parent to purchase shares of Parent Common Stock). All rights with respect to Company Common Stock under Company Options assumed by Parent shall thereupon be converted into rights with respect to Parent Common Stock. Accordingly, from and after the Effective Time: (i) each Company Option assumed by Parent may be exercised solely for shares of Parent Common Stock: (ii) the number of shares of Parent Common Stock subject to each Company Option assumed by Parent shall be determined by multiplying (A) the number of shares of Company Common Stock that were subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Parent Common Stock; (iii) the per share exercise price for the Parent Common Stock issuable upon exercise of each Company Option assumed by Parent shall be determined by dividing (A) the per share exercise price of Company Common Stock subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any Company Option assumed by Parent shall continue in full force and effect and the term, exercisability, vesting schedule and other provisions of such Company Option shall otherwise remain unchanged;

provided, however, that: (A) to the extent provided under the terms of the respective grant agreements governing the Company Options and the Company Plan, Parent may amend the terms of the Company Options and the Company Plan, in accordance with the terms thereof to reflect Parent's substitution of the Company Options with options to purchase Parent Common Stock (such as by making any change in control or similar definition relate to Parent and having any provision that provides for the adjustment of Company Options upon the occurrence of certain corporate events relate to corporate events that relate to Parent or Parent Common Stock); and (B) the Parent Board or a committee thereof shall succeed to the authority and responsibility of the Company Board or any committee thereof with respect to each Company Option assumed by Parent. Each Company Option so assumed by Parent is intended to qualify following the Effective Time as an incentive stock option as defined in Section 422 of the Code to the extent permitted under Section 422 of the Code and to the extent such Company Option qualified as an incentive stock option prior to the Effective Time, and, further, the assumption of such Company Option pursuant to this Section 5.5(a) shall be effected in a manner that satisfies the requirements of Sections 409A and 424(a) of the Code and the Treasury Regulations promulgated thereunder, and this Section 5.5(a) will be construed consistent with this intent.

(b) Parent shall file with the SEC, promptly, but no later than thirty (30) calendar days after the Effective Time, a registration statement on Form S-8 (or any successor form), if available for use by Parent, relating to the shares of Parent Common Stock that are either (i) issuable with respect to Company Options assumed by Parent in accordance with <u>Section 5.5(a)</u> or (ii) reserved for future grants under the Company Plan.

(c) Prior to the Effective Time, the Company shall take all actions that may be necessary (under the Company Plan and otherwise) to effectuate the provisions of this <u>Section 5.5</u> and to ensure that, from and after the Effective Time, holders of Company Options have no rights with respect thereto other than those specifically provided in this <u>Section 5.5</u>.

5.6 Indemnification of Officers and Directors.

(a) From the Effective Time through the sixth (6^{th}) anniversary of the date on which the Effective Time occurs, each of Parent and the Surviving Corporation, jointly and severally, shall indemnify and hold harmless each person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Effective Time, a director, officer, fiduciary or agent of Parent or any of its Subsidiaries or the Company, respectively (the "D&O Indemnified Parties"), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that the D&O Indemnified Party is or was a director, officer, fiduciary or agent of Parent or of the Company or their respective Subsidiaries, whether asserted or claimed prior to, at or after the Effective Time, in each case, to the fullest extent permitted by Parent's Organizational Documents or the Company's Organizational Documents, as applicable, or pursuant to indemnification agreements set forth on Schedule 5.6(a), as applicable. Each D&O Indemnified Party will be entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from each of Parent and the Surviving Corporation, jointly and severally, upon receipt by Parent or the Surviving Corporation from the D&O Indemnified Party of a request therefor; provided that any such person to whom expenses are advanced provides an undertaking to Parent, to the extent then required by the DGCL, to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

(b) The provisions of the Organizational Documents of Parent or any of its Subsidiaries with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers of Parent or any of its Subsidiaries that are set forth in the Organizational Documents of Parent or any of its Subsidiaries as of the date of this Agreement shall not be amended, modified or repealed for a period of six (6) years from the Effective Time in a manner that would adversely affect the rights thereunder of individuals who, at or prior to the Effective Time, were officers or directors of Parent or any of its Subsidiaries. The Organizational Documents of the Surviving Corporation shall contain, and Parent shall cause the Organizational Documents

of the Surviving Corporation to so contain, provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers as those set forth in the Organizational Documents of the Company as of the date of this Agreement.

(c) From and after the Effective Time, (i) the Surviving Corporation shall fulfill and honor in all respects the obligations of the Company to its D&O Indemnified Parties as of immediately prior to the Closing pursuant to any indemnification provisions under the Organizational Documents of the Company and pursuant to any indemnification agreements between the Company and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time and (ii) Parent shall fulfill and honor in all respects the obligations of Parent or any of its Subsidiaries to its D&O Indemnified Parties as of immediately prior to the Closing pursuant to any indemnification provisions under the Organizational Documents of Parent or any of its Subsidiaries and pursuant to any indemnification agreements between Parent or any of its Subsidiaries and pursuant to any indemnification agreements between Parent or any of its Subsidiaries and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time.

(d) From and after the Effective Time, Parent shall maintain directors' and officers' liability insurance policies, with an effective date as of the Closing Date, on commercially available terms and conditions and with coverage limits customary for U.S. public companies similarly situated to Parent. In addition, Parent shall purchase, prior to the Effective Time, a six (6)-year prepaid "tail policy" for the non-cancellable extension of the directors' and officers' liability coverage of Parent's and any of its Subsidiaries' existing directors' and officers' insurance policies and Parent's existing fiduciary liability insurance policies (if any), in each case, for a claims reporting or discovery period of at least six (6) years from and after the Effective Time with respect to any claim related to any period of time at or prior to the Effective Time. During the term of the "tail" policy, Parent shall not take any action following the Effective Time to cause such "tail" policy to be cancelled or any provision therein to be amended or waived in any manner that would adversely affect in any material respect the rights of its or any of its Subsidiaries' former and current officers and directors.

(e) From and after the Effective Time, Parent shall pay all expenses, including reasonable attorneys' fees, that are incurred by the persons referred to in this <u>Section 5.6</u> in connection with their successful enforcement of the rights provided to such persons in this <u>Section 5.6</u>.

(f) All rights to exculpation, indemnification and advancement of expenses for acts or omissions occurring at or prior to the Effective Time, whether asserted or claimed prior to, at or after the Closing, now existing in favor of the current or former directors, officers or employees, as the case may be, of Parent or the Company or any of their respective Subsidiaries as provided in their respective Organizational Documents or in any agreement shall survive the Merger and shall continue in full force and effect. The provisions of this <u>Section 5.6</u> are intended to be in addition to the rights otherwise available to the current and former officers and directors of Parent and the Company and any of their respective Subsidiaries by Law, charter, statute, bylaw or Contract, and shall operate for the benefit of, and shall be enforceable by, each of the D&O Indemnified Parties, their heirs and their representatives.

(g) From and after the Effective Time, in the event Parent or the Surviving Corporation or any of their respective successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in each such case, proper provision shall be made so that the successors and assigns of Parent or the Surviving Corporation, as the case may be, shall succeed to the obligations set forth in this Section 5.6. Parent shall cause the Surviving Corporation to perform all of the obligations of the Surviving Corporation under this Section 5.6.

(h) The obligations set forth in this <u>Section 5.6</u> shall not be terminated, amended or otherwise modified in any manner that adversely affects any D&O Indemnified Party, or any

person who is a beneficiary under the policies referred to in this <u>Section 5.6</u> and their heirs and representatives, without the prior written consent of such affected D&O Indemnified Party or such other beneficiary.

5.7 Additional Agreements. The Parties shall (a) use commercially reasonable efforts to cause to be taken all actions necessary to consummate the Contemplated Transactions and (b) reasonably cooperate with the other Parties and provide the other Parties with such assistance as may be reasonably requested for the purpose of facilitating the performance by each Party of its respective obligations under this Agreement and to enable the Surviving Corporation to continue to meet its obligations under this Agreement following the Closing. Without limiting the generality of the foregoing, each Party shall use reasonable best efforts to: (i) make all filings and other submissions (if any) and give all notices (if any) required to be made and given by such Party in connection with the Contemplated Transactions, (ii) obtain each Consent (if any) reasonably required to be obtained (pursuant to any applicable Law or Contract, or otherwise) by such Party in connection with the Contemplated Transactions or for such Contract (with respect to Contracts set forth in <u>Section 5.7</u> of the Company Disclosure Schedule) to remain in full force and effect, (iii) lift any injunction prohibiting, or any other legal bar to, the Contemplated Transactions and (iv) satisfy the conditions precedent to the consummation of the Merger.

5.8 <u>Public Announcement</u>. The initial press release relating to this Agreement shall be a joint press release issued by the Company and Parent and thereafter Parent and the Company shall consult with each other before issuing any further press release(s) or otherwise making any public statement or making any announcement to Parent Associates or Company Associates (to the extent not previously issued or made in accordance with this Agreement) with respect to the Contemplated Transactions and shall not issue any such press release, public statement or announcement to Parent Associates or Company Associates without the other Party's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing: (a) each Party may, without such consultation or prior written consent, make any public statement in response to questions from the press, analysts, investors or those attending industry conferences, make internal announcements to employees and make disclosures in Parent SEC Documents, so long as such statements are consistent with and do not disclose material information not previously disclosed in previous press releases, public disclosures or public statements made jointly by the Parties (or individually, if approved by the other Party); (b) a Party may, without the prior written consent of the other Party but subject to giving advance notice to the other Party of, and consulting with the other Party regarding, the text of such press release, announcement or statement, issue any such press release or make any such public announcement or statement which Parent shall have determined in good faith, upon the advice of legal counsel, is required by any applicable Law; and (c) Parent need not consult with the Company in connection with such portion of any press release, public statement or filing to be issued or made pursuant to Section 5.3(e) or with respect to any Acquisition Proposal or Parent Board Adverse Recommendation Change.

5.9 Listing. Parent shall use its commercially reasonable efforts, (a) to maintain its existing listing on Nasdaq until the Closing Date and to obtain approval of the listing of the combined company on Nasdaq; (b) without derogating from the generality of the requirements of the foregoing clause (a) and to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Parent Common Stock to be issued in connection with the Contemplated Transactions, and to cause such shares to be approved for listing (subject to official notice of issuance), (c) to effect the Nasdaq Reverse Split, and (d) to the extent required by Nasdaq (the "*Nasdaq Listing Application*") and to cause such Nasdaq Listing Application to be conditionally approved prior to the Effective Time. The Parties will use commercially reasonable efforts to coordinate with respect to compliance with Nasdaq rules and regulations and will reasonably promptly inform the other Party of all verbal or written communications between Nasdaq and such Party or its representatives. The Company agrees to pay all Nasdaq fees associated with the Nasdaq Listing Application and promptly furnish to Parent all information concerning the

Company and its stockholders that may be required or reasonably requested in connection with any action contemplated by this <u>Section 5.9</u>.

5.10 Tax Matters.

(a) For United States federal income Tax purposes, (i) the Parties intend that the Merger qualify as a "reorganization" within the meaning of Section 368(a) of the Code (the "*Intended Tax Treatment*"), and (ii) this Agreement is intended to be, and is hereby adopted as, a "plan of reorganization" for purposes of Section 354 and 361 of the Code and Treasury Regulations Section 1.368-2(g) and 1.368-3(a), to which Parent, Merger Sub and the Company are parties under Section 368(b) of the Code.

(b) The Parties shall use their respective reasonable best efforts to cause the Merger to qualify, and will not take (or knowingly fail to take) any action or cause (or knowingly fail to cause) any action to be taken which action would reasonably be expected to prevent the Merger from qualifying, for the Intended Tax Treatment. The Parties shall use commercially reasonable efforts to operate the Surviving Corporation so as to meet the "continuity of business enterprise" requirement and any other requirements pursuant to Section 368(a)(2)(E) of the Code. The Parties shall not file any U.S. federal, state or local Tax Return in a manner that is inconsistent with the treatment of the Merger as a reorganization within the meaning of Section 368(a) of the Code for U.S. federal, state and other relevant Tax purposes, unless otherwise required by a "determination" within the meaning of Section 1313(a) of the Code.

(c) At least ten (10) Business Days prior to Closing, Parent will provide the Company with its determinations regarding the applicability of Section 280G of the Code and reasonable supporting calculations to any employee, officer, director or other service provider of Parent or any of its Subsidiaries that, in connection with the Contemplated Transactions (i) may receive the payment of any "parachute payment" within the meaning of Section 280G of the Code or (ii) may receive a benefit in the form of accelerated vesting, payment, funding or delivery of, or increase the amount or value of, any payment or benefit received.

(d) Each Party, shall cooperate and shall cause its respective Affiliates to cooperate with each other Party and with each other Party's agents, including accounting firms and legal counsel, in connection with any Tax Proceeding in respect of Taxes assessed or proposed to be assessed against the Company or any of its Subsidiaries or the preparation of any Tax Return. Such cooperation shall include each Party making such information and documents in its possession relating to the Company or any of its Subsidiaries reasonably necessary in connection with any such Tax Proceeding available to the other Party. The Parties shall retain all Tax Returns, schedules, and work papers, and all material records and other documents relating thereto, until the expiration of the applicable statute of limitations (including, to the extent noticed by any Party, any extensions thereof) of the Tax period to which such Tax Returns and other documents and information relate. Each of the Parties shall also make available to the other Party, as reasonably requested and available on a mutually convenient basis, personnel responsible for preparing, maintaining, and interpreting information and documents relevant to Taxes to provide reasonable explanation of any documents or information provided hereunder. Any information or documents provided under this Agreement shall be kept confidential by the Party receiving such information or documents, except as may otherwise be necessary in connection with the filing of Tax Returns or in connection with a Tax Proceeding.

(e) Fifty percent (50%) of any Transfer Taxes shall be borne and paid by each of Parent and the Company if and when due. Each of Parent and the Company shall, at its own expense, timely file any Tax Return or other documents with respect to such Taxes or fees.

5.11 <u>Directors and Officers</u>. The Parties shall take all necessary action so that immediately after the Effective Time, (a) the Parent Board is comprised of seven (7) members, with one (1) such member designated by Parent and six (6) such members designated by the Company, (b) the Persons listed on <u>Schedule 5.11</u> under the heading "Officers" are elected or appointed, as applicable, to the positions of officers of Parent, as set forth therein, to serve in such positions effective as of the Effective Time until



successors are duly appointed and qualified in accordance with applicable Law and (c) the Persons listed on <u>Schedule 5.11</u> under the heading "Directors" are elected or appointed, as applicable, to the positions of directors of Parent, as set forth therein, and to the classes of such director positions as set forth therein, to serve in such positions effective as of the Effective Time until successors are duly appointed and qualified in accordance with applicable Law. If any Person listed on Schedule 5.11 under the heading "Officers" is unable or unwilling to serve as an officer of Parent, as set forth therein, as of the Effective Time, the Parties shall mutually agree upon a successor. If any Person listed on Schedule 5.11 is unable or unwilling to serve as a director of Parent, as set forth therein, as of the Effective Time, the Party appointing such Person (as set forth on Schedule 5.11) shall designate a successor. The Person listed on Schedule 5.11 under the heading "Board Designee - Parent" shall be Parent's designee pursuant to clause (c) of this Section 5.11 (which may be changed by Parent at any time prior to the Closing by written notice to the Company to include a different board designee who is reasonably acceptable to the Company) (the "Parent Designee"). The Persons listed on Schedule 5.11 under the heading "Board Designees - Company" shall be the Company's designees pursuant to clause (c) of this Section 5.11 (which initial list may include vacancies and be supplemented or changed by the Company at any time prior to the Closing by written notice to Parent to include different board designees who are reasonably acceptable to Parent).

5.12 Termination of Certain Agreements and Rights.

(a) The Company shall cause the Investor Agreements set forth on <u>Schedule 5.12(a)</u> to be terminated immediately prior to the Effective Time, without any liability being imposed on the part of Parent or the Surviving Corporation.

(b) In addition to its obligations with respect to the Asset Disposition under <u>Section 4.7</u>, Parent agrees to use commercially reasonable efforts to (i) terminate, assign or fully perform all Parent Contracts, including as set forth on <u>Schedule 5.12(b)(1)</u> (except (x) Parent Contracts set forth and indicated as such on <u>Schedule 5.12(b)(2)</u> and (y) any other Parent Contract agreed to by Parent and Company) (the "*Specified Parent Contracts*") and (ii) fully satisfy, waive or otherwise discharge all obligations of Parent under all Specified Parent Contracts, in each case prior to the Closing.

5.13 Section 16 Matters. Prior to the Effective Time, Parent and the Company shall take all such steps as may be required (to the extent permitted under applicable Laws) to cause any acquisitions of Parent Common Stock, restricted stock awards to acquire Parent Common Stock and any options to purchase Parent Common Stock in connection with the Contemplated Transactions, by each individual who is reasonably expected to become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent, to be exempt under Rule 16b-3 promulgated under the Exchange Act. At least ten (10) days prior to the Closing Date, the Company shall furnish the following information to Parent for each individual who, immediately after the Effective Time, will become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent: (a) the number of shares of Company Capital Stock owned by such individual and expected to be exchanged for shares of Parent Common Stock pursuant to the Merger, and (b) the number of other derivative securities (if any) with respect to Company Capital Stock owned by such individual and expected to be converted into shares of Parent Common Stock, restricted stock awards to acquire Parent Common Stock or derivative securities with respect to Parent Common Stock in connection with the Merger.

5.14 <u>Cooperation</u>. Each Party shall cooperate reasonably with the other Party and shall provide the other Party with such assistance as may be reasonably requested for the purpose of facilitating the performance by each Party of its respective obligations under this Agreement and to enable the combined entity to continue to meet its obligations following the Effective Time.

5.15 Allocation Certificate; Parent Outstanding Shares Certificate.

(a) The Company will prepare and deliver to Parent at least ten (10) Business Days prior to the Closing Date a certificate signed by the Chief Financial Officer of the Company in a form reasonably acceptable to Parent setting forth (as of immediately prior to the Effective Time) (i) each

holder of Company Capital Stock and Company Options, (ii) such holder's name and address; (iii) the number and type of Company Capital Stock held or underlying the Company Options as of the immediately prior to the Effective Time for each such holder; and (iv) the number of shares of Parent Common Stock to be issued to such holder, or to underlie any Parent Option to be issued to such holder, pursuant to this Agreement in respect of the Company Capital Stock or Company Options held by such holder as of immediately prior to the Effective Time (the "*Allocation Certificate*").

(b) Parent will prepare and deliver to the Company at least ten (10) Business Days prior to the Closing Date a certificate signed by the Chief Financial Officer of Parent in a form reasonably acceptable to the Company, setting forth, as of immediately prior to the Effective Time (i) each record holder of Parent Common Stock, Parent Options or Parent RSUs, (ii) such record holder's name and address, and (iii) the number of shares of Parent Common Stock held or underlying the Parent Options or Parent RSUs as of the Effective Time for such holder (the "*Parent Outstanding Shares Certificate*").

5.16 <u>Company Financial Statements</u>. To the extent required, the Company will use commercially reasonable efforts to, (i) no later than March 31, 2025, furnish to Parent audited financial statements for the fiscal year ended 2024 for inclusion in the Proxy Statement and the Registration Statement (the "Company 2024 Audited Financial Statements" and, collectively with the Company 2023 and 2022 Audited Financial Statements, the "Company Audited Financial Statements") and (ii) and no later than May 14, 2025, furnish to Parent unaudited interim financial statements for each interim period completed prior to the Closing that would be required to be included in the Registration Statement or any periodic report due prior to the Closing if the Company were subject to the periodic reporting requirements under the Securities Act or the Exchange Act (the "Company 2025 Interim Financial Statements" and collectively with the Company 2024 Interim Financial Statements, the "Company Interim Financial Statements"). Each of the Company 2024 Audited Financial Statements and the Company 2025 Interim Financial Statements will be suitable for inclusion in the Proxy Statement and the Registration Statement and prepared in accordance with GAAP as applied on a consistent basis during the periods involved (except in each case as described in the notes thereto) and on that basis will present fairly, in all material respects, the consolidated financial position and the results of operations, changes in stockholders' equity, and cash flows of the Company as of the dates of and for the periods referred to in the Company 2024 Audited Financial Statements or the Company 2025 Interim Financial Statements, as the case may be.

5.17 <u>Takeover Statutes</u>. If any Takeover Statute is or may become applicable to the Contemplated Transactions, each of the Company, the Company Board, Parent and the Parent Board, as applicable, shall grant such approvals and take such actions as are necessary so that the Contemplated Transactions may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise act to eliminate or minimize the effects of such Takeover Statute on the Contemplated Transactions.

5.18 <u>Stockholder Litigation</u>. Until the earlier of the termination of this Agreement in accordance with its terms or the Effective Time, Parent shall (a) promptly advise the Company in writing of any stockholder litigation or investigation against it or its directors relating to this Agreement, the Merger or the Contemplated Transactions and keep the Company fully informed regarding such stockholder litigation and (b) give the Company the opportunity to participate in the defense or settlement of any stockholder litigation or investigation relating to this Agreement or any of the Contemplated Transactions, and not settle any such litigation or investigation without the Company's written consent, which will not be unreasonably withheld, conditioned or delayed.

5.19 Equity Plans. Prior to or as of the Effective Time, Parent shall approve, adopt and submit for approval by the stockholders of Parent, and recommend and use commercially reasonable efforts to cause the stockholders of Parent to approve, (a) the 2025 Equity Incentive Plan in the form attached hereto as Exhibit F (the "2025 Plan") which will provide for new awards for a number of shares of Parent Common Stock not exceeding 10% of the Parent Common Stock issued and expected to be outstanding immediately after the Effective Time, as mutually agreed upon by Parent and the Company, and subject to approval by the Parent Board (for avoidance of doubt, such number of shares shall be in

addition to the number of shares of Parent Common Stock subject to outstanding Parent Options or subject to Company Options assumed by Parent as contemplated by <u>Section 5.5</u>), and which may include an annual increase pursuant to an "evergreen" provision to provide for optional annual increases of up to 5% of the total number of fully diluted shares of capital stock of Parent as of the day prior to such increase; and (b) the 2025 Employee Stock Purchase Plan (the "2025 ESPP"), in the form attached hereto as Exhibit G, with a total pool of shares of Parent Common Stock not exceeding 1% of the Parent Common Stock issued and expected to be outstanding immediately after the Effective Time, and may include an annual increase pursuant to an "evergreen" provision providing for an annual increase of up to 1% of the total number of fully diluted shares of capital stock of Parent outstanding as of the day prior to such increase ((a) and (b), collectively, the "Equity Plan Proposals"). Subject to the approval of the 2025 Plan by the stockholders of Parent, Parent shall file with the SEC, promptly after the Effective Time, a registration statement on Form S-8 (or any successor form), if available for use by Parent, relating to the shares of Parent Common Stock issuable with respect to the 2025 Plan.

5.20 <u>Parent SEC Documents</u>. From the date of this Agreement until the Effective Time, Parent shall use commercially reasonable efforts to timely file with the SEC all Parent SEC Documents. As of its filing date, or if amended after the date of this Agreement, as of the date of the last such amendment, each Parent SEC Document filed by Parent with the SEC shall comply in all material respects with the applicable requirements of the Exchange Act and the Securities Act.

5.21 <u>Parent Options and RSUs</u>. Before the Effective Time, Parent shall take all actions necessary to provide that all Parent Options and Parent RSUs shall be fully vested as of the Effective Time and that no Parent Option shall be exercised later than ninety (90) days following the termination of service of the holder of the Parent Option.

Section 6. CONDITIONS PRECEDENT TO OBLIGATIONS OF EACH PARTY

The obligations of each Party to effect the Merger and otherwise consummate the Contemplated Transactions to be consummated at the Closing are subject to the satisfaction (or, to the extent permitted by applicable Law, written waiver by each of the Parties) of each of the following conditions:

6.1 <u>No Restraints</u>. No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Contemplated Transactions shall have been issued by any court of competent jurisdiction or other Governmental Body of competent jurisdiction and remain in effect and there shall not be any Law which has the effect of making the consummation of the Contemplated Transactions illegal.

6.2 <u>Stockholder Approval</u>. (a) Parent shall have obtained the Required Parent Stockholder Vote and (b) the Company shall have obtained the Required Company Stockholder Vote and such Required Company Stockholder Vote shall remain in full force and effect and shall not have been revoked.

6.3 <u>Listing</u>. (a) The existing shares of Parent Common Stock shall have been continually listed on Nasdaq as of and from the date of this Agreement through the Closing Date and (b) the shares of Parent Common Stock to be issued in the Merger pursuant to this Agreement shall have been approved for listing (subject to official notice of issuance) on Nasdaq as of the Closing.

6.4 <u>Effectiveness of Registration Statement</u>. The Registration Statement shall have become effective in accordance with the provisions of the Securities Act and shall not be subject to any stop order or proceeding (or threatened proceeding by the SEC) seeking a stop order with respect to the Registration Statement that has not been withdrawn.

6.5 <u>Parent Net Cash Determination</u>. Parent Net Cash shall have been finally determined in accordance with <u>Section 1.6</u>.

Section 7. ADDITIONAL CONDITIONS PRECEDENT TO OBLIGATIONS OF PARENT AND MERGER SUB

The obligations of Parent and Merger Sub to effect the Merger and otherwise consummate the Contemplated Transactions to be consummated at the Closing are subject to the satisfaction (or, to the extent permitted by applicable Law, written waiver by Parent) of each of the following conditions:

7.1 Accuracy of Representations. (i) The representation and warranty of the Company set forth in <u>Section 2.8(b)</u> shall have been true and correct in all respects as of the date of this Agreement and shall be true and correct in all respects on and as of the Closing Date with the same force and effect as if made on and as of such date; (ii) the Company Fundamental Representations shall have been true and correct in all material respects as of the date of this Agreement and shall be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct in all material respects as of such date); and (iii) the representations and warranties of the Company contained in this Agreement (other than the Company Fundamental Representations and Section 2.8(b) shall have been true and correct as of the date of this Agreement and shall be true and correct on and as of the Closing Date with the same force and effect as if made on and as of the Closing Date except (a) in each case, or in the aggregate, where the failure to be so true and correct would not reasonably be expected to have a Company Material Adverse Effect (without giving effect to any references therein to any Company Material Adverse Effect or other materiality qualifications), or (b) for those representations and warranties which address matters only as of a particular date (which representations shall have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date) (it being understood that, for purposes of determining the accuracy of such representations and warranties, any update of or modification to the Company Disclosure Schedule made or purported to have been made after the date of this Agreement shall be disregarded).

7.2 <u>Performance of Covenants</u>. The Company shall have performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it under this Agreement at or prior to the Effective Time.

7.3 <u>Documents</u>. Parent shall have received the following documents, each of which shall be in full force and effect:

(a) a certificate executed by the Chief Executive Officer or Chief Financial Officer of the Company certifying (i) that the conditions set forth in <u>Sections 7.1</u>, <u>7.2</u>, <u>7.4</u> and <u>7.5</u> have been duly satisfied and (ii) that the information set forth in the Allocation Certificate delivered by the Company in accordance with <u>Section 5.15</u> is true and accurate in all respects as of the Closing Date; and

(b) the Allocation Certificate.

7.4 <u>FIRPTA Certificate</u>. Parent shall have received (i) an original signed statement from the Company that the Company is not, and has not been at any time during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code, a "United States real property holding corporation," as defined in Section 897(c)(2) of the Code, conforming to the requirements of Treasury Regulations Section 1.1445-2(c)(3) and 1.897-2(h), and (ii) an original signed notice to be delivered to the IRS in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2), together with written authorization for Parent to deliver such notice to the IRS on behalf of the Company following the Closing, each dated as of the Closing Date, duly executed by an authorized officer of the Company, and in form and substance reasonably acceptable to Parent.

7.5 <u>No Company Material Adverse Effect</u>. Since the date of this Agreement, there shall not have occurred any Company Material Adverse Effect that is continuing.

7.6 <u>Termination of Investor Agreements</u>. The Investor Agreements set forth on <u>Schedule 5.12(a)</u> shall have been terminated (or will be terminated as of the Closing).

7.7 <u>Company Lock-Up Agreements</u>. Parent shall have received the Company Lock-Up Agreements duly executed by each of the Company Lock-Up Signatories and each executive officer and director of the Company who is elected or appointed, as applicable, as an executive officer and director of Parent as of immediately following the Closing, each of which shall be in full force and effect as of immediately following the Effective Time.

Section 8. ADDITIONAL CONDITIONS PRECEDENT TO OBLIGATION OF THE COMPANY

The obligation of the Company to effect the Merger and otherwise consummate the Contemplated Transactions to be consummated at the Closing is subject to the satisfaction (or, to the extent permitted by applicable Law, written waiver by the Company) of each of the following conditions:

8.1 Accuracy of Representations. (i) The representations and warranties of Parent and Merger Sub set forth in Section 3.8(b) shall have been true and correct in all respects as of the date of this Agreement and shall be true and correct in all respects on and as of the Closing Date with the same force and effect as if made on and as of such date; (ii) the Parent Fundamental Representations shall have been true and correct in all material respects as of the date of this Agreement and shall be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct in all material respects as of such date); and (iii) the representations and warranties of Parent and Merger Sub contained in this Agreement (other than the Parent Fundamental Representations and Section 3.8(b)) shall have been true and correct as of the date of this Agreement and shall be true and correct on and as of the Closing Date with the same force and effect as if made on and as of the Closing Date except (a) in each case, or in the aggregate, where the failure to be so true and correct would not reasonably be expected to have a Parent Material Adverse Effect (without giving effect to any references therein to any Parent Material Adverse Effect or other materiality qualifications), or (b) for those representations and warranties which address matters only as of a particular date (which representations shall have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date) (it being understood that, for purposes of determining the accuracy of such representations and warranties, any update of or modification to the Parent Disclosure Schedule made or purported to have been made after the date of this Agreement shall be disregarded).

8.2 <u>Performance of Covenants</u>. Parent and Merger Sub shall have performed or complied with in all material respects all of their agreements and covenants required to be performed or complied with by each of them under this Agreement at or prior to the Effective Time.

8.3 <u>Documents</u>. The Company shall have received the following documents, each of which shall be in full force and effect:

(a) a certificate executed by the Chief Executive Officer or Chief Financial Officer of Parent certifying that the conditions set forth in <u>Sections 8.1</u>, <u>8.2</u>, and <u>8.4</u> have been duly satisfied;

(b) the Parent Outstanding Shares Certificate;

(c) the Parent Closing Financial Certificate, a draft of which shall have been provided at least five (5) Business Days prior to the Closing, which certificate shall be accompanied by such supporting documentation, information and calculations as are reasonably requested by the Company to verify and determine the information contained therein; and

(d) a written resignation, in a form reasonably satisfactory to the Company, dated as of the Closing Date and effective as of the Effective Time, executed by each of the directors of Parent who are not to continue as directors of Parent after the Effective Time pursuant to <u>Section 5.11</u> hereof.

8.4 <u>No Parent Material Adverse Effect</u>. Since the date of this Agreement, there shall not have occurred any Parent Material Adverse Effect that is continuing.

8.5 <u>Parent Net Cash</u>. Parent Net Cash determined in accordance with <u>Section 1.6</u> shall be greater than or equal to \$18,000,000.

8.6 <u>Termination of Contracts</u>. The Company shall have received evidence, in form and substance reasonably satisfactory to it, that (a) the Specified Parent Contracts (except, for the avoidance of doubt, (i) any Parent Contracts set forth on <u>Schedule 5.12(b)(2)</u> and (ii) any other Parent Contract agreed to by Parent and Company) have been terminated, assigned, or fully performed by Parent, (b) all obligations of Parent under the Specified Parent Contracts have been fully satisfied, waived or

otherwise discharged, including as set forth on <u>Schedule 5.12(b)</u>, if applicable and (c) the Asset Disposition will be consummated substantially concurrently with the Closing.

8.7 <u>Parent Lock-Up Agreements</u>. Parent shall have received the Parent Lock-Up Agreements duly executed by each of the Parent Lock-Up Signatories, each of which shall be in full force and effect as of immediately following the Effective Time.

Section 9. TERMINATION

9.1 <u>Termination</u>. This Agreement may be terminated prior to the Effective Time (whether before or after approval of the Company Stockholder Matters by the Company's stockholders and whether before or after approval of the Parent Stockholder Matters by Parent's stockholders, unless otherwise specified below):

(a) by mutual written consent of Parent and the Company;

(b) by either Parent or the Company if the Contemplated Transactions shall not have been consummated by June 30, 2025 (subject to possible extension as provided in this <u>Section 9.1(b)</u>, the "*End Date*"); *provided*, *however*, that the right to terminate this Agreement under this <u>Section 9.1(b)</u>) shall not be available to the Company, on the one hand, or to Parent, on the other hand, if such Party's action or failure to act has been a principal cause of the failure of the Contemplated Transactions to occur on or before the End Date and such action or failure to act constitutes a breach of this Agreement, *provided, further, however*, that, in the event that the SEC has not declared the Registration Statement effective under the Securities Act by the date which is thirty (30) calendar days prior to the End Date, then Parent shall be entitled to extend the End Date for an additional sixty (60) calendar days by written notice to the Company;

(c) by either Parent or the Company if a court of competent jurisdiction or other Governmental Body shall have issued a final and nonappealable order, decree or ruling, or shall have taken any other action, having the effect of permanently restraining, enjoining or otherwise prohibiting the Contemplated Transactions;

(d) by Parent if the Company Stockholder Written Consent executed by each Company Signatory shall not have been obtained within seven (7) Business Days of the Registration Statement becoming effective in accordance with the provisions of the Securities Act; *provided*, *however*, that once the Company Stockholder Written Consent has been obtained, Parent may not terminate this Agreement pursuant to this <u>Section 9.1(d)</u>;

(e) by either Parent or the Company if (i) the Parent Stockholders' Meeting (including any adjournments and postponements thereof) shall have been held and completed and Parent's stockholders shall have taken a final vote on the Parent Stockholder Matters and (ii) the Parent Stockholder Matters shall not have been approved at the Parent Stockholders' Meeting (or at any adjournment or postponement thereof) by the Required Parent Stockholder Vote *provided, however*, that the right to terminate this Agreement under this <u>Section 9.1(e)</u> shall not be available to Parent where the failure to obtain the Required Parent Stockholder Vote shall have been caused by the action or failure to act of Parent and such action or failure to act constitutes a material breach by Parent of this Agreement;

(f) by the Company (at any time prior to the approval of the Parent Stockholder Matters by the Required Parent Stockholder Vote) if a Parent Triggering Event shall have occurred;

(g) by Parent (at any time prior to the Required Company Stockholder Vote being obtained) if a Company Triggering Event shall have occurred;

(h) by the Company, upon a breach of any representation, warranty, covenant or agreement set forth in this Agreement by Parent or Merger Sub or if any representation or warranty of Parent or Merger Sub shall have become inaccurate, in either case, such that the conditions set forth in <u>Section 8.1</u> or <u>Section 8.2</u> would not be satisfied as of the time of such breach or as of the time such representation or warranty shall have become inaccurate; *provided* that the Company is not then in material breach of any representation, warranty, covenant or agreement under this Agreement;

provided, further, that if such inaccuracy in Parent's or Merger Sub's representations and warranties or breach by Parent or Merger Sub is curable by the End Date by Parent or Merger Sub, then this Agreement shall not terminate pursuant to this <u>Section 9.1(h)</u> as a result of such particular breach or inaccuracy until the earlier of (i) the End Date and (ii) the expiration of a thirty (30) calendar day period commencing upon delivery of written notice from the Company to Parent of such breach or inaccuracy and its intention to terminate pursuant to this <u>Section 9.1(h)</u> (it being understood that this Agreement shall not terminate pursuant to this <u>Section 9.1(h)</u> as a result of such particular breach or inaccuracy if such breach by Parent or Merger Sub is cured prior to such termination becoming effective); or

(i) by Parent, upon a breach of any representation, warranty, covenant or agreement set forth in this Agreement by the Company or if any representation or warranty of the Company shall have become inaccurate, in either case, such that the conditions set forth in <u>Section 7.1</u> or <u>Section 7.2</u> would not be satisfied as of the time of such breach or as of the time such representation or warranty shall have become inaccurate; *provided* that neither Parent nor Merger Sub is then in material breach of any representation, warranty, covenant or agreement under this Agreement; *provided*, *further*, that if such inaccuracy in the Company's representations and warranties or breach by the Company is curable by the End Date by the Company then this Agreement shall not terminate pursuant to this <u>Section 9.1(i)</u> as a result of such particular breach or inaccuracy until the earlier of (i) the End Date and (ii) the expiration of a thirty (30) calendar day period commencing upon delivery of written notice from Parent to the Company of such breach or inaccuracy and its intention to terminate pursuant to this <u>Section 9.1(i)</u> as a result of such particular breach or inaccuracy if such breach or inaccuracy if such particular breach or inaccuracy and its intention to terminate pursuant to this <u>Section 9.1(i)</u> as a result of such particular breach or inaccuracy if such breach by the Company is cured prior to such termination becoming effective).

The Party desiring to terminate this Agreement pursuant to this <u>Section 9.1</u>, shall give the other Party written notice of such termination, specifying the provisions hereof pursuant to which such termination is made and the basis therefor described in reasonable detail.

9.2 Effect of Termination. In the event of the termination of this Agreement as provided in Section 9.1, this Agreement shall be of no further force or effect; *provided*, *however*, that (a) this Section 9.2, Section 5.8, Section 9.3, Section 10 and the definitions of the defined terms in such Sections (including the definitions of such defined terms set forth in Exhibit A) shall survive the termination of this Agreement and shall remain in full force and effect following such termination, and (b) the termination of this Agreement and the provisions of <u>Section 9.3</u> shall not relieve any Party of any liability for fraud or for any willful and material breach of any representation, warranty, covenant, obligation or other provision contained in this Agreement.

9.3 Expenses; Termination Fees.

(a) Except as set forth in this <u>Section 9.3</u>, <u>Section 1.6(e)</u> and <u>Section 5.9</u>, the Transaction Expenses shall be paid by the Party incurring such expenses, whether or not the Merger is consummated; *provided* that Parent and the Company shall each pay 50% of all fees and expenses incurred in relation to (i) the printing and filing with the SEC of the Registration Statement and Proxy Statement and any amendments and supplements thereto and paid to a financial printer or the SEC, and (ii) the proxy solicitation firm engaged in connection with the Parent Stockholders' Meeting. It is understood and agreed that all fees and expenses incurred or to be incurred by or payable by the Company in connection with the Contemplated Transactions and preparing, negotiating and entering into this Agreement and the performance of its obligations under this Agreement shall be paid by the Company in cash at or prior to the Closing.

(b) If:

(i) (A) this Agreement is terminated pursuant to <u>Section 9.1(b)</u>, <u>Section 9.1(e)</u> or <u>Section 9.1(h)</u>, (B) an Acquisition Proposal with respect to Parent shall have been publicly announced, disclosed or otherwise communicated to Parent or the Parent Board at any time after the date of this Agreement but prior to the termination of this Agreement (which shall not have been withdrawn) and (C) within twelve (12) months after the date of such termination,

Parent enters into a definitive agreement with respect to a Subsequent Transaction or consummates a Subsequent Transaction in respect of the Acquisition Proposal referred to in clause (B) or in respect of any other Acquisition Proposal; or

(ii) this Agreement is terminated by the Company pursuant to Section 9.1(f) (or, at the time this Agreement is terminated, the Company had the right to terminate this Agreement pursuant to Section 9.1(f));

then Parent shall pay to the Company a nonrefundable fee in an amount equal to \$2,250,000 (the "*Company Termination Fee*"), in the case of <u>Section 9.3(b)(i)</u>, upon the consummation of such Subsequent Transaction or, in the case of <u>Section 9.3(b)(ii)</u>, concurrently with the termination of this Agreement plus any amount payable to the Company pursuant to <u>Section 9.3(f)</u>.

(c) If:

(i) (A) this Agreement is terminated pursuant to <u>Section 9.1(b)</u>, <u>Section 9.1(d)</u>, or <u>Section 9.1(i)</u>, (B) an Acquisition Proposal with respect to the Company shall have been publicly announced, disclosed or otherwise communicated to the Company or the Company Board at any time after the date of this Agreement but prior to obtaining the Required Company Stockholder Vote (which shall not have been withdrawn, (1) in the case of a termination pursuant to <u>Section 9.1(b)</u> or <u>Section 9.1(i)</u>, at the time the Required Company Stockholder Vote is obtained and (2) in the case of a termination pursuant to <u>Section 9.1(d)</u>, at the time of such termination) and (C) within twelve (12) months after the date of such termination, the Company enters into a definitive agreement with respect to a Subsequent Transaction or consummates a Subsequent Transaction in respect of the Acquisition Proposal referred to in clause (B) or in respect of any other Acquisition Proposal; or

(ii) this Agreement is terminated by Parent pursuant to <u>Section 9.1(g)</u> (or, at the time this Agreement is terminated, Parent had the right to terminate this Agreement pursuant to <u>Section 9.1(g)</u>);

then the Company shall pay to Parent an amount equal to 2,250,000 (the "*Parent Termination Fee*"), in the case of <u>Section 9.3(c)(i)</u>, upon the consummation of such Subsequent Transaction or, in the case of <u>Section 9.3(c)(i)</u>, concurrently with the termination of this Agreement, plus any amount payable to Parent pursuant to <u>Section 9.3(f)</u>.

(d) (i) If this Agreement is terminated pursuant to Section 9.1(e), Section 9.1(f), or Section 9.1(h) or (ii) in the event of the failure of the Company to consummate the transactions to be contemplated at the Closing solely as a result of a Parent Material Adverse Effect as set forth in Section 8.4 (provided, that at such time all of the other conditions precedent to Parent's obligation to close set forth in Section 6 and Section 7 have been satisfied by the Company, are capable of being satisfied by the Company or have been waived by Parent), then Parent shall reimburse the Company for all reasonable out-of-pocket fees and expenses incurred by the Company in connection with this Agreement and the Contemplated Transactions (such expenses, collectively, the "Third Party Expenses"), up to a maximum of \$750,000, by wire transfer of same-day funds within ten (10) Business Days following the date on which the Company submits to Parent true and correct copies of reasonable documentation supporting such Third Party Expenses; provided, however, that such Third Party Expenses shall not include any amounts for financial advisors to the Company except for reasonably documented out-of-pocket expenses otherwise reimbursable by the Company to such financial advisors pursuant to the terms of the Company's engagement letter or similar arrangement with such financial advisors. For the avoidance of doubt, to the extent any Third Party Expenses are paid, such amounts shall be credited against any Company Termination Fee which becomes payable thereafter.

(e) (i) If this Agreement is terminated pursuant to Section 9.1(d), Section 9.1(g), or Section 9.1(i) or (ii) in the event of the failure of Parent to consummate the transactions to be consummated to the Closing solely as a result of a Company Material Adverse Effect as set forth in Section 7.5 provided, that at such time all of the other conditions precedent to the Company's obligation to close set forth in Section 6 and Section 8 have been satisfied by Parent are capable

of being satisfied by Parent or have been waived by the Company, the Company shall reimburse Parent for all Third Party Expenses incurred by Parent up to a maximum of \$750,000, by wire transfer of same-day funds within ten (10) Business Days following the date on which Parent submits to the Company true and correct copies of reasonable documentation supporting such Third Party Expenses; *provided, however*, that such Third Party Expenses shall not include any amounts for financial advisors to Parent except for reasonably documented out-of-pocket expenses otherwise reimbursable by Parent to such financial advisors pursuant to the terms of Parent's engagement letter or similar arrangement with such financial advisors. For the avoidance of doubt, to the extent any Third Party Expenses are paid, such amounts shall be credited against any Parent Termination Fee which becomes payable thereafter.

(f) Any Company Termination Fee or Parent Termination Fee due under this <u>Section 9.3</u> shall be paid by wire transfer of same day funds. If a Party fails to pay when due any amount payable by it under this <u>Section 9.3</u>, then (i) such Party shall reimburse the other Party for reasonable out-of-pocket costs and expenses (including reasonable and out-of-pocket fees and disbursements of counsel) incurred in connection with the collection of such overdue amount and the enforcement by the other Party of its rights under this <u>Section 9.3</u>, and (ii) such Party shall pay to the other Party interest on such overdue amount (for the period commencing as of the date such overdue amount is actually paid to the other Party in full) at a rate per annum equal to the "prime rate" (as published in *The Wall Street Journal* or any successor thereto) in effect on the date such overdue amount was originally required to be paid plus three percent (3%).

(g) The Parties agree that, (i) subject to Section 9.2, payment of the Company Termination Fee shall, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of the Company following the termination of this Agreement under the circumstances described in Section 9.3(b), it being understood that in no event shall Parent be required to pay the amounts payable pursuant to this Section 9.3 on more than one occasion and (ii) following payment of the Company Termination Fee (x) Parent shall have no further liability to the Company in connection with or arising out of this Agreement or the termination thereof, any breach of this Agreement by Parent giving rise to such termination, or the failure of the Contemplated Transactions to be consummated, (y) neither the Company nor any of its Affiliates shall be entitled to bring or maintain any other claim, action or proceeding against Parent or Merger Sub or seek to obtain any recovery, judgment or damages of any kind against such Parties (or any partner, member, stockholder, director, officer, employee, Subsidiary, Affiliate, agent or other Representative of such Parties) in connection with or arising out of this Agreement or the termination thereof, any breach by any such Parties giving rise to such termination or the failure of the Contemplated Transactions to be consummated and (z) the Company and its Affiliates shall be precluded from any other remedy against Parent, Merger Sub and their respective Affiliates, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such Party giving rise to such termination or the failure of the Contemplated Transactions to be consummated; provided, however, that nothing in this Section 9.3(g) shall limit the rights of Parent and Merger Sub under Section 10.11.

(h) The Parties agree that, (i) subject to Section 9.2, payment of the Parent Termination Fee shall, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of Parent following the termination of this Agreement under the circumstances described in Section 9.3(c), it being understood that in no event shall the Company be required to pay the amounts payable pursuant to this Section 9.3 on more than one occasion and (ii) following payment of the Parent Termination Fee (x) the Company shall have no further liability to Parent in connection with or arising out of this Agreement or the termination, or the failure of the Contemplated Transactions to be consummated, (y) neither Parent nor any of its Affiliates shall be entitled to bring or maintain any other claim, action or proceeding against the Company or seek to obtain any recovery, judgment or damages of any kind against the Company (or any partner, member, stockholder, director, officer, employee, Subsidiary, Affiliate, agent or other Representative of the Company) in connection with or arising out of this Agreement or the

termination thereof, any breach by the Company giving rise to such termination or the failure of the Contemplated Transactions to be consummated and (z) Parent and its Affiliates shall be precluded from any other remedy against the Company and its Affiliates, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such Party giving rise to such termination or the failure of the Contemplated Transactions to be consummated; *provided, however*, that nothing in this <u>Section 9.3(h)</u> shall limit the rights of the Company under <u>Section 10.11</u>.

(i) Each of the Parties acknowledges that (i) the agreements contained in this <u>Section 9.3</u> are an integral part of the Contemplated Transactions, (ii) without these agreements, the Parties would not enter into this Agreement and (iii) any amount payable pursuant to this <u>Section 9.3</u> is not a penalty, but rather is liquidated damages in a reasonable amount that will compensate the applicable Party in the circumstances in which such amount is payable.

Section 10. MISCELLANEOUS PROVISIONS

10.1 <u>Non-Survival of Representations and Warranties</u>. The representations, warranties and covenants of the Company, Parent and Merger Sub contained in this Agreement or any certificate or instrument delivered pursuant to this Agreement shall terminate at the Effective Time, and only the covenants that by their terms survive the Effective Time and this <u>Section 10</u> shall survive the Effective Time.

10.2 <u>Amendment</u>. This Agreement may be amended with the approval of the Company, Merger Sub and Parent at any time (whether before or after obtaining the Required Company Stockholder Vote or before or after obtaining the Required Parent Stockholder Vote); *provided, however*, that after any such approval of this Agreement by a Party's stockholders, no amendment shall be made which by Law requires further approval of such stockholders without the further approval of such stockholders. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the Company, Merger Sub and Parent.

10.3 <u>Waiver</u>.

(a) No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(b) No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

10.4 Entire Agreement; Counterparts; Exchanges by Electronic Transmission. This Agreement, the Company Disclosure Schedule, the Parent Disclosure Schedule and the other agreements referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; *provided, however*, that the Confidentiality Agreement shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by electronic transmission in PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

10.5 <u>Applicable Law; Jurisdiction; WAIVER OF JURY TRIAL</u>. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws. In any action or proceeding between any of the Parties arising out of or relating to this Agreement or any of the

Contemplated Transactions, each of the Parties: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 10.5; (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any Party; (e) agrees that service of process upon such Party in any such action or proceeding shall be effective if notice is given in accordance with Section 10.8 of this Agreement; and (f) IRREVOCABLY AND UNCONDITIONALLY WAIVES THE RIGHT TO TRIAL BY JURY.

10.6 <u>Attorneys' Fees</u>. In any action at law or suit in equity to enforce this Agreement or the rights of any of the Parties, the prevailing Party in such action or suit (as determined by a court of competent jurisdiction) shall be entitled to recover its reasonable out-of-pocket attorneys' fees and all other reasonable costs and expenses incurred in such action or suit.

10.7 <u>Assignability</u>. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and permitted assigns; *provided*, *however*, that neither this Agreement nor any of a Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect.

10.8 <u>Notices</u>. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, (b) upon delivery in the case of delivery by hand, or (c) on the date delivered in the place of delivery if sent by email (provided that no bounceback or similar "undeliverable" message is received by such sender) prior to 5:00 p.m. Eastern Time, otherwise on the next succeeding Business Day, in each case to the intended recipient as set forth below:

if to Parent or Merger Sub:

Cara Therapeutics, Inc. 400 Atlantic Street, Suite 500 Stamford, Connecticut 06901 Attention: Scott Terrillion, Esq. Email: [***]

with a copy to (which shall not constitute notice):

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. 919 Third Avenue New York, NY 10012 Attention: Daniel Bagliebter; Kenneth Koch Email: [***]

if to the Company:

Tvardi Therapeutics, Inc. 3 Sugar Creek Ctr. Blvd. Ste. 525 Sugar Land, TX 77478 Attention: Legal Department Email: [***] with a copy to (which shall not constitute notice):

Cooley LLP 10265 Science Center Dr San Diego, CA 92121 Attention: Rama Padmanabhan Email: [***]

10.9 <u>Cooperation</u>. Each Party agrees to cooperate fully with the other Party and to execute and deliver such further documents, certificates, agreements and instruments and to take such other actions as may be reasonably requested by the other Party to evidence or reflect the Contemplated Transactions and to carry out the intent and purposes of this Agreement.

10.10 <u>Severability</u>. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

10.11 Other Remedies; Specific Performance. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. The Parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that any Party does not perform the provisions of this Agreement (including failing to take such actions as are required of it hereunder to consummate this Agreement) in accordance with their specified terms or otherwise breaches such provisions. Accordingly, the Parties acknowledge and agree that the Parties shall be entitled to an injunction, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof in any court of the United States or any state thereof having jurisdiction, in addition to any other remedy to which they are entitled at law or in equity. Each of the Parties agrees that it will not oppose the granting of an injunction, specific performance or other equitable relief on the basis that any other Party has an adequate remedy at law or that any award of specific performance is not an appropriate remedy for any reason at law or in equity. Any Party seeking an injunction or injunctions to prevent breaches of this Agreement shall not be required to provide any bond, surety or other security in connection with any such order or injunction.

10.12 <u>No Third Party Beneficiaries</u>. Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person (other than the Parties and the D&O Indemnified Parties to the extent of their respective rights pursuant to <u>Section 5.6</u>) any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.13 Construction.

(a) References to "cash," "dollars" or "\$" are to U.S. dollars.

(b) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(c) The Parties have participated jointly in the negotiating and drafting of this Agreement and agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

(d) As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation."

(e) As used in this Agreement, the word "extent" in the phrase "to the extent" means the degree to which a subject extends and does not simply mean "if."

(f) As used in this Agreement, the word "or" shall not be exclusive (*i.e.*, "or" shall be deemed to mean "and/or").

(g) Except as otherwise indicated, all references in this Agreement to "Sections," "Exhibits" and "Schedules" are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement, respectively.

(h) Any reference to legislation or to any provision of any legislation shall include any modification, amendment, re-enactment thereof, any legislative provision substituted therefore and all rules, regulations, and statutory instruments issued or related to such legislations.

(i) The bold-faced headings and table of contents contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

(j) The Parties agree that each of the Company Disclosure Schedule and the Parent Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Agreement. The disclosures in any section or subsection of the Company Disclosure Schedule or the Parent Disclosure Schedule shall qualify other sections and subsections in this Agreement to the extent it is readily apparent on its face from a reading of the disclosure that such disclosure is applicable to such other sections and subsections.

(k) Each of "delivered" or "made available" means, with respect to any documentation, that prior to 11:59 p.m. Eastern Time on the date that is two (2) calendar days prior to the date of this Agreement (i) a copy of such material has been posted to and made available by a Party to the other Party and its Representatives in the electronic data room maintained by such disclosing Party or (ii) such material is disclosed in the Parent SEC Documents filed with the SEC prior to the date hereof and publicly made available on the SEC's Electronic Data Gathering Analysis and Retrieval system.

(1) Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall upon a Saturday, Sunday, or any date on which banks in New York, New York are authorized or obligated by Law to be closed, the Party having such privilege or duty may exercise such privilege or discharge such duty on the next succeeding day which is a regular Business Day.

(m) Unless otherwise indicated, (i) when calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period will be excluded; (ii) if the last day of such period is not a Business Day, then the period in question will end on the next Business Day; (iii) if any action (other than any action described in <u>Section 5.4</u>) must be taken on or by a day that is not a Business Day, then such action may be validly taken on or by the next day that is a Business Day; (iv) the measure of a period of one month or year for purposes of this Agreement will be the day of the following month or year corresponding to the starting date; and (v) if no corresponding date exists, then the end date of such period being measured will be the next actual day of the

following month or year (for example, one month following February 18 is March 18 and one month following March 31 is May 1). References to "from" or "through" any date mean, unless otherwise specified, from and including or through and including such date, respectively.

10.14 Defined Terms Defined Elsewhere.

Term	Section
2025 ESPP	5.19
2025 Plan	5.19
Accounting Firm	1.6(e)
Agreement	Preamble
Allocation Certificate	5.15(a)
Anti-Bribery Laws	2.23
Anticipated Closing Date	1.6(a)
Asset Disposition(s)	4.7
Certificate of Merger	1.3
Certifications	3.7(a)
Closing	1.3
Closing Date	1.3
Company	Preamble
Company Benefit Plan	2.17(a)
Company Board Adverse Recommendation Change	5.2(d)
Company Board Recommendation	5.2(d)
Company Budget	4.2(b)(v)
Company Disclosure Schedule	Section 2
Company Financials	2.7(a)
Company In-Licensed IP	2.12(b)
Company In-bound License	2.12(d)
Company Lock-Up Agreement	Recitals
Company Lock-Up Signatories	Recitals
Company Material Contract	2.13(a)
Company Material Contracts	2.13(a)
Company Out-bound License	2.12(d)
Company Owned Registered IP	2.12(a)
Company Permits	2.14(b)
Company Real Estate Leases	2.11
Company Stock Certificate	1.7
Company Stockholder Matters	5.2(a)
Company Stockholder Support Agreement	Recitals
Company Stockholder Written Consent(s)	Recitals
Company Termination Fee	9.3(b)
Determination Notice	5.3(d)(i)
Dispute Notice	1.6(b)
Dissenting Shares	1.9(a)
D&O Indemnified Parties	5.6(a)
Drug Regulatory Agency	2.14(a)
Effective Time	1.3
End Date	9.1(b)
Equity Plan Proposals	5.19
Exchange Agent	1.8(a)

Term	Section
Exchange Fund	1.8(a)
FDA	2.14(a)
FDCA	2.14(a)
Information Statement	5.2(a)
Intended Tax Treatment	5.10(a)
Investor Agreements	2.22(b)
Liability	2.9
Merger	Recitals
Merger Sub	Preamble
Nasdaq Listing Application	5.9
Net Cash Calculation	1.6(a)
Net Cash Schedule	1.6(a)
Parent	Preamble
Parent Benefit Plan	3.17(a)
Parent Board Adverse Recommendation Change	5.3(c)
Parent Board Recommendation	5.3(c)
Parent Designees	5.11
Parent Disclosure Schedule	3
Parent In-bound License	3.12(d)
Parent Lock-Up Agreement	Recitals
Parent Material Contract	3.13(a)
Parent Material Contracts	3.13(a)
Parent Notice Period	5.3(d)(i)
Parent Out-bound License	3.12(d)
Parent Outstanding Shares Certificate	5.15(b)
Parent Owned Registered IP	3.12(a)
Parent Permits	3.14(b)
Parent SEC Documents	3.7(a)
Parent Share Issuance	5.3(a)(ii)
Parent Stockholder Matters	5.3(a)(viii)
Parent Stockholders' Meeting	5.3(a)(viii)
Parent Stockholder Support Agreement	Recitals
Parent Termination Fee	9.3(c)
Pre-Closing Period	4.1(a)
Regulation M-A Filing	2.21
Required Company Stockholder Vote	2.4
Required Parent Stockholder Vote	3.4
Response Date	1.6(b)
Sensitive Data	2.12(g)
Specified Parent Contracts	5.12(b)
Stockholder Notice	5.2(c)
Surviving Corporation	1.1
Tax Opinion	5.1(c)
Third Party Expenses	9.3(d)

[Signature pages follow]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first above written.

CARA THERAPEUTICS, INC.

By: /s/ Christopher Posner

Name: Christopher Posner Title: President and Chief Executive Officer

CT CONVERGENCE MERGER SUB, INC.

By: /s/ Christopher Posner

Name:Christopher PosnerTitle:President and Chief Executive Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first above written.

TVARDI THERAPEUTICS, INC.

By: /s/ Imran Alibhai, Ph.D.

Name: Imran Alibhai, Ph.D. Title: Chief Executive Officer

EXHIBIT A

CERTAIN DEFINITIONS

For purposes of this Agreement (including this Exhibit A):

"Acquisition Inquiry" means, with respect to a Party, an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by the Company or any of its Affiliates, on the one hand, or Parent or any of its Affiliates, on the other hand, to the other Party) that could reasonably be expected to lead to an Acquisition Proposal; *provided, however*, that the term "Acquisition Inquiry" shall not include the Merger or the other Contemplated Transactions or any transactions related to the Asset Dispositions.

"Acquisition Proposal" means, with respect to a Party, any offer or proposal, whether written or oral (other than an offer or proposal made or submitted by or on behalf of the Company or any of its Affiliates, on the one hand, or by or on behalf of Parent or any of its Affiliates, on the other hand, to the other Party) contemplating or otherwise relating to any Acquisition Transaction with such Party, other than the Asset Dispositions.

"*Acquisition Transaction*" means any transaction or series of related transactions (other than the Asset Dispositions) involving:

any merger, consolidation, amalgamation, share exchange, business combination, issuance of securities, acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or other similar transaction: (i) in which a Party is a constituent entity; (ii) in which a Person or "group" (as defined in the Exchange Act) of Persons directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of a Party or any of its Subsidiaries; or (iii) in which a Party or any of its Subsidiaries; or securities of any class of voting securities of any class of voting securities of such Party or any of its Subsidiaries; *provided*, *however*, that the Bridge Note Conversion shall not be, nor shall securities to be acquired thereby, be deemed or trigger an "Acquisition Transaction"; or

any sale, lease, exchange, transfer, license, acquisition or disposition of any business or businesses or assets that constitute or account for 20% or more of the consolidated book value or the fair market value of the assets of a Party and its Subsidiaries, taken as a whole.

"Affiliate" means, with respect to a Person, any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the corollary terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by Contract or otherwise.

"*Agreement*" means the Agreement and Plan of Merger and Reorganization to which this **Exhibit A** is attached, as it may be amended from time to time.

"Authorized Share Increase" means an amendment to Parent's amended and restated certificate of incorporation to increase the number of authorized shares of Parent Common Stock.

"*Bridge Note Conversion*" means the automatic conversion of the Bridge Notes and any other outstanding convertible notes of the Company into shares of Parent Common Stock at the Effective Time in accordance with the relevant provisions of the Bridge Notes.

"Business Day" means any day other than a Saturday, Sunday or other day on which banks in New York, New York are authorized or obligated by Law to be closed.

"*Cash and Cash Equivalents*" means cash, currency, and cash equivalents as determined in accordance with GAAP, including (a) all cash and cash equivalents in deposit accounts or other similar accounts, (b) marketable securities with maturities of three (3) months or less, (c) checks, money orders, and other negotiable instruments, and (d) cash in transit. Cash and Cash Equivalents shall be

net of the amount of any outstanding checks or other payment obligations that have been issued but not yet cleared. For the avoidance of doubt, "Cash and Cash Equivalents" excludes any restricted cash, escrowed amounts, or amounts held as collateral for obligations, including letters of credit and performance bonds.

"Code" means the Internal Revenue Code of 1986.

"*Company Associate*" means any current or former employee, independent contractor, officer or director of the Company.

"Company Board" means the board of directors of the Company.

"Company Capital Stock" means the Company Common Stock and the Company Preferred Stock.

"Company Common Stock" means the Common Stock, \$0.001 par value per share, of the Company.

"*Company Contract*" means any Contract: (a) to which the Company is a party; (b) by which the Company or any Company IP or any other asset of the Company is or may become bound or under which the Company or any of its Subsidiaries has, or may become subject to, any obligation; or (c) under which the Company has or may acquire any right or interest.

"*Company ERISA Affiliate*" means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with the Company as a single employer within the meaning of Section 414 of the Code.

"*Company Fundamental Representations*" means the representations and warranties of the Company set forth in <u>Sections 2.1</u> (*Due Organization; Subsidiaries*), <u>2.3</u> (*Authority; Binding Nature of Agreement*), <u>2.4</u> (*Vote Required*), <u>2.6(a)</u> and (c) (*Capitalization*) and <u>2.20</u> (*No Financial Advisors*).

"*Company IP*" means all Intellectual Property Rights that are owned or co-owned or purported to be owned or co-owned by the Company.

"Company Material Adverse Effect" means any Effect that, considered together with all other Effects, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities or results of operations of the Company, taken as a whole; provided, however, that any Effect, individually or together with other Effects, arising or resulting from the following shall not be taken into account in determining whether there has been a Company Material Adverse Effect: (a) general business, political, or economic conditions generally affecting the industry in which the Company operates; (b) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions; (c) changes in financial, banking or securities markets; (d) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP); (e) the announcement of this Agreement or the pendency of the Contemplated Transactions; (f) resulting from the taking of any action expressly required to be taken by this Agreement; or (g) continued losses from operations or decreases in cash balances of the Company; except, with respect to clauses (a) through (d), to the extent such Effect disproportionately affects the Company, taken as a whole, relative to other similarly situated companies in the industries in which the Company operate, in which case, such Effect shall be taken into account to the extent of such disproportionate effect on the Company.

"*Company Option*" means any option or other right to purchase shares of Company Capital Stock issued by the Company.

"*Company Preferred Stock*" means the Series A Preferred Stock, \$0.001 par value per share, and the Series B Preferred Stock, \$0.001 par value per share, of the Company.

"*Company Signatories*" means the officers, directors and stockholders of the Company set forth on Schedule A hereto.

"Company Triggering Event" shall be deemed to have occurred if: (a) the Company Board shall have made a Company Board Adverse Recommendation Change; (b) the Company Board or any committee thereof shall have publicly approved, endorsed or recommended any Acquisition Proposal; or (c) following the date of this Agreement, the Company shall have entered into any letter of intent or similar document or any Contract relating to any Acquisition Proposal.

"*Company Unaudited Interim Balance Sheet*" means the unaudited consolidated balance sheet of the Company for the period ended September 30, 2024 provided to Parent prior to the date of this Agreement.

"*Company's Knowledge*" means the actual knowledge of Imran Alibhai, Ph.D., Dan Conn and John Kauh and such knowledge as such Persons would reasonably be expected to have obtained in the course of their performance of their duties to the Company (after due inquiry). With respect to matters involving Intellectual Property Rights, knowledge requires consultation with external intellectual property counsel but does not require that such Persons conduct or have conducted or obtain or have obtained any freedom-to-operate opinions or similar opinions of counsel or any intellectual property clearance searches, and no knowledge of any third party intellectual property that would have been revealed by such inquiries, opinions or searches will be imputed to such Persons.

"*Confidentiality Agreement*" means the Non-Disclosure Agreement, dated as of July 28, 2024, by and between the Company and Parent.

"*Consent*" means any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

"*Contemplated Transactions*" means the Merger and the other transactions and actions contemplated by this Agreement, including the Bridge Note Conversion, the Nasdaq Reverse Split and the Asset Dispositions.

"*Contract*" means, with respect to any Person, any agreement, contract, subcontract, lease (whether for real or personal property), mortgage, license, sublicense or other legally binding commitment or undertaking of any nature to which such Person is a party or by which such Person or any of its assets are bound or affected under applicable Law.

"COVID-19" means the novel coronavirus (SARS-CoV-2) and related variants thereof.

"*CSL Asset Purchase Agreement*" means that certain Asset Purchase Agreement by and among Parent, Cara Royalty Sub, LLC and Vifor Fresenius Medical Care Renal Pharma, Ltd, dated as of December 17, 2024.

"DGCL" means the General Corporation Law of the State of Delaware.

"Effect" means any effect, change, event, circumstance or development.

"*Encumbrance*" means any lien, pledge, hypothecation, charge, mortgage, security interest, lease, license, option, easement, reservation, servitude, adverse title, claim, infringement, interference, option, right of first refusal, preemptive right, community property interest or restriction or encumbrance of any nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

"Enforceability Exceptions" means the (a) Laws of general application relating to bankruptcy, insolvency and the relief of debtors; and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

"*Entity*" means any corporation (including any non-profit corporation), partnership (including any general partnership, limited partnership or limited liability partnership), joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity, and each of its successors.

"Environmental Law" means any federal, state, local or foreign Law relating to pollution or protection of human health or the environment (including ambient air, surface water, ground water, land surface or subsurface strata), including any Law or regulation relating to emissions, discharges, releases or threatened releases of Hazardous Materials, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials.

"ERISA" means the Employee Retirement Income Security Act of 1974.

"Exchange Act" means the Securities Exchange Act of 1934.

"*Exchange Ratio*" means, subject to Section 1.5(f), the following ratio (rounded to four decimal places): the quotient obtained by *dividing* (a) the Company Merger Shares by (b) the Company Outstanding Shares, in which:

- "Aggregate Convertible Note Valuation" means the aggregate principal amount of the Bridge Notes plus all accrued and unpaid interest.
- "*Aggregate Post-Bridge Valuation*" means the sum of (i) the Company Valuation, *plus* (ii) the Parent Valuation *plus* (iii) the Implied Note Valuation.
- "*Aggregate Valuation*" means the sum of (i) the Company Valuation, *plus* (ii) the Parent Valuation *plus* (iii) the Aggregate Convertible Note Valuation.
- "Company Allocation Percentage" means 1.00 minus the Parent Allocation Percentage.
- "Company Merger Shares" means the Total Company Merger Shares less the Conversion Shares.
- "Company Valuation" means \$210,000,000.
- "Company Outstanding Shares" means the total number of shares of Company Capital Stock outstanding immediately prior to the Effective Time, after giving effect to the Preferred Stock Conversion and excluding any Conversion Shares, expressed on a fully diluted and as-converted to Company Common Stock basis, expressed on a fully-diluted and as-converted to Company Common Stock basis and using the treasury stock method, but assuming, without limitation or duplication, (i) the exercise of all Company Options outstanding as of immediately prior to the Effective Time, and (ii) the issuance of shares of Company Capital Stock in respect of all other outstanding options, restricted stock awards, restricted stock units, warrants or rights to receive such shares, whether conditional or unconditional and including any outstanding options, warrants, restricted stock awards, restricted stock units or rights triggered by or associated with the consummation of the Merger (but excluding any shares of Company Capital Stock reserved for issuance other than with respect to outstanding Company Options under the Company Plan as of immediately prior to the Effective Time).
- "*Conversion Shares*" means the product obtained by multiplying (a) the Post-Closing Parent Shares *by* (b) the quotient obtained by *dividing* (i) the Implied Note Valuation *by* (ii) the Aggregate Post-Bridge Valuation.
- "*Implied Note Valuation*" means the quotient obtained by *dividing* (a) (i) the principal amount of the Bridge Notes *plus* (ii) all accrued and unpaid interest *by* (b) 80%.
- "Parent Allocation Percentage" means the Parent Valuation divided by the Aggregate Valuation.
- "Parent Equity Value" means \$20,000,000.
- "Parent Outstanding Shares" means, subject to Section 1.5(f) (that addresses, among other things, the possibility to effect the Nasdaq Reverse Split) and the immediately following sentence, the total number of shares of Parent Common Stock outstanding immediately prior to the Effective Time, but excluding any Conversion Shares, expressed on a fully-diluted basis and using the treasury stock method (and shall include, for the avoidance of doubt, all In the Money Parent Options), but assuming, without limitation or duplication, the issuance of shares of Parent Common Stock in respect of all Parent Options, Parent RSUs and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the

Effective Time (assuming cashless exercise), whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger (but excluding any shares of Parent Common Stock reserved for issuance other than with respect to outstanding Parent Options and Parent RSUs as of immediately prior to the Effective Time and as set forth above) and assuming issuance of such shares on a per share basis assuming the Aggregate Post-Bridge Valuation. For the avoidance of doubt, no Out-of-the-Money Parent Options shall be included in the total number of shares of Parent Common Stock outstanding for purposes of determining the Parent Outstanding Shares.

- "*Parent Valuation*" means (i) if Parent Net Cash is greater than \$23,125,000, the sum of (w) the Parent Equity Value plus (x) \$23,000,000 plus (y) the amount by which Parent Net Cash exceeds \$23,125,000, (ii) if Parent Net Cash is greater than or equal to \$22,875,000 but less than or equal to \$23,125,000, the sum of (x) the Parent Equity Value plus (y) \$23,000,000, or (iii) if Parent Net Cash is less than \$22,875,000, the sum of (w) the Parent Equity Value plus (x) \$23,000,000 minus (y) the amount by which \$22,875,000 exceeds Parent Net Cash.
- "*Post-Closing Parent Shares*" means the quotient obtained by *dividing* the Parent Outstanding Shares *by* the Parent Allocation Percentage.
- *"Total Company Merger Shares"* means the product determined by *multiplying* (a) the Post-Closing Parent Shares *by* (b) the Company Allocation Percentage.

Set forth on <u>Schedule I</u> is an illustrative example of Exchange Ratio calculations as of the date of this Agreement.

"*GAAP*" means generally accepted accounting principles and practices in effect from time to time within the United States applied consistently throughout the period involved.

"Governmental Authorization" means any: (a) permit, license, certificate, franchise, permission, variance, exception, order, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Law; or (b) right under any Contract with any Governmental Body.

"Governmental Body" means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, bureau, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any taxing authority); or (d) self-regulatory organization (including Nasdaq).

"*Hazardous Material*" means any pollutant, chemical, substance and any toxic, infectious, carcinogenic, reactive, corrosive, ignitable or flammable chemical, or chemical compound, or hazardous substance, material or waste, whether solid, liquid or gas, that is subject to regulation, control or remediation under any Environmental Law, including crude oil or any fraction thereof and any petroleum product or by-product.

"Intellectual Property Rights" means all past, present, and future rights, titles, and interests of the following types, which may exist or be created under the laws of any jurisdiction in the world: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, software, databases, and mask works; (b) trademarks, service marks, trade dress, logos, trade names and other source identifiers, domain names and URLs and similar rights and any goodwill associated therewith; (c) rights associated with trade secrets, know how, inventions, invention disclosures, methods, processes, protocols, specifications, techniques and other forms of technology; (d) patents and industrial property rights; and (e) other similar proprietary rights in intellectual property of every kind and nature; (f) rights of privacy and publicity; and (g) all registrations, renewals, extensions, statutory invention registrations, provisionals, continuations, continuations-in-part, divisions, or reissues of, and applications for, any of the rights referred to in clauses (a) through (f) (whether or not in tangible form and including all tangible embodiments of any of the foregoing, such as samples, studies and summaries), along with all rights to prosecute and perfect the same through administrative prosecution,

registration, recordation or other administrative proceeding, and all causes of action and rights to sue or seek other remedies arising from or relating to the foregoing.

"*In the Money Parent Options*" shall mean any Parent Options with an exercise price less than or equal to \$0.66 (subject to adjustment to reflect any stock split, division or subdivision of shares, stock dividend, reverse stock split, consolidation of shares, reclassification, recapitalization or other similar transaction with respect to Parent Common Stock).

"IRS" means the United States Internal Revenue Service.

"*Law*" means any federal, state, national, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of Nasdaq or the Financial Industry Regulatory Authority).

"*Legal Proceeding*" means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Body or any arbitrator or arbitration panel.

"Merger Consideration" means, on a per share basis, the number of shares of Parent Common Stock (and cash in lieu of any fractional shares of Parent Common Stock) issuable in exchange for each share of Company Capital Stock, as applicable, in accordance with <u>Section 1.5(a)</u>.

"Merger Sub Board" means the board of directors of Merger Sub.

"*Nasdaq*" means the Nasdaq Stock Market, including the Nasdaq Global Select Market or such other Nasdaq market on which shares of Parent Common Stock are then listed.

"*Nasdaq Reverse Split*" means a reverse stock split of all outstanding shares of Parent Common Stock at a reverse stock split ratio in the range of 1:2 to 1:12 or as otherwise mutually agreed to by Parent and the Company that is effected by Parent for the purpose of maintaining compliance with Nasdaq listing standards.

"Ordinary Course of Business" means, in the case of each of the Company and Parent, such actions taken in the ordinary course of its and its Subsidiaries' normal operations and consistent with its and its Subsidiaries' past practices and the Ordinary Course of Business of Parent shall also include actions required to effect the Asset Dispositions or effect the winding down of Parent's prior research and development activities (including the termination of ongoing contractual obligations relating to Parent's current products or product candidates).

"Organizational Documents" means, with respect to any Person (other than an individual), (a) the certificate or articles of association or incorporation or organization or limited partnership or limited liability company, and any joint venture, limited liability company, operating or partnership agreement and other similar documents adopted or filed in connection with the creation, formation or organization of such Person and (b) all bylaws, regulations and similar documents or agreements relating to the organization or governance of such Person, in each case, as amended or supplemented.

"Out of the Money Parent Options or Parent Warrants" shall mean Parent Options with an exercise price greater than \$0.66 (subject to adjustment to reflect any stock split, division or subdivision of shares, stock dividend, reverse stock split, consolidation of shares, reclassification, recapitalization or other similar transaction with respect to Parent Common Stock).

"*Pandemic Response Laws*" means the Coronavirus Aid, Relief, and Economic Security Act, the Families First Coronavirus Response Act, the COVID-related Tax Relief Act of 2020, the Presidential Memorandum on Deferring Payroll Tax Obligations in Light of the Ongoing COVID-19 Disaster (as issued on August 8, 2020 and including any administrative or other guidance published with respect thereto by any Tax authority (including IRS Notice 2020-65)), and any other similar or additional U.S.

federal, state, or local or non-U.S. Law, or administrative guidance intended to benefit taxpayers in response to the COVID-19 pandemic and associated economic downturn.

"*Parent Associate*" means any current or former employee, independent contractor, officer or director of Parent or any of its Subsidiaries.

"*Parent Balance Sheet*" means the unaudited balance sheet of Parent as of September 30, 2024 included in Parent's Report on Form 10-Q for the quarterly period ended September 30, 2024, as filed with the SEC.

"Parent Board" means the board of directors of Parent.

"Parent Change in Circumstance" means a change in circumstances (other than any such event, development or change to the extent related to (A) any Acquisition Proposal, Acquisition Inquiry or the consequences thereof, or (B) the fact, in and of itself, that Parent meets or exceeds internal budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations) that affects the business, assets or operations of Parent or any of its Subsidiaries that occurs or arises after the date of this Agreement.

"*Parent Closing Financial Certificate*" means a certificate executed by the Chief Financial Officer of Parent, on behalf of Parent and not in his or her personal capacity, certifying Parent Net Cash as of the Anticipated Closing Date.

"*Parent Closing Price*" means the average closing trading price of a share of Parent Common Stock on Nasdaq for the five (5) consecutive trading days ending three (3) trading days immediately prior to the date of the public announcement of this Agreement.

"Parent Common Stock" means the Common Stock, \$0.001 par value per share, of Parent.

"*Parent Contract*" means any Contract: (a) to which Parent or any of its Subsidiaries is a party; (b) by which Parent or any of its Subsidiaries or any Parent IP or any other asset of Parent or its Subsidiaries is or may become bound or under which Parent or any of its Subsidiaries has, or may become subject to, any obligation; or (c) under which Parent or any of its Subsidiaries has or may acquire any right or interest.

"*Parent Equity Incentive Plans*" means (a) Parent's 2014 Equity Incentive Plan and (b) Parent's 2019 Inducement Plan.

"*Parent ERISA Affiliate*" means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with Parent or any of its Subsidiaries as a single employer within the meaning of Section 414 of the Code.

"*Parent Fundamental Representations*" means the representations and warranties of Parent and Merger Sub set forth in <u>Sections 3.1(a)</u> (*Due Organization; Subsidiaries*), <u>3.3</u> (*Authority; Binding Nature of Agreement*), <u>3.4</u> (*Vote Required*), <u>3.6(a)</u> and <u>(c)</u> (*Capitalization*) and <u>3.21</u> (*No Financial Advisors*).

"*Parent IP*" means all Intellectual Property Rights that are owned or co-owned or purported to be owned or co-owned by Parent or its Subsidiaries.

"Parent Material Adverse Effect" means any Effect that, considered together with all other Effects, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities or results of operations of Parent or its Subsidiaries, taken as a whole; *provided, however*, that any Effect, individually or together with other Effects, arising or resulting from the following shall not be taken into account in determining whether there has been a Parent Material Adverse Effect: (a) general business, political or economic conditions generally affecting the industry in which Parent or any of its Subsidiaries operate; (b) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions; (c) changes in financial, banking or securities markets; (d) any change in, or any compliance with or action taken for the purpose

of complying with, any Law or GAAP (or interpretations of any Law or GAAP); (e) any change in the stock price or trading volume of Parent Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Parent Common Stock may be taken into account in determining whether a Parent Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition); (f) the failure of Parent to meet internal or analysts' expectations or projections or the results of operations of Parent (it being understood, however, that any Effect causing or contributing to the failure of Parent to meet internal or analysts' expectations or projections or the results of operations of Parent may be taken into account in determining whether a Parent Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition); (g) any changes in or affecting clinical trial programs or studies conducted by or on behalf of Parent or its Subsidiaries, including any adverse data, event or outcome arising out of or related to any such programs or studies; (h) the announcement of this Agreement or the pendency of the Contemplated Transactions; (i) the Asset Dispositions; (j) any reduction in the amount of Parent's Cash and Cash Equivalents as a result of expenditures made by Parent related to wind down activities of Parent associated with the termination of its research and development activities (including the termination of ongoing contractual obligations relating to Parent current products or product candidates); or (k) the taking of any action expressly required to be taken by this Agreement; except, with respect to clauses (a) through (d), to the extent disproportionately affecting Parent and its Subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which Parent and its Subsidiaries operate, in which case, such Effect shall be taken into account to the extent of such disproportionate effect on Parent and its Subsidiaries.

"Parent Net Cash" means, without duplication and with an illustrative example as of the date of this Agreement set forth Schedule II, including the principles set forth therein, (a) the sum of (i) Parent's Cash and Cash Equivalents as of the Anticipated Closing Date, (ii) the prepaid expenses and deposits, (iii) expenses paid, or liabilities incurred, prior to Closing, that are approved in writing prior to the Response Date by the insurance carrier prior to Closing (with such evidence delivered to the Company) to be covered pursuant to any directors' and officers' insurance policy in excess of any applicable deductible and reasonably expected to be received by Parent within 90 days of the Anticipated Closing Date, (iv) any tax receivables reasonably expected to be received by Parent within 90 days of the Anticipated Closing Date, (v) any net proceeds of the Asset Dispositions (which amount may be positive or negative) which Parent will pay or receive, as applicable, on or about the Anticipated Closing Date, (vi)(A) if the Net Cash Calculation is prepared pursuant to Section 1.6 before February 28, 2025, if Parent delivers to the Company (I) the royalty report received from Maruishi Pharmaceutical Co. Ltd. or its Affiliates and (II) a certificate signed by the Chief Financial Officer of Parent in a form reasonably acceptable to the Company to the effect that the milestone has been earned pursuant to Parent's agreement with HCRX Investments Holdco, L.P. and Healthcare Royalty Partners IV, L.P. or their respective Affiliates (collectively, "HCR"), then the amount set forth in this clause (vi) shall be up to \$2,500,000 as indicated in the certificate required by clause (II) above, (B) if the Net Cash Calculation is prepared pursuant to Section 1.6 after February 28, 2025 but before May 1, 2025, if Parent delivers to the Company the report and certificate required by clauses "(I)" and "(II)", respectively, and the officer's certificate delivered from Parent to HCR pursuant to Parent's agreement with HCR, then the amount set forth in this clause (vi) shall be up to \$2,500,000 as indicated in the certificate required by clause (II) above, or (C) if the Net Cash Calculation is prepared pursuant to Section 1.6 on or after May 1, 2025, then the amount set forth in this clause (vi) shall be equal to \$0 and Parent shall only receive credit for any amounts collected from HCR on or prior to the Closing Date as included in the definition of "Cash and Cash Equivalents" in clause (i) above, and (vii) profit sharing payments received by Parent at least fifteen (15) calendar days prior to the Parent Stockholders' Meeting from CSL Vifor or its Affiliates (collectively, "CSL"), which amount shall be net of any Taxes and, for the avoidance of doubt, shall be equal to \$0 unless included in the definition of "Cash and Cash Equivalents" in clause (i) above, *minus* (b) the sum of (i) Parent's accounts payable, accrued expenses (including legal settlements that are not covered by any directors' and officers' insurance policy, Parent's unpaid Transaction Expenses and the costs of any tail policy associated with any directors' and officers' insurance policy to be bound at the Closing) and other bona fide current and long-term liabilities payable in cash that would be required to be set forth in a balance sheet prepared in accordance with GAAP, (ii) notice payments, fines or other payments to be made by Parent in order to terminate, assign or fully perform

all Specified Parent Contracts and to discharge of all other Liabilities of Parent as contemplated by Section 8.6 (for any existing agreement to which Parent is a party and to wind down any current and future clinical trial obligations and research and development activities), (iii) 50% of the aggregate costs (excluding any legal fees incurred by Parent) related to any outstanding stockholder litigation brought or threatened in writing against Parent or its directors or officers relating to the Contemplated Transaction (not covered by any directors' and officers' insurance policy) (the "Parent Litigation Cost"); provided that in no event shall Parent pay the Parent Litigation Cost more than once, (iv) all costs and expenses of continuing to fund Parent's operations, including all activities required to continue to develop the Potentially Transferable Assets (including without limitation any PDUFA fees that become due and payable), including (A) unpaid costs and expenses incurred or reasonably expected to be incurred by Parent in connection with the Asset Dispositions (including, if applicable, any such amounts that would come due post-Closing) and (B) unpaid costs and expenses incurred or reasonably expected to be incurred by Parent in connection with the realization of any milestone payments to be received from HCR or profit sharing payments to be received from CSL, (v) the fees and expenses of the Accounting Firm in accordance with Section 1.6(e), (vi) 50% of all fees and expenses incurred in relation to the printing and filing with the SEC of the Registration Statement and Proxy Statement and any amendments and supplements thereto and paid to a financial printer or the SEC, and (vii) any bonus, severance, change-in-control or retention payments or similar payment obligations (including payments pursuant to "single-trigger" or "double-trigger" provisions triggered at and as of the Closing) that become due or payable to any director, officer, employee or consultant of Parent or any of its Subsidiaries or other Person in connection with the consummation of the Contemplated Transactions. Notwithstanding the foregoing, in no case shall Parent Net Cash be reduced for any costs or expenses, including attorney's fees or settlement costs, incurred in connection with any Dissenting Shares.

"*Parent Option*" means any option or other right to purchase shares of Parent Common Stock granted pursuant to the Parent Equity Incentive Plans or otherwise.

"Parent Preferred Stock" means the Preferred Stock, \$0.001 par value per share, of Parent.

"*Parent RSU*" means any restricted stock unit award granted pursuant to the Parent Equity Incentive Plans or otherwise.

"Parent Triggering Event" shall be deemed to have occurred if: (a) Parent shall have failed to include in the Proxy Statement the Parent Board Recommendation or shall have made a Parent Board Adverse Recommendation Change; (b) the Parent Board or any committee thereof shall have publicly approved, endorsed or recommended any Acquisition Proposal; (c) following the date of this Agreement, Parent shall have entered into any letter of intent or similar document or Contract relating to any Acquisition Proposal (other than a confidentiality agreement permitted pursuant to Section 4.4) in violation of the terms of this Agreement; (d) Parent or any director or officer of Parent shall have willfully and intentionally breached the provisions set forth in Section 4.4 or Section 5.3; or (e) the Parent Board shall have failed to publicly reaffirm the Parent Board Recommendation within ten (10) Business Days after the Company so requests in writing, *provided*, that the Company may only make such request once every thirty (30) days unless there has been a publicly disclosed change regarding an Acquisition Proposal.

"Parent's Knowledge" means the actual knowledge of Christopher Posner, Ryan Maynard and Scott M. Terrillion, such knowledge as such Persons would reasonably be expected to have obtained in the course of their performance of their duties to Parent or any of its Subsidiaries (after due inquiry). With respect to matters involving Intellectual Property Rights, knowledge requires consultation with external intellectual property counsel but does not require that such Persons conduct or have conducted or obtain or have obtained any freedom-to-operate opinions or similar opinions of counsel or any intellectual property clearance searches.

"Party" or "Parties" means, each of or collectively, as applicable, the Company, Merger Sub and Parent.

"*Permitted Alternative Agreement*" means a definitive agreement that contemplates or otherwise relates to an Acquisition Transaction that constitutes a Superior Offer.

"Permitted Encumbrance" means: (a) any liens for current Taxes not yet due and payable or for Taxes that are being contested in good faith and for which adequate reserves have been made on the Company Unaudited Interim Balance Sheet or the Parent Balance Sheet, as applicable; (b) minor liens that have arisen in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the assets or properties subject thereto or materially impair the operations of the Company or Parent or any of its Subsidiaries, as applicable; (c) statutory liens to secure obligations to landlords, lessors or renters under leases or rental agreements; (d) deposits or pledges made in connection with, or to secure payment of, workers' compensation, unemployment insurance or similar programs mandated by Law; (e) non-exclusive licenses of Intellectual Property Rights granted by the Company or Parent or any of its Subsidiaries, as applicable, in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the Intellectual Property Rights subject thereto; and (f) statutory liens in favor of carriers, warehousemen, mechanics and materialmen, to secure claims for labor, materials or supplies.

"Person" means any individual, Entity or Governmental Body.

"*Potentially Transferable Assets*" means all assets, technology and Intellectual Property of Parent as they existed at any time prior to the date of this Agreement.

"*Proxy Statement*" means the definitive proxy statement/prospectus to be sent to Parent's stockholders in connection with the Parent Stockholders' Meeting.

"Reference Date" means December 16, 2024.

"*Registered IP*" means any Intellectual Property Rights that are registered or issued under the authority of any Governmental Body, including any patents, registered copyrights, registered mask works, and registered trademarks, service marks and trade dress, registered domain names and any applications for any of the foregoing.

"*Registration Statement*" means the registration statement on Form S-4 (or any other applicable form under the Securities Act to register Parent Common Stock) to be filed with the SEC by Parent registering the public offering and sale of Parent Common Stock to some or all holders of Company Capital Stock in the Merger and holders of Bridge Notes, including all shares of Parent Common Stock to be issued in exchange for all shares of Company Capital Stock in the Merger and upon the Bridge Note Conversion, as such registration statement may be amended prior to the time it is declared effective by the SEC.

"*Representatives*" means, with respect to a Person, such Person's directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors and representatives.

"Sarbanes-Oxley Act" means the Sarbanes-Oxley Act of 2002.

"SEC" means the United States Securities and Exchange Commission.

"Securities Act" means the Securities Act of 1933.

"*Subsequent Transaction*" means any Acquisition Transaction (with all references to 20% in the definition of Acquisition Transaction being treated as references to greater than 50% for these purposes).

"*Subsidiary*" means, with respect to a Person, an Entity that such Person directly or indirectly owns or purports to own, beneficially or of record, (a) an amount of voting securities or other interests in such Entity that is sufficient to enable such Person to elect at least a majority of the members of such Entity's board of directors or other governing body, or (b) at least 50% of the outstanding equity, voting, beneficial or financial interests in such Entity.

"Superior Offer" means an unsolicited bona fide written Acquisition Proposal (with all references to 20% in the definition of Acquisition Transaction being treated as references to greater than 50% for these purposes) that: (a) was not obtained or made as a result of a breach of (or in violation of) this Agreement; and (b) is on terms and conditions that the Parent Board determines in good faith, based on such matters that it deems relevant (including the likelihood of consummation thereof and the

financing terms thereof), as well as any written offer by the Company to amend the terms of this Agreement, and following consultation with its outside legal counsel and outside financial advisors, are more favorable, from a financial point of view, to Parent's stockholders than the terms of the Contemplated Transactions and is not subject to any financing condition (and if financing is required, such financing is then fully committed to the third party).

"*Takeover Statute*" means any "fair price," "moratorium," "control share acquisition" or other similar anti-takeover Law.

"*Tax*" means any federal, state, local, foreign or other tax, including any income, capital gain, gross receipts, capital stock, profits, transfer, estimated, registration, stamp, premium, escheat, unclaimed property, customs duty, ad valorem, occupancy, occupation, alternative, add-on, windfall profits, value added, severance, property, business, production, sales, use, license, excise, franchise, employment, payroll, social security, disability, unemployment, workers' compensation, national health insurance, withholding or other taxes, duties, fees, assessments or governmental charges, surtaxes or deficiencies thereof in the nature of a tax, however denominated, and including any fine, penalty, addition to tax or interest imposed by a Governmental Body with respect thereto.

"Tax Proceeding" means any proposed audit, assessment, examination, claim or other controversy or proceeding relating to an amount of Taxes of the Company or any of its Subsidiaries.

"*Tax Return*" means any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information, and any amendment or supplement to any of the foregoing, filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax.

"Transaction Expenses" means, with respect to each Party, all fees and expenses incurred by such Party at or prior to the Effective Time in connection with the Contemplated Transactions and this Agreement, including (a) any fees and expenses of legal counsel and accountants and the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of such Party; (b) fees paid to the SEC in connection with filing the Registration Statement, the Proxy Statement, and any amendments and supplements thereto, with the SEC; (c) any fees and expenses in connection with the printing, mailing and distribution of the Registration Statement and any amendments thereto; (d) any fees and expenses payable to Nasdaq.

"Treasury Regulations" means the United States Treasury regulations promulgated under the Code.



ANNEX B

PIPER SANDLER & CO.

December 17, 2024

Board of Directors Cara Therapeutics, Inc. 400 Atlantic Street, Suite 500 Stamford, CT 06901

Members of the Board:

You have requested our opinion as to the fairness, from a financial point of view, to Cara Therapeutics, Inc. (the "Company") of the Exchange Ratio (as defined below) pursuant to the terms of the Agreement and Plan of Merger and Reorganization, to be dated as of December 17, 2024 (the "Agreement"), by and among the Company, CT CONVERGENCE MERGER SUB, INC. ("Merger Sub"), a newly formed, wholly owned subsidiary of the Company, and Tvardi Therapeutics, Inc. ("Tvardi"). The Agreement provides for, among other things, the merger (the "Merger") of Merger Sub with and into Tvardi, with Tvardi surviving the Merger as a wholly owned subsidiary of the Company. At the effective time of the Merger (the "Effective Time"), by virtue of the Merger and without any further action by the Company, Merger Sub, Tvardi, any stockholder of any of them or any other party, each share of common stock of Tvardi, par value \$0.001 per share ("Tvardi Common Stock"), outstanding immediately prior to the Effective Time shall be, subject to certain exceptions, automatically converted into the right to receive a number of shares of common stock of the Company, par value \$0.001 per share ("Company Common Stock"), based on the Exchange Ratio (as such term is defined in the Agreement), subject to certain adjustments set forth in the Agreement. We express no opinion as to the amounts or the effects on the Exchange Ratio of any such adjustments. The terms and conditions of the Merger are more fully set forth in the Agreement.

In connection with our review of the Merger, and in arriving at our opinion, we have: (i) reviewed and analyzed the financial terms of a draft of the Agreement dated December 15, 2024; (ii) reviewed certain financial and other data with respect to the Company which was publicly available; (iii) reviewed and analyzed certain information regarding the Company furnished to us by management of the Company, including financial forecasts relating to the estimated cash expenditures and receipts of the Company from October 31, 2024 through March 31, 2025, estimated balance sheet data with respect to the cash and debt positions of the Company as of November 30, 2024, and a liquidation analysis of the Company prepared by management of the Company, dated as of December 6, 2024 (the "Management Liquidation Analysis"); (iv) reviewed and analyzed certain information regarding Tvardi furnished to us by management of the Company, including balance sheet data with respect to the cash and debt positions of Tvardi as of November 30, 2024 and quarterly financial forecasts relating to the business, earnings, cash flows, and prospects of Tvardi from December 31, 2024 through December 31, 2026; (v) conducted discussions with members of senior management and representatives of each of the Company and Tvardi concerning the matters described in clauses (ii), (iii), and (iv) above, as well as the Company's business and prospects before and after giving effect to the Merger; (vi) reviewed the current and historical reported prices and trading activity of Company Common Stock; (vii) compared the business profile of Tvardi to the business profile of certain other companies, the securities of which are publicly traded, that were deemed by us to be comparable to Tvardi for purposes of this opinion; and (viii) reviewed the valuations of certain companies implied by the pricing of such companies' initial public offerings which companies were deemed by us to be comparable to Tvardi for purposes of this opinion.

In addition, we have conducted such other analyses, examinations and inquiries and considered such other financial, economic and market criteria as we have deemed necessary in arriving at our opinion.

We have relied upon and assumed, without assuming liability or responsibility for independent verification, the accuracy and completeness of all information that was publicly available or was furnished, or otherwise made available, to us or discussed with or reviewed by us. We have further relied upon the assurances of management of the Company that the financial information provided has been prepared on a reasonable basis in accordance with industry practice, and that they are not aware of any information or facts that would make any information provided to us incomplete or misleading. Without limiting the

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generality of the foregoing, for the purpose of this opinion, we have assumed, with respect to financial forecasts, estimates (including with respect to the estimated cash expenditures) and other forward-looking information, that such financial forecasts, estimates and forward-looking information have been reasonably prepared based on assumptions reflecting the best currently available estimates and judgments of the managements of Tvardi and the Company, as applicable. Further, we express no opinion as to any such financial forecasts, estimates or forward-looking information or the assumptions on which they were based.

In addition, our opinion and the underlying analyses relating thereto are, with your knowledge and approval, based upon the following additional key assumptions: (i) the estimated amount of Parent Net Cash (as defined in the Agreement), as provided to us by management of the Company, would not result in an adjustment to the Exchange Ratio; (ii) the Nasdaq Reverse Split (as such term is defined in the Agreement) will not have been completed as of the Effective Time; (iii) the Management Liquidation Analysis has been reasonably prepared in good faith based on assumptions reflecting the best currently available estimates and judgments of management of the Company as to (a) the expected realizable value for the Company's assets, assuming an orderly liquidation of such assts, and (b) the remaining amounts estimated to be available upon completion of such liquidation for distribution to the Company's equity holders; (iv) immediately prior to the Effective Time, the fully diluted outstanding shares of Company Common Stock (calculated using the treasury stock method and taking into account outstanding in the money options and restricted stock units) will be approximately 56.076 million, and the fully diluted outstanding shares of Tvardi Common Stock will be approximately 54.204 million, as provided to us by management of the Company; and (v) the pro forma ownership of the Company, immediately following the Effective Time, assuming completion of (Y) the Preferred Stock Conversion and the Bridge Note Conversion (as each such term is defined in the Agreement) and (Z) the conversion of all other instruments convertible into Tvardi Common Stock, but without giving effect to the Nasdaq Reverse Split, will be 15.25% held by the holders of Company Common Stock immediately prior to the Effective Time and 84.75% by the holders of Tvardi Common Stock immediately prior to the Effective Time (including, for this purpose, the holders of Bridge Notes), as provided to us by management of the Company.

We express no view or opinion with respect to the Management Liquidation Analysis or the assumptions on which it is based. With your knowledge and approval, we have not analyzed, or otherwise considered the effect of the Nasdaq Reverse Split on the Exchange Ratio as of the Effective Time.

We have further assumed that the Merger will have the tax consequences described in the Agreement. We have relied, with your knowledge and approval, on the conclusions of the outside counsel and the independent accountants to the Company, and on the assumptions of management of the Company as to all accounting, legal, tax and financial reporting matters with respect to the Company, Tvardi and the Agreement.

In arriving at our opinion, we have assumed that the executed Agreement will be in all material respects identical to the last draft reviewed by us. We have relied upon and assumed, without independent verification, that (i) the representations and warranties of all parties to the Agreement and all other related documents and instruments that are referred to therein are true and correct; (ii) each party to such agreements will fully and timely perform all of the covenants and agreements required to be performed by such party; (iii) the Merger will be consummated pursuant to the terms of the Agreement without amendments thereto; and (iv) all conditions to the consummation of the Merger will be satisfied without waiver by any party of any conditions or obligations thereunder. Additionally, we have assumed that all the necessary regulatory approvals and consents required for the Merger will be obtained in a manner that will not adversely affect the Company, Tvardi or the contemplated benefits of the Merger.

In arriving at our opinion, (i) we did not perform a discounted cash flow analysis of the Company or Tvardi, because managements of the Company and Tvardi advised us that neither the Company nor Tvardi has, or could reasonably be expected to prepare, current and reliable financial forecasts regarding the Company's or Tvardi's future financial performance, in each case, for a sufficient period of time that would allow Piper Sandler to perform a discounted cash flow analysis, (ii) we did not perform an analysis of precedent merger transactions with publicly available financial terms because we did not identify a sufficient number of transactions that we deemed to be comparable to the Merger, and (iii) with respect to the Company, we did not perform an analysis of companies with publicly traded equity securities that we

deemed comparable to the Company, because we did not identify a sufficient number of publicly traded companies that we deemed to be sufficiently comparable to the Company.

In addition, in arriving at our opinion, we have not performed any appraisals or valuations of any specific assets or liabilities (fixed, contingent or other) of the Company or Tvardi, and have not been furnished or provided with any such appraisals or valuations, nor have we evaluated the solvency of the Company or Tvardi under any state or federal law relating to bankruptcy, insolvency or similar matters. The analyses performed by us with respect to Tvardi in connection with this opinion were going concern analyses. We express no view or opinion regarding the liquidation value of the Company, Tvardi or any other entity. Without limiting the generality of the foregoing, we have undertaken no independent analysis of any pending or threatened litigation, regulatory action, possible unasserted claims or other contingent liabilities, to which the Company, Tvardi or any of their respective affiliates is a party or may be subject, and our opinion makes no assumption concerning, and therefore does not consider, the possible assertion of claims, outcomes or damages arising out of any such matters. We have also assumed, based on information furnished to us by management of the Company and management of Tvardi, that neither the Company nor Tvardi is party to any material pending transaction, including without limitation any financing, recapitalization, acquisition or merger, or divestiture or spin-off, other than the Merger, the Bridge Notes financing, the Asset Dispositions (as defined in the Agreement), and the Nasdaq Reverse Split.

No company or transaction used in any analysis for purposes of comparison is identical to the Company, Tvardi or the Merger. Accordingly, an analysis of the results of the comparisons is not mathematical; rather, it involves complex considerations and judgments about differences in the companies and transactions to which the Company, Tvardi and the Merger were compared and other factors that could affect the public trading value or transaction value of the companies.

This opinion is necessarily based upon the information available to us and facts and circumstances as they exist and are subject to evaluation on the date hereof; events occurring after the date hereof could materially affect the assumptions used in preparing this opinion. We are not expressing any opinion herein as to the price at which shares of Company Common Stock may trade following announcement of the Merger or at any future time. We have not undertaken to reaffirm or revise this opinion or otherwise comment upon any events occurring after the date hereof and do not have any obligation to update, revise or reaffirm this opinion.

We have been engaged by the Company to act as its financial advisor in connection with the Merger and we will receive a fee from the Company for providing our services, a significant portion of which is contingent upon the consummation of the Merger. We will also receive a fee for rendering this opinion. Our opinion fee is not contingent upon the consummation of the Merger or the conclusions reached in our opinion. The Company has also agreed to indemnify us against certain liabilities and reimburse us for certain expenses in connection with our services.

In addition, in the ordinary course of our business, we and our affiliates may actively trade securities of the Company for our own account or the account of our customers and, accordingly, may at any time hold a long or short position in such securities. We may also, in the future, provide investment banking and financial advisory services to the Company, or entities that are affiliated with the Company, for which we would expect to receive compensation.

Consistent with applicable legal and regulatory requirements, Piper Sandler has adopted policies and procedures to establish and maintain the independence of Piper Sandler's Research Department and personnel. As a result, Piper Sandler's research analysts may hold opinions, make statements or recommendations, and/or publish research reports with respect to the Company and the Merger and other participants in the Merger that differ from the views of Piper Sandler's investment banking personnel.

This opinion is provided solely to the Board of Directors of the Company (in the Board members' individual capacities as directors and not in any other capacity) in connection with, and solely for purposes of, its consideration of the Merger and is not intended to, and does not, constitute a recommendation to the Board of Directors of the Company, the Company, any security holder of the Company, or any other party as to how to vote or otherwise act with respect to the Merger or any other matter relating thereto. Except with respect to the use of this opinion in connection with the proxy statement/prospectus relating to

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the Merger, in accordance with our engagement letter with the Company, this opinion shall not be disclosed, referred to, published or otherwise used (in whole or in part), nor shall any public references to us be made, without our prior written approval. This opinion has been approved for issuance by the Piper Sandler Opinion Committee.

This opinion addresses solely the fairness, from a financial point of view, to the Company of the Exchange Ratio (without giving effect to the Nasdaq Reverse Split) and does not address any other terms or agreement relating to the Merger or any other terms of the Agreement. We were not requested to opine as to, and this opinion does not address: (i) the basic business decision to proceed with or effect the Merger; (ii) the merits of the Merger relative to any alternative transaction or business strategy that may be available to the Company; (iii) the fairness of any portion or aspect of the Merger (or of the Bridge Notes financing or the Nasdaq Reverse Split) to any one class or group of the Company's or Tvardi's or any other party's security holders or other constituents vis-à-vis any other class or group of the Company's, Tvardi's or such other party's security holders or other constituents (including, without limitation, the allocation of any consideration amongst or within such classes or groups of security holders or other constituents), (iv) any other terms contemplated by the Agreement (or the agreements entered into in connection with the Bridge Notes financing, or the Nasdaq Reverse Split) or the fairness of the Merger to any creditor or other constituency of the Company; (v) whether or not the Company, Tvardi, their respective security holders or any other party is receiving or paying reasonably equivalent value in the Merger (or the Bridge Notes financing or the Nasdaq Reverse Split); or (vi) the solvency or financial viability of the Company or Tvardi at the date hereof, upon consummation of the Merger, or at any future time. Furthermore, we express no opinion with respect to the amount or nature of compensation to any officer, director or employee of any party to the Merger, or any class of such persons, relative to the Merger Consideration (as defined in the Agreement) to be paid by the Company in the Merger or with respect to the fairness of any such compensation, including whether such payments are reasonable in the context of the Merger.

Based upon and subject to the foregoing, and based upon such other factors as we consider relevant, it is our opinion that the Exchange Ratio (without giving effect to the Nasdaq Reverse Split) is fair, from a financial point of view, to the Company as of the date hereof.

Sincerely,

PIPER SANDLER & CO.

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ANNEX C

GENERAL CORPORATION LAW OF THE STATE OF DELAWARE REGARDING APPRAISAL RIGHTS, SECTION 262

§ 262. Appraisal rights

- (a) Any stockholder of a corporation of this State who holds shares of stock on the date of the making of a demand pursuant to subsection (d) of this section with respect to such shares, who continuously holds such shares through the effective date of the merger or consolidation, who has otherwise complied with subsection (d) of this section and who has neither voted in favor of the merger or consolidation nor consented thereto in writing pursuant to § 228 of this title shall be entitled to an appraisal by the Court of Chancery of the fair value of the stockholder's shares of stock under the circumstances described in subsections (b) and (c) of this section. As used in this section, the word "stockholder" means a holder of record of stock in a corporation; the words "stock" and "share" mean and include what is ordinarily meant by those words; and the words "depository receipt" mean a receipt or other instrument issued by a depository representing an interest in one or more shares, or fractions thereof, solely of stock of a corporation, which stock is deposited with the depository.
- (b) Appraisal rights shall be available for the shares of any class or series of stock of a constituent corporation in a merger or consolidation to be effected pursuant to § 251 (other than a merger effected pursuant to § 251(g) of this title), § 252, § 254, § 255, § 256, § 257, § 258, § 263 or § 264 of this title:
 - (1) Provided, however, that, except as expressly provided in § 363(b) of this title, no appraisal rights under this section shall be available for the shares of any class or series of stock, which stock, or depository receipts in respect thereof, at the record date fixed to determine the stockholders entitled to receive notice of the meeting of stockholders to act upon the agreement of merger or consolidation (or, in the case of a merger pursuant to § 251(h), as of immediately prior to the execution of the agreement of merger), were either: (i) listed on a national securities exchange or (ii) held of record by more than 2,000 holders; and further provided that no appraisal rights shall be available for any shares of stock of the constituent corporation surviving a merger if the merger did not require for its approval the vote of the stockholders of the surviving corporation as provided in § 251(f) of this title.
 - (2) Notwithstanding paragraph (b)(1) of this section, appraisal rights under this section shall be available for the shares of any class or series of stock of a constituent corporation if the holders thereof are required by the terms of an agreement of merger or consolidation pursuant to §§ 251, 252, 254, 255, 256, 257, 258, 263 and 264 of this title to accept for such stock anything except:
 - a. Shares of stock of the corporation surviving or resulting from such merger or consolidation, or depository receipts in respect thereof;
 - b. Shares of stock of any other corporation, or depository receipts in respect thereof, which shares of stock (or depository receipts in respect thereof) or depository receipts at the effective date of the merger or consolidation will be either listed on a national securities exchange or held of record by more than 2,000 holders;
 - c. Cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a. and b. of this section; or
 - d. Any combination of the shares of stock, depository receipts and cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a., b. and c. of this section.
 - (3) In the event all of the stock of a subsidiary Delaware corporation party to a merger effected

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under § 253 or § 267 of this title is not owned by the parent immediately prior to the merger, appraisal rights shall be available for the shares of the subsidiary Delaware corporation.

- (4) In the event of an amendment to a corporation's certificate of incorporation contemplated by § 363(a) of this title, appraisal rights shall be available as contemplated by § 363(b) of this title, and the procedures of this section, including those set forth in subsections (d) and (e) of this section, shall apply as nearly as practicable, with the word "amendment" substituted for the words "merger or consolidation," and the word "corporation" substituted for the words "constituent corporation" and/or "surviving or resulting corporation."
- (c) Any corporation may provide in its certificate of incorporation that appraisal rights under this section shall be available for the shares of any class or series of its stock as a result of an amendment to its certificate of incorporation, any merger or consolidation in which the corporation is a constituent corporation or the sale of all or substantially all of the assets of the corporation. If the certificate of incorporation contains such a provision, the provisions of this section, including those set forth in subsections (d), (e), and (g) of this section, shall apply as nearly as is practicable.
- (d) Appraisal rights shall be perfected as follows:
 - (1) If a proposed merger or consolidation for which appraisal rights are provided under this section is to be submitted for approval at a meeting of stockholders, the corporation, not less than 20 days prior to the meeting, shall notify each of its stockholders who was such on the record date for notice of such meeting (or such members who received notice in accordance with § 255(c) of this title) with respect to shares for which appraisal rights are available pursuant to subsection (b) or (c) of this section that appraisal rights are available for any or all of the shares of the constituent corporations, and shall include in such notice a copy of this section and, if one of the constituent corporations is a nonstock corporation, a copy of \$ 114 of this title. Each stockholder electing to demand the appraisal of such stockholder's shares shall deliver to the corporation, before the taking of the vote on the merger or consolidation, a written demand for appraisal of such stockholder's shares; provided that a demand may be delivered to the corporation by electronic transmission if directed to an information processing system (if any) expressly designated for that purpose in such notice. Such demand will be sufficient if it reasonably informs the corporation of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such stockholder's shares. A proxy or vote against the merger or consolidation shall not constitute such a demand. A stockholder electing to take such action must do so by a separate written demand as herein provided. Within 10 days after the effective date of such merger or consolidation, the surviving or resulting corporation shall notify each stockholder of each constituent corporation who has complied with this subsection and has not voted in favor of or consented to the merger or consolidation of the date that the merger or consolidation has become effective; or
 - (2) If the merger or consolidation was approved pursuant to § 228, § 251(h), § 253, or § 267 of this title, then either a constituent corporation before the effective date of the merger or consolidation or the surviving or resulting corporation within 10 days thereafter shall notify each of the holders of any class or series of stock of such constituent corporation who are entitled to appraisal rights of the approval of the merger or consolidation and that appraisal rights are available for any or all shares of such class or series of stock of such constituent corporation, and shall include in such notice a copy of this section and, if 1 of the constituent corporations is a nonstock corporation, a copy of § 114 of this title. Such notice may, and, if given on or after the effective date of the merger or consolidation, shall, also notify such stockholders of the effective date of the merger or consolidation. Any stockholder entitled to appraisal rights may, within 20 days after the date of giving such notice or, in the case of a merger approved pursuant to \$ 251(h) of this title, within the later of the consummation of the offer contemplated by § 251(h) of this title and 20 days after the date of giving such notice, demand in writing from the surviving or resulting corporation the appraisal of such holder's shares; provided that a demand may be delivered to the corporation by electronic transmission if directed to an information processing system (if any) expressly designated for that purpose in such notice. Such demand will be sufficient if it reasonably informs the corporation of

the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such holder's shares. If such notice did not notify stockholders of the effective date of the merger or consolidation, either (i) each such constituent corporation shall send a second notice before the effective date of the merger or consolidation notifying each of the holders of any class or series of stock of such constituent corporation that are entitled to appraisal rights of the effective date of the merger or consolidation or (ii) the surviving or resulting corporation shall send such a second notice to all such holders on or within 10 days after such effective date; provided, however, that if such second notice is sent more than 20 days following the sending of the first notice or, in the case of a merger approved pursuant to § 251(h) of this title, later than the later of the consummation of the offer contemplated by § 251(h) of this title and 20 days following the sending of the first notice, such second notice need only be sent to each stockholder who is entitled to appraisal rights and who has demanded appraisal of such holder's shares in accordance with this subsection. An affidavit of the secretary or assistant secretary or of the transfer agent of the corporation that is required to give either notice that such notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein. For purposes of determining the stockholders entitled to receive either notice, each constituent corporation may fix, in advance, a record date that shall be not more than 10 days prior to the date the notice is given, provided, that if the notice is given on or after the effective date of the merger or consolidation, the record date shall be such effective date. If no record date is fixed and the notice is given prior to the effective date, the record date shall be the close of business on the day next preceding the day on which the notice is given.

- (e) Within 120 days after the effective date of the merger or consolidation, the surviving or resulting corporation or any stockholder who has complied with subsections (a) and (d) of this section hereof and who is otherwise entitled to appraisal rights, may commence an appraisal proceeding by filing a petition in the Court of Chancery demanding a determination of the value of the stock of all such stockholders. Notwithstanding the foregoing, at any time within 60 days after the effective date of the merger or consolidation, any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party shall have the right to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger or consolidation. Within 120 days after the effective date of the merger or consolidation, any stockholder who has complied with the requirements of subsections (a) and (d) of this section hereof, upon request given in writing (or by electronic transmission directed to an information processing system (if any) expressly designated for that purpose in the notice of appraisal), shall be entitled to receive from the corporation surviving the merger or resulting from the consolidation a statement setting forth the aggregate number of shares not voted in favor of the merger or consolidation (or, in the case of a merger approved pursuant to § 251(h) of this title, the aggregate number of shares (other than any excluded stock (as defined in § 251(h)(6)d. of this title)) that were the subject of, and were not tendered into, and accepted for purchase or exchange in, the offer referred to in (251(h)(2)), and, in either case, with respect to which demands for appraisal have been received and the aggregate number of holders of such shares. Such statement shall be given to the stockholder within 10 days after such stockholder's request for such a statement is received by the surviving or resulting corporation or within 10 days after expiration of the period for delivery of demands for appraisal under subsection (d) of this section hereof, whichever is later. Notwithstanding subsection (a) of this section, a person who is the beneficial owner of shares of such stock held either in a voting trust or by a nominee on behalf of such person may, in such person's own name, file a petition or request from the corporation the statement described in this subsection.
- (f) Upon the filing of any such petition by a stockholder, service of a copy thereof shall be made upon the surviving or resulting corporation, which shall within 20 days after such service file in the office of the Register in Chancery in which the petition was filed a duly verified list containing the names and addresses of all stockholders who have demanded payment for their shares and with whom agreements as to the value of their shares have not been reached by the surviving or resulting corporation. If the petition shall be filed by the surviving or resulting corporation, the petition shall be accompanied by such a duly verified list. The Register in Chancery, if so ordered by the Court, shall give notice of the time and place fixed for the hearing of such petition by

registered or certified mail to the surviving or resulting corporation and to the stockholders shown on the list at the addresses therein stated. Such notice shall also be given by one or more publications at least one week before the day of the hearing, in a newspaper of general circulation published in the City of Wilmington, Delaware or such publication as the Court deems advisable. The forms of the notices by mail and by publication shall be approved by the Court, and the costs thereof shall be borne by the surviving or resulting corporation.

- (g) At the hearing on such petition, the Court shall determine the stockholders who have complied with this section and who have become entitled to appraisal rights. The Court may require the stockholders who have demanded an appraisal for their shares and who hold stock represented by certificates to submit their certificates of stock to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with such direction, the Court may dismiss the proceedings as to such stockholder. If immediately before the merger or consolidation the shares of the class or series of stock of the constituent corporation as to which appraisal rights are available were listed on a national securities exchange, the Court shall dismiss the proceedings as to all holders of such shares who are otherwise entitled to appraisal rights unless (1) the total number of shares entitled to appraisal exceeds 1% of the outstanding shares of the class or series eligible for appraisal, (2) the value of the consideration provided in the merger or consolidation for such total number of shares exceeds \$1 million, or (3) the merger was approved pursuant to § 253 or § 267 of this title.
- (h) After the Court determines the stockholders entitled to an appraisal, the appraisal proceeding shall be conducted in accordance with the rules of the Court of Chancery, including any rules specifically governing appraisal proceedings. Through such proceeding the Court shall determine the fair value of the shares exclusive of any element of value arising from the accomplishment or expectation of the merger or consolidation, together with interest, if any, to be paid upon the amount determined to be the fair value. In determining such fair value, the Court shall take into account all relevant factors. Unless the Court in its discretion determines otherwise for good cause shown, and except as provided in this subsection, interest from the effective date of the merger through the date of payment of the judgment shall be compounded quarterly and shall accrue at 5% over the Federal Reserve discount rate (including any surcharge) as established from time to time during the period between the effective date of the merger and the date of payment of the judgment. At any time before the entry of judgment in the proceedings, the surviving corporation may pay to each stockholder entitled to appraisal an amount in cash, in which case interest shall accrue thereafter as provided herein only upon the sum of (1) the difference, if any, between the amount so paid and the fair value of the shares as determined by the Court, and (2) interest theretofore accrued, unless paid at that time. Upon application by the surviving or resulting corporation or by any stockholder entitled to participate in the appraisal proceeding, the Court may, in its discretion, proceed to trial upon the appraisal prior to the final determination of the stockholders entitled to an appraisal. Any stockholder whose name appears on the list filed by the surviving or resulting corporation pursuant to subsection (f) of this section and who has submitted such stockholder's certificates of stock to the Register in Chancery, if such is required, may participate fully in all proceedings until it is finally determined that such stockholder is not entitled to appraisal rights under this section.
- (i) The Court shall direct the payment of the fair value of the shares, together with interest, if any, by the surviving or resulting corporation to the stockholders entitled thereto. Payment shall be so made to each such stockholder, in the case of holders of uncertificated stock forthwith, and the case of holders of shares represented by certificates upon the surrender to the corporation of the certificates representing such stock. The Court's decree may be enforced as other decrees in the Court of Chancery may be enforced, whether such surviving or resulting corporation be a corporation of this State or of any state.
- (j) The costs of the proceeding may be determined by the Court and taxed upon the parties as the Court deems equitable in the circumstances. Upon application of a stockholder, the Court may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorney's fees and the fees and expenses of experts, to be charged pro rata against the value of all the shares entitled to an appraisal.

- (k) From and after the effective date of the merger or consolidation, no stockholder who has demanded appraisal rights as provided in subsection (d) of this section shall be entitled to vote such stock for any purpose or to receive payment of dividends or other distributions on the stock (except dividends or other distributions payable to stockholders of record at a date which is prior to the effective date of the merger or consolidation); provided, however, that if no petition for an appraisal shall be filed within the time provided in subsection (e) of this section, or if such stockholder shall deliver to the surviving or resulting corporation a written withdrawal of such stockholder's demand for an appraisal and an acceptance of the merger or consolidation, either within 60 days after the effective date of the merger or consolidation as provided in subsection (e) of this section or thereafter with the written approval of the corporation, then the right of such stockholder to an appraisal shall cease. Notwithstanding the foregoing, no appraisal proceeding in the Court of Chancery shall be dismissed as to any stockholder without the approval of the Court, and such approval may be conditioned upon such terms as the Court deems just; provided, however that this provision shall not affect the right of any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger or consolidation within 60 days after the effective date of the merger or consolidation, as set forth in subsection (e) of this section
- (1) The shares of the surviving or resulting corporation to which the shares of such objecting stockholders would have been converted had they assented to the merger or consolidation shall have the status of authorized and unissued shares of the surviving or resulting corporation.

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ANNEX D

TVARDI THERAPEUTICS, INC.

2025 EQUITY INCENTIVE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: [] APPROVED BY THE STOCKHOLDERS: []

1. GENERAL.

(a) **Plan Purpose.** The Company, by means of the Plan, seeks to secure and retain the services of Employees, Directors and Consultants, to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and to provide a means by which such persons may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Awards.

(b) Available Awards. The Plan provides for the grant of the following Awards: (i) Incentive Stock Options; (ii) Nonstatutory Stock Options; (iii) SARs; (iv) Restricted Stock Awards; (v) RSU Awards; (vi) Performance Awards; and (vii) Other Awards.

(c) Adoption Date; Effective Date. The Plan will come into existence on the Adoption Date, but no Award may be granted prior to the Effective Date.

2. SHARES SUBJECT TO THE PLAN.

(a) **Share Reserve.** Subject to adjustment in accordance with Section 2(c) and any adjustments as necessary to implement any Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Awards will not exceed [] shares (the "*Initial Share Reserve*").¹ In addition, subject to any adjustments as necessary to implement any Capitalization Adjustments, such aggregate number of shares of Common Stock may be increased at the Board's discretion (and without any further action by the Company's stockholders) on January 1 of each year for a period of five years commencing on January 1, 2026 and ending on (and including) January 1, 2030, in an amount not to exceed five percent (5%) of the total number of shares of Fully Diluted Common Stock outstanding on December 31 of the preceding year; *provided, however*, that the Board must act prior to January 1st of a given year to provide that the increase for such year will occur and to determine the applicable number of additional shares of Common Stock. In the absence of Board action, no such increase will automatically occur.

(b) Aggregate Incentive Stock Option Limit. Notwithstanding anything to the contrary in Section 2(a) and subject to any adjustments as necessary to implement any Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options is three (3) multiplied by the Initial Share Reserve.

(c) Share Reserve Operation.

(i) Limit Applies to Common Stock Issued Pursuant to Awards. For clarity, the Share Reserve is a limit on the number of shares of Common Stock that may be issued pursuant to Awards and does not limit the granting of Awards, except that the Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy its obligations to issue shares pursuant to such Awards. Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, Nasdaq Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, NYSE American Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(ii) Actions that Do Not Constitute Issuance of Common Stock and Do Not Reduce ShareReserve. The following actions do not result in an issuance of shares under the Plan and accordingly

¹ NTD: Equal to 10% of the total number of shares of Common Stock issued and outstanding immediately after the Effective Time.

do not reduce the number of shares subject to the Share Reserve and available for issuance under the Plan: (1) the expiration or termination of any portion of an Award without the shares covered by such portion of the Award having been issued; (2) the settlement of any portion of an Award in cash (*i.e.*, the Participant receives cash rather than Common Stock); (3) the withholding of shares that would otherwise be issued by the Company to satisfy the exercise, strike or purchase price of an Award; or (4) the withholding of shares that would otherwise be issued by the Company to satisfy a tax withholding obligation in connection with an Award.

(iii) **Reversion of Previously Issued Shares of Common Stock to Share Reserve.** The following shares of Common Stock previously issued pursuant to an Award and accordingly initially deducted from the Share Reserve will be added back to the Share Reserve and again become available for issuance under the Plan: (1) any shares that are forfeited back to or repurchased by the Company because of a failure to meet a contingency or condition required for the vesting of such shares; (2) any shares that are reacquired by the Company to satisfy the exercise, strike or purchase price of an Award; and (3) any shares that are reacquired by the Company to satisfy a tax withholding obligation in connection with an Award.

3. ELIGIBILITY AND LIMITATIONS.

(a) **Eligible Award Recipients.** Subject to the terms of the Plan, Employees, Directors and Consultants are eligible to receive Awards.

(b) Specific Award Limitations.

(i) **Limitations on Incentive Stock Option Recipients.** Incentive Stock Options may be granted only to Employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and (f) of the Code).

(ii) **Incentive Stock Option \$100,000 Limitation.** To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds \$100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(iii) Limitations on Incentive Stock Options Granted to Ten Percent Stockholders. A Ten Percent Stockholder may not be granted an Incentive Stock Option unless (1) the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant of such Option, and (2) the Option is not exercisable after the expiration of five years from the date of grant of such Option.

(iv) Limitations on Nonstatutory Stock Options and SARs. Nonstatutory Stock Options and SARs may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company (as such term is defined in Rule 405) unless the stock underlying such Awards is treated as "service recipient stock" under Section 409A because the Awards are granted pursuant to a corporate transaction (such as a spin off transaction) or unless such Awards otherwise comply with the distribution requirements of Section 409A.

(c) Aggregate Incentive Stock Option Limit. The aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options is the number of shares specified in Section 2(b).

(d) Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid, as applicable, to any individual for service as a Non-Employee Director with respect to any period commencing on the date of the Company's Annual Meeting of Stockholders for a particular year and ending on the day immediately prior to the date of the Company's Annual Meeting of Stockholders for the next subsequent year (the "*Annual Period*"), including Awards granted and cash fees paid by the Company to such Non-Employee Director, will not exceed (i) \$750,000 in total value or (ii) in the event such Non-Employee

Director is first appointed or elected to the Board during such Annual Period, \$1,000,000 in total value, in each case, calculating the value of any equity awards based on the grant date fair value of such equity awards for financial reporting purposes. The limitations in this Section 3(d) shall apply commencing with the Annual Period that begins on the Company's first Annual Meeting of Stockholders following the Effective Date. For avoidance of doubt, compensation will count towards this limit for the Annual Period year in which it was granted or earned, and not later when distributed, in the event it is deferred.

4. OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option and SAR will have such terms and conditions as determined by the Board. Each Option will be designated in writing as an Incentive Stock Option or Nonstatutory Stock Option at the time of grant; provided, however, that if an Option is not so designated or if an Option designated as an Incentive Stock Option fails to qualify as an Incentive Stock Option, then such Option will be a Nonstatutory Stock Option, and the shares purchased upon exercise of each type of Option will be separately accounted for. Each SAR will be denominated in shares of Common Stock equivalents. The terms and conditions of separate Options and SARs need not be identical; provided, however, that each Option Agreement and SAR Agreement will conform (through incorporation of provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

(a) **Term.** Subject to Section 3(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten years from the date of grant of such Award or such shorter period specified in the Award Agreement.

(b) **Exercise or Strike Price.** Subject to Section 3(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will not be less than 100% of the Fair Market Value on the date of grant of such Award. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value on the date of grant of such Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Sections 409A and, if applicable, 424(a) of the Code.

(c) **Exercise Procedure and Payment of Exercise Price for Options.** In order to exercise an Option, the Participant must provide notice of exercise to the Plan Administrator in accordance with the procedures specified in the Option Agreement or otherwise provided by the Company. The Board has the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The exercise price of an Option may be paid, to the extent permitted by Applicable Law and as determined by the Board, by one or more of the following methods of payment to the extent set forth in the Option Agreement:

(i) by cash or check, bank draft or money order payable to the Company;

(ii) pursuant to a "cashless exercise" program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock that are already owned by the Participant free and clear of any liens, claims, encumbrances or security interests, with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) at the time of exercise the Common Stock is publicly traded, (2) any remaining balance of the exercise price not satisfied by such delivery is paid by the Participant in cash or other permitted form of payment, (3) such delivery would not violate any Applicable Law or agreement restricting the redemption of the Common Stock, (4) any certificated shares are endorsed or accompanied by an executed assignment separate from certificate, and (5) such shares have been held by the Participant for any minimum period necessary to avoid adverse accounting treatment as a result of such delivery;

(iv) if the Option is a Nonstatutory Stock Option, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) such shares used to pay the exercise price will not be exercisable thereafter, and (2) any remaining balance of the exercise price not satisfied by such net exercise is paid by the Participant in cash or other permitted form of payment; or

(v) in any other form of consideration that may be acceptable to the Board and permissible under Applicable Law.

(d) **Exercise Procedure and Payment of Appreciation Distribution for SARs.** In order to exercise any SAR, the Participant must provide notice of exercise to the Plan Administrator in accordance with the SAR Agreement. The appreciation distribution payable to a Participant upon the exercise of a SAR will not be greater than an amount equal to the excess of (i) the aggregate Fair Market Value on the date of exercise of a number of shares of Common Stock equal to the number of Common Stock equivalents that are vested and being exercised under such SAR, over (ii) the strike price of such SAR. Such appreciation distribution may be paid to the Participant in the form of Common Stock or cash (or any combination of Common Stock and cash) or in any other form of payment, as determined by the Board and specified in the SAR Agreement.

(e) **Transferability.** Options and SARs may not be transferred to third party financial institutions for value. The Board may impose such additional limitations on the transferability of an Option or SAR as it determines. In the absence of any such determination by the Board, the following restrictions on the transferability of Options and SARs will apply, provided that except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration and *provided, further*, that if an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer:

(i) **Restrictions on Transfer.** An Option or SAR will not be transferable, except by will or by the laws of descent and distribution, and will be exercisable during the lifetime of the Participant only by the Participant; provided, however, that the Board may permit transfer of an Option or SAR in a manner that is not prohibited by applicable tax and securities laws upon the Participant's request, including to a trust if the Participant is considered to be the sole beneficial owner of such trust (as determined under Section 671 of the Code and applicable U.S. state law) while such Option or SAR is held in such trust, provided that the Participant and the trustee enter into a transfer and other agreements required by the Company.

(ii) **Domestic Relations Orders.** Notwithstanding the foregoing, subject to the execution of transfer documentation in a format acceptable to the Company and subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to a domestic relations order.

(f) **Vesting.** The Board may impose such restrictions on or conditions to the vesting and/or exercisability of an Option or SAR as determined by the Board. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Options and SARs will cease upon termination of the Participant's Continuous Service.

(g) **Termination of Continuous Service for Cause.** Except as explicitly otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service is terminated for Cause, the Participant's Options and SARs will terminate and be forfeited immediately upon such termination of Continuous Service, and the Participant will be prohibited from exercising any portion (including any vested portion) of such Awards on and after the date of such termination of Continuous Service and the Participant will have no further right, title or interest in such forfeited Award, the shares of Common Stock subject to the forfeited Award, or any consideration in respect of the forfeited Award.

(h) **Post-Termination Exercise Period Following Termination of Continuous Service for Reasons Other than Cause.** Subject to Section 4(i), if a Participant's Continuous Service terminates for any reason other than for Cause, the Participant may exercise his or her Option or SAR to the extent vested,

but only within the following period of time or, if applicable, such other period of time provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate; provided, however, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)):

(i) three months following the date of such termination if such termination is a termination without Cause (other than any termination due to the Participant's Disability or death);

(ii) 12 months following the date of such termination if such termination is due to the Participant's Disability;

(iii) 18 months following the date of such termination if such termination is due to the Participant's death; or

(iv) 18 months following the date of the Participant's death if such death occurs following the date of such termination but during the period such Award is otherwise exercisable (as provided in (i) or (ii) above).

Following the date of such termination, to the extent the Participant does not exercise such Award within the applicable Post-Termination Exercise Period (or, if earlier, prior to the expiration of the maximum term of such Award), such unexercised portion of the Award will terminate, and the Participant will have no further right, title or interest in the terminated Award, the shares of Common Stock subject to the terminated Award, or any consideration in respect of the terminated Award.

(i) **Restrictions on Exercise; Extension of Exercisability.** A Participant may not exercise an Option or SAR at any time that the issuance of shares of Common Stock upon such exercise would violate Applicable Law. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason other than for Cause and, at any time during the last thirty days of the applicable Post-Termination Exercise Period: (i) the exercise of the Participant's Option or SAR would be prohibited solely because the issuance of shares of Common Stock upon such exercise would violate Applicable Law, or (ii) the immediate sale of any shares of Common Stock issued upon such exercise would violate the Company's Trading Policy, then the applicable Post-Termination Exercise Period will be extended to the last day of the calendar month that commences following the date the Award would otherwise expire, with an additional extension of the exercise period to the last day of the next calendar month to apply if any of the foregoing restrictions apply at any time during such extended exercise period, generally without limitation as to the maximum permitted number of extensions; provided, however, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)).

(j) Non-Exempt Employees. No Option or SAR, whether or not vested, granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, will be first exercisable for any shares of Common Stock until at least six months following the date of grant of such Award. Notwithstanding the foregoing, in accordance with the provisions of the Worker Economic Opportunity Act, any vested portion of such Award may be exercised earlier than six months following the date of grant of such Award in the event of (i) such Participant's death or Disability, (ii) a Corporate Transaction in which such Award is not assumed, continued or substituted, (iii) a Change in Control, or (iv) such Participant's retirement (as such term may be defined in the Award Agreement or another applicable agreement or, in the absence of any such definition, in accordance with the Company's then current employment policies and guidelines). This Section 4(j) is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay.

(k) Whole Shares. Options and SARs may be exercised only with respect to whole shares of Common Stock or their equivalents.

5. AWARDS OTHER THAN OPTIONS AND STOCK APPRECIATION RIGHTS.

(a) **Restricted Stock Awards and RSU Awards.** Each Restricted Stock Award and RSU Award will have such terms and conditions as determined by the Board; provided, however, that each Restricted Stock Award Agreement and RSU Award Agreement will conform (through incorporation of the provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

(i) Form of Award.

(1) Restricted Stock Awards: To the extent consistent with the Company's Bylaws, at the Board's election, shares of Common Stock subject to a Restricted Stock Award may be (A) held in book entry form subject to the Company's instructions until such shares become vested or any other restrictions lapse, or (B) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. Unless otherwise determined by the Board, a Participant will have voting and other rights as a stockholder of the Company with respect to any shares subject to a Restricted Stock Award.

(2) RSU Awards: An RSU Award represents a Participant's right to be issued on a future date the number of shares of Common Stock that is equal to the number of restricted stock units subject to the RSU Award. As a holder of an RSU Award, a Participant is an unsecured creditor of the Company with respect to the Company's unfunded obligation, if any, to issue shares of Common Stock in settlement of such Award and nothing contained in the Plan or any RSU Award Agreement, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between a Participant and the Company or an Affiliate or any other person. A Participant will not have voting or any other rights as a stockholder of the Company with respect to any RSU Award (unless and until shares are actually issued in settlement of a vested RSU Award).

(ii) Consideration.

(1) Restricted Stock Awards: A Restricted Stock Award may be granted in consideration for (A) cash or check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of consideration (including future services) as the Board may determine and permissible under Applicable Law.

(2) RSU Awards: Unless otherwise determined by the Board at the time of grant, an RSU Award will be granted in consideration for the Participant's services to the Company or an Affiliate, such that the Participant will not be required to make any payment to the Company (other than such services) with respect to the grant or vesting of the RSU Award, or the issuance of any shares of Common Stock pursuant to the RSU Award. If, at the time of grant, the Board determines that any consideration must be paid by the Participant (in a form other than the Participant's services to the Company or an Affiliate) upon the issuance of any shares of Common Stock in settlement of the RSU Award, such consideration may be paid in any form of consideration as the Board may determine and permissible under Applicable Law.

(iii) **Vesting.** The Board may impose such restrictions on or conditions to the vesting of a Restricted Stock Award or RSU Award as determined by the Board. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Restricted Stock Awards and RSU Awards will cease upon termination of the Participant's Continuous Service.

(iv) **Termination of Continuous Service.** Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason, (1) the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant under his or her Restricted Stock Award that have not vested as of the date of such termination as set forth in the Restricted Stock Award Agreement, and (2) any portion of his or her RSU Award that has not vested will be forfeited upon such termination and the Participant will have no further right, title or

interest in the RSU Award, the shares of Common Stock issuable pursuant to the RSU Award, or any consideration in respect of the RSU Award.

(v) **Dividends and Dividend Equivalents.** Dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to a Restricted Stock Award or RSU Award, as determined by the Board and specified in the Award Agreement.

(vi) Settlement of RSU Awards. An RSU Award may be settled by the issuance of shares of Common Stock or cash (or any combination thereof) or in any other form of payment, as determined by the Board and specified in the RSU Award Agreement. At the time of grant, the Board may determine to impose such restrictions or conditions that delay such delivery to a date following the vesting of the RSU Award.

(b) **Performance Awards.** With respect to any Performance Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, the other terms and conditions of such Award, and the measure of whether and to what degree such Performance Goals have been attained will be determined by the Board.

(c) **Other Awards.** Other forms of Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value at the time of grant), may be granted either alone or in addition to Awards provided for under Section 4 and the preceding provisions of this Section 5. Subject to the provisions of the Plan, the Board will have sole and complete discretion to determine the persons to whom and the time or times at which such Other Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Awards and all other terms and conditions of such Other Awards.

6. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) **Capitalization Adjustments.** In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of shares of Common Stock subject to the Plan and the maximum number of shares by which the Share Reserve may annually increase pursuant to Section 2(a); (ii) the class(es) and maximum number of shares that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 2(b); and (iii) the class(es) and number of securities and exercise price, strike price or purchase price of Common Stock subject to outstanding Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive. Notwithstanding the foregoing, no fractional shares or rights for fractional shares of Common Stock shall be created in order to implement any Capitalization Adjustment. The Board shall determine an appropriate equivalent benefit, if any, for any fractional shares or rights to fractional shares that might be created by the adjustments referred to in the preceding provisions of this Section.

(b) **Dissolution or Liquidation.** Except as otherwise provided in the Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Awards (other than Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Award is providing Continuous Service, provided, however, that the Board may determine to cause some or all Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) **Corporate Transaction.** The following provisions will apply to Awards in the event of a Corporate Transaction, unless otherwise provided in the instrument evidencing the Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of an Award.

(i) Awards May Be Assumed. In the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or

continue any or all Awards outstanding under the Plan or may substitute similar awards for Awards outstanding under the Plan (including but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to Awards may be assigned by the Company to the successor of the Company (or the successor's parent company, if any), in connection with such Corporate Transaction. A surviving corporation or acquiring corporation (or its parent) may choose to assume or continue only a portion of an Award or substitute a similar award for only a portion of an Award, or may choose to assume, continue or substitute the Awards held by some, but not all Participants. The terms of any assumption, continuation or substitution will be set by the Board.

(ii) Awards Held by Current Participants. In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Awards or substitute similar awards for such outstanding Awards, then with respect to Awards that have not been assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction (referred to as the "Current Participants"), the vesting of such Awards (and, with respect to Options and Stock Appreciation Rights, the time when such Awards may be exercised) will be accelerated in full to a date prior to the effective time of such Corporate Transaction (contingent upon the effectiveness of the Corporate Transaction) as the Board determines (or, if the Board does not determine such a date, to the date that is five days prior to the effective time of the Corporate Transaction), and such Awards will terminate if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and any reacquisition or repurchase rights held by the Company with respect to such Awards will lapse (contingent upon the effectiveness of the Corporate Transaction). With respect to the vesting of Performance Awards that will accelerate upon the occurrence of a Corporate Transaction pursuant to this subsection (ii) and that have multiple vesting levels depending on the level of performance, unless otherwise provided in the Award Agreement, the vesting of such Performance Awards will accelerate at 100% of the target level upon the occurrence of the Corporate Transaction in which the Awards are not assumed, continued or substituted in accordance with Section 6(c)(i). With respect to the vesting of Awards that will accelerate upon the occurrence of a Corporate Transaction pursuant to this subsection (ii) and are settled in the form of a cash payment, such cash payment will be made no later than 30 days following the occurrence of the Corporate Transaction or such later date as required to comply with Section 409A of the Code.

(iii) Awards Held by Persons other than Current Participants. In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Awards or substitute similar awards for such outstanding Awards, then with respect to Awards that have not been assumed, continued or substituted and that are held by persons other than Current Participants, such Awards will terminate if not exercised (if applicable) prior to the occurrence of the Corporate Transaction; provided, however, that any reacquisition or repurchase rights held by the Company with respect to such Awards will not terminate and may continue to be exercised notwithstanding the Corporate Transaction.

(iv) **Payment for Awards in Lieu of Exercise.** Notwithstanding the foregoing, in the event an Award will terminate if not exercised prior to the effective time of a Corporate Transaction, the Board may provide, in its sole discretion, that the holder of such Award may not exercise such Award but will receive a payment, in such form as may be determined by the Board, equal in value, at the effective time, to the excess, if any, of (1) the value of the property the Participant would have received upon the exercise of the Award (including, at the discretion of the Board, any unvested portion of such Award), over (2) any exercise price payable by such holder in connection with such exercise. For the avoidance of doubt, if the exercise price to be payable by a holder with respect to an Option or SAR exceeds the value of the property the Participant would have received upon the exercise of the Award (including, at the discretion of such Award), such Option or SAR may be cancelled without any consideration.

(d) **Appointment of Stockholder Representative.** As a condition to the receipt of an Award under this Plan, a Participant will be deemed to have agreed that the Award will be subject to the terms of any

agreement governing a Corporate Transaction involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on the Participant's behalf with respect to any escrow, indemnities and any contingent consideration.

(e) No Restriction on Right to Undertake Transactions. The grant of any Award under the Plan and the issuance of shares pursuant to any Award does not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, rights or options to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

7. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in subsection (c) below.

(b) **Powers of Board.** The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time (1) which of the persons eligible under the Plan will be granted Awards; (2) when and how each Award will be granted; (3) what type or combination of types of Award will be granted; (4) the provisions of each Award granted (which need not be identical), including the time or times when a person will be permitted to receive an issuance of Common Stock or other payment pursuant to an Award; (5) the number of shares of Common Stock or cash equivalent with respect to which an Award will be granted to each such person; (6) the Fair Market Value applicable to an Award; and (7) the terms of any Performance Award that is not valued in whole or in part by reference to, or otherwise based on, the Common Stock, including the amount of cash payment or other property that may be earned and the timing of payment.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it deems necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest, notwithstanding the provisions in the Award Agreement stating the time at which it may first be exercised or the time during which it will vest.

(v) To prohibit the exercise of any Option, SAR or other exercisable Award during a period of up to 30 days prior to the consummation of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Common Stock or the share price of the Common Stock, including any Corporate Transaction, for reasons of administrative convenience.

(vi) To suspend or terminate the Plan at any time. Suspension or termination of the Plan will not Materially Impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

(vii) To amend the Plan in any respect the Board deems necessary or advisable; provided, however, that stockholder approval will be required for any amendment to the extent required by Applicable Law. Except as provided above, rights under any Award granted before amendment of the Plan will not be Materially Impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(viii) To submit any amendment to the Plan for stockholder approval.

(ix) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however*, that, a Participant's rights under any Award will not be Materially Impaired by any such amendment unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(x) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(xi) To adopt such procedures and sub-plans as are necessary or appropriate to permit and facilitate participation in the Plan by, or take advantage of specific tax treatment for Awards granted to, Employees, Directors or Consultants who are non-U.S. nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement to ensure or facilitate compliance with the laws of the relevant non-U.S. jurisdiction).

(xii) To effect, at any time and from time to time, subject to the consent of any Participant whose Award is Materially Impaired by such action, (1) the reduction of the exercise price (or strike price) of any outstanding Option or SAR; (2) the cancellation of any outstanding Option or SAR and the grant in substitution therefor of (A) a new Option, SAR, Restricted Stock Award, RSU Award or Other Award, under the Plan or another equity plan of the Company, covering the same or a different number of shares of Common Stock, (B) cash and/or (C) other valuable consideration (as determined by the Board); or (3) any other action that is treated as a repricing under generally accepted accounting principles.

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to another Committee or a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. Each Committee may retain the authority to concurrently administer the Plan with the Committee or subcommittee to which it has delegated its authority hereunder and may, at any time, revest in such Committee some or all of the powers previously delegated. The Board may retain the authority to concurrently administer the Plan with any Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) **Rule 16b-3 Compliance.** To the extent an Award is intended to qualify for the exemption from Section 16(b) of the Exchange Act that is available under Rule 16b-3 of the Exchange Act, the Award will be granted by the Board or a Committee that consists solely of two or more Non-Employee Directors, as determined under Rule 16b-3(b)(3) of the Exchange Act and thereafter any action establishing or modifying the terms of the Award will be approved by the Board or a Committee meeting such requirements to the extent necessary for such exemption to remain available.

(d) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board or any Committee in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e) **Delegation to Other Person or Body.** The Board or any Committee may delegate to one or more persons or bodies the authority to do one or more of the following to the extent permitted by Applicable Law: (i) designate recipients, other than Officers, of Options and SARs (and, to the extent permitted by Applicable Law, other Awards), provided that no person or body may be delegated authority to grant an

Award to themself; (ii) determine the number of shares subject to such Awards; and (iii) determine the terms of such Awards; provided, however, that the Board or Committee action regarding such delegation will fix the terms of such delegation in accordance with Applicable Law, including without limitation Sections 152 and 157 of the Delaware General Corporation Law. Unless provided otherwise in the Board or Committee action regarding such delegation, each Award granted pursuant to this section will be granted on the applicable form of Award Agreement most recently approved for use by the Board or the Committee, with any modifications necessary to incorporate or reflect the terms of such Award. Notwithstanding anything to the contrary herein, neither the Board nor any Committee may delegate to any person or body (who is not a Director or that is not comprised solely of Directors, respectively) the authority to determine the Fair Market Value.

8. TAX WITHHOLDING

(a) **Withholding Authorization.** As a condition to acceptance of any Award under the Plan, a Participant authorizes withholding from payroll and any other amounts payable to such Participant, and otherwise agrees to make adequate provision for (including), any sums required to satisfy any U.S. federal, state, local and/or non-U.S. tax or social insurance contribution withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise, vesting or settlement of such Award, as applicable. Accordingly, a Participant may not be able to exercise an Award even though the Award is vested, and the Company shall have no obligation to issue shares of Common Stock subject to an Award, unless and until such obligations are satisfied.

(b) **Satisfaction of Withholding Obligation.** To the extent permitted by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any U.S. federal, state, local and/or non-U.S. tax or social insurance withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; (v) by allowing a Participant to effectuate a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board; or (vi) by such other method as may be set forth in the Award Agreement.

(c) No Obligation to Notify or Minimize Taxes; No Liability to Claims. Except as required by Applicable Law, the Company has no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Award. Furthermore, the Company has no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award and will not be liable to any holder of an Award for any adverse tax consequences to such holder in connection with an Award. As a condition to accepting an Award under the Plan, each Participant (i) agrees to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from such Award or other Company compensation, and (ii) acknowledges that such Participant was advised to consult with his or her own personal tax, financial and other legal advisors regarding the tax consequences of the Award and has either done so or knowingly and voluntarily declined to do so. Additionally, each Participant acknowledges any Option or SAR granted under the Plan is exempt from Section 409A only if the exercise or strike price is at least equal to the "fair market value" of the Common Stock on the date of grant as determined by the Internal Revenue Service and there is no other impermissible deferral of compensation associated with the Award. Additionally, as a condition to accepting an Option or SAR granted under the Plan, each Participant agrees to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates in the event that the Internal Revenue Service asserts that such exercise price or strike price is less than the "fair market value" of the Common Stock on the date of grant as subsequently determined by the Internal Revenue Service.

(d) **Withholding Indemnification.** As a condition to accepting an Award under the Plan, in the event that the amount of the Company's and/or its Affiliate's withholding obligation in connection with such Award was greater than the amount actually withheld by the Company and/or its Affiliates, each Participant agrees to indemnify and hold the Company and/or its Affiliates harmless from any failure by the Company and/or its Affiliates to withhold the proper amount.

9. MISCELLANEOUS.

(a) **Source of Shares.** The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

(b) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

(c) **Corporate Action Constituting Grant of Awards.** Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action approving the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(d) **Stockholder Rights.** No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Award unless and until (i) such Participant has satisfied all requirements for exercise of the Award pursuant to its terms, if applicable, and (ii) the issuance of the Common Stock subject to such Award is reflected in the records of the Company.

(e) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or affect the right of the Company or an Affiliate to terminate at will and without regard to any future vesting opportunity that a Participant may have with respect to any Award (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the U.S. state or non-U.S. jurisdiction in which the Company or the Affiliate is incorporated, as the case may be. Further, nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award will constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or service or confer any right or benefit under the Award or the Plan unless such right or benefit has specifically accrued under the terms of the Award Agreement and/or Plan.

(f) **Change in Time Commitment.** In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board may determine, to the extent permitted by Applicable Law, to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(g) **Execution of Additional Documents.** As a condition to accepting an Award under the Plan, the Participant agrees to execute any additional documents or instruments necessary or desirable, as determined in the Plan Administrator's sole discretion, to carry out the purposes or intent of the Award, or facilitate compliance with securities and/or other regulatory requirements, in each case at the Plan Administrator's request.

(h) **Electronic Delivery and Participation.** Any reference herein or in an Award Agreement to a "written" agreement or document will include any agreement or document delivered electronically, filed

publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access). By accepting any Award the Participant consents to receive documents by electronic delivery and to participate in the Plan through any on-line electronic system established and maintained by the Plan Administrator or another third party selected by the Plan Administrator. The form of delivery of any Common Stock (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

(i) **Clawback/Recovery.** All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other Applicable Law and any clawback policy that the Company otherwise adopts, to the extent applicable and permissible under Applicable Law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a Participant's right to voluntarily terminate employment upon a "resignation for good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

(j) Securities Law Compliance. A Participant will not be issued any shares in respect of an Award unless either (i) the shares are registered under the Securities Act or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Each Award also must comply with other Applicable Law governing the Award, and a Participant will not receive such shares if the Company determines that such receipt would not be in material compliance with Applicable Law.

(k) **Transfer or Assignment of Awards; Issued Shares.** Except as expressly provided in the Plan or the form of Award Agreement, Awards granted under the Plan may not be transferred or assigned by the Participant. After the vested shares subject to an Award have been issued, or in the case of a Restricted Stock Award and similar awards, after the issued shares have vested, the holder of such shares is free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, the terms of the Trading Policy and Applicable Law.

(1) Effect on Other Employee Benefit Plans. The value of any Award granted under the Plan, as determined upon grant, vesting or settlement, shall not be included as compensation, earnings, salaries, or other similar terms used when calculating any Participant's benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

(m) **Deferrals.** To the extent permitted by Applicable Law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may also establish programs and procedures for deferral elections to be made by Participants. Deferrals will be made in accordance with the requirements of Section 409A.

(n) Section 409A. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A, and, to the extent not so exempt, in compliance with the requirements of Section 409A. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A is a "specified employee" for purposes of Section 409A, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A without regard to alternative definitions thereunder) will be issued or paid before the date that is six months and one day

following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

(o) **Choice of Law.** This Plan and any controversy arising out of or relating to this Plan shall be governed by, and construed in accordance with, the internal laws of the State of Delaware, without regard to conflict of law principles that would result in any application of any law other than the law of the State of Delaware.

10. COVENANTS OF THE COMPANY.

The Company will seek to obtain from each regulatory commission or agency, as may be deemed to be necessary, having jurisdiction over the Plan such authority as may be required to grant Awards and to issue and sell shares of Common Stock upon exercise or vesting of the Awards; provided, however, that this undertaking will not require the Company to register under the Securities Act the Plan, any Award or any Common Stock issued or issuable pursuant to any such Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary or advisable for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise or vesting of such Awards unless and until such authority is obtained. A Participant is not eligible for the grant of an Award or the subsequent issuance of Common Stock pursuant to the Award if such grant or issuance would be in violation of any Applicable Law.

11. SEVERABILITY.

If all or any part of the Plan or any Award Agreement is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of the Plan or such Award Agreement not declared to be unlawful or invalid. Any Section of the Plan or any Award Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

12. TERMINATION OF THE PLAN.

The Board may suspend or terminate the Plan at any time. No Incentive Stock Options may be granted after the tenth anniversary of the earlier of: (a) the Adoption Date, or (b) the date the Plan is approved by the Company's stockholders. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

13. DEFINITIONS.

As used in the Plan, the following definitions apply to the capitalized terms indicated below:

(a) *"Acquiring Entity"* means the surviving or acquiring corporation (or its parent company) in connection with a Corporate Transaction.

(b) "*Adoption Date*" means the date the Plan is first approved by the Board or Compensation Committee, as applicable.

(c) "*Affiliate*" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 promulgated under the Securities Act. The Board may determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(d) "*Applicable Law*" means the Code and any applicable U.S. and non-U.S. securities, exchange control, tax, federal, state, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, listing rule, regulation, judicial decision, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of any applicable



self-regulating organization such as the Nasdaq Stock Market, New York Stock Exchange, or the Financial Industry Regulatory Authority).

(e) "*Award*" means any right to receive Common Stock, cash or other property granted under the Plan (including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, an RSU Award, a SAR, a Performance Award or any Other Award).

(f) "*Award Agreement*" means a written or electronic agreement between the Company and a Participant evidencing the terms and conditions of an Award. The Award Agreement generally consists of the Grant Notice and the agreement containing the written summary of the general terms and conditions applicable to the Award and which is provided, including through electronic means, to a Participant along with the Grant Notice.

(g) "*Board*" means the Board of Directors of the Company (or its designee). Any decision or determination made by the Board shall be a decision or determination that is made in the sole discretion of the Board (or its designee), and such decision or determination shall be final and binding on all Participants.

(h) "*Capitalization Adjustment*" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Award after the date the Plan is adopted by the Board without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(i) "Cause" has the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant's material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; (v) such Participant's gross misconduct; (vi) such Participant's failure or refusal to comply with a lawful material directive from the Board, the Participant's supervisor or, if applicable, the board of directors of any Affiliate; or (vii) such Participant's breach of a fiduciary duty to the Company. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Board with respect to Participants who are executive officers of the Company and by the Company's Chief Executive Officer with respect to Participants who are not executive officers of the Company. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(j) "*Change in Control*" or "*Change of Control*" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (1) on account of the acquisition of securities of the Company directly from the Company, (2) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related

transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (3) solely because the level of Ownership held by any Exchange Act Person (the "*Subject Person*") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (1) outstanding voting securities representing more than 50% of the combined outstanding voting power of the Acquiring Entity in such merger, consolidation or similar transaction or (2) more than 50% of the combined outstanding voting power of the parent of the Acquiring Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;

(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the "*Incumbent Board*") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, (1) the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, (2) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Awards subject to such agreement; provided, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply, and (3) with respect to any nonqualified deferred compensation that becomes payable on account of the Change in Control, the transaction or event described in clause (i), (ii), (iii), or (iv) also constitutes a Section 409A Change in Control if required in order for the payment not to violate Section 409A of the Code.

(k) "*Code*" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(1) "*Committee*" means the Compensation Committee and any other committee of one or more Directors to whom authority has been delegated by the Board or Compensation Committee in accordance with the Plan.

(m) "Common Stock" means the common stock of the Company.

- (n) "Company" means Tvardi Therapeutics, Inc., a Delaware corporation.
- (o) "Compensation Committee" means the Compensation Committee of the Board.

(p) "*Consultant*" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(q) "*Continuous Service*" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; provided, however, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(r) "*Corporate Transaction*" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(s) "*determine*" or "*determined*" means as determined by the Board or the Committee (or its designee) in its sole discretion.

(t) "Director" means a member of the Board.

(u) "*Disability*" means, with respect to a Participant, such Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous

period of not less than 12 months, as provided in Section 22(e)(3) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(v) "*Effective Date*" means the effective date of this Plan, which is the date of the closing of the transactions contemplated by the Merger Agreement, provided that this Plan is approved by the Company's stockholders prior to such date.

(w) "Effective Time" has the meaning set forth in the Merger Agreement.

(x) "*Employee*" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(y) "*Employer*" means the Company or the Affiliate that employs the Participant.

(z) "Entity" means a corporation, partnership, limited liability company or other entity.

(aa) "*Exchange Act*" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(bb) "*Exchange Act Person*" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company or the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company, or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(cc) "*Fair Market Value*" means, as of any date, unless otherwise determined by the Board, the value of the Common Stock (as determined on a per share or aggregate basis, as applicable) determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value will be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) If there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, or if otherwise determined by the Board, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(dd) "*Fully Diluted Common Stock*" means the number of shares of Common Stock, determined as of the applicable time of measurement, equal to the sum of (i) the total number of shares of Common Stock issued and outstanding and (ii) the total number of shares of Common Stock subject to securities that are convertible into or exercisable for shares of Common Stock (whether vested or unvested).

(ee) "*Governmental Body*" means any: (i) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (ii) U.S. or non-U.S. federal, state, local, municipal or other government; (iii) governmental or regulatory body, or quasi-governmental body of any nature (including any governmental division, department, administrative agency or bureau,

commission, authority, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any tax authority) or other body exercising similar powers or authority; or (iv) self-regulatory organization (including the Nasdaq Stock Market, New York Stock Exchange, and the Financial Industry Regulatory Authority).

(ff) "*Grant Notice*" means the notice provided to a Participant that he or she has been granted an Award under the Plan and which includes the name of the Participant, the type of Award, the date of grant of the Award, number of shares of Common Stock subject to the Award or potential cash payment right, (if any), the vesting schedule for the Award (if any) and other key terms applicable to the Award.

(gg) "*Incentive Stock Option*" means an option granted pursuant to Section 4 of the Plan that is intended to be, and qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

(hh) "*Materially Impair*" means any amendment to the terms of the Award that materially adversely affects the Participant's rights under the Award. A Participant's rights under an Award will not be deemed to have been Materially Impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights. For example, the following types of amendments to the terms of an Award do not Materially Impair the Participant's rights under the Award: (i) imposition of reasonable restrictions on the minimum number of shares subject to an Option or SAR that may be exercised; (ii) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (iii) to change the terms of an Incentive Stock Option in a manner that disqualifies, impairs or otherwise affects the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (iv) to clarify the manner of exemption from, or to bring the Award into compliance with or qualify it for an exemption from, Section 409A; or (v) to comply with other Applicable Laws.

(ii) "*Merger Agreement*" means that certain Agreement and Plan of Merger and Reorganization, dated as of December 17, 2024, by and among Cara Therapeutics, Inc., CT Convergence Merger Sub, Inc. and Tvardi Therapeutics, Inc.

(jj) "*Non-Employee Director*" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("*Regulation S-K*")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(kk) "*Nonstatutory Stock Option*" means any option granted pursuant to Section 4 of the Plan that does not qualify as an Incentive Stock Option.

(11) "Officer" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(mm) "*Option*" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(nn) "**Option Agreement**" means a written or electronic agreement between the Company and the Optionholder evidencing the terms and conditions of the Option grant. The Option Agreement includes the Grant Notice for the Option and the agreement containing the written summary of the general terms and conditions applicable to the Option and which is provided including through electronic means, to a Participant along with the Grant Notice. Each Option Agreement will be subject to the terms and conditions of the Plan.

(oo) "*Optionholder*" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(pp) "*Other Award*" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 5(c).

(qq) "*Other Award Agreement*" means a written or electronic agreement between the Company and a holder of an Other Award evidencing the terms and conditions of an Other Award grant. Each Other Award Agreement will be subject to the terms and conditions of the Plan.

(rr) "**Own**," "**Owned**," "**Owner**," "**Ownership**" means that a person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ss) "*Participant*" means an Employee, Director or Consultant to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

(tt) "*Performance Award*" means an Award that may vest or may be exercised or a cash award that may vest or become earned and paid contingent upon the attainment during a Performance Period of certain Performance Goals and which is granted under the terms and conditions of Section 5(b) pursuant to such terms as are approved by the Board. In addition, to the extent permitted by Applicable Law and set forth in the applicable Award Agreement, the Board may determine that cash or other property may be used in payment of Performance Awards. Performance Awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the Common Stock.

(uu) "Performance Criteria" means the one or more criteria that the Board will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Board: earnings (including earnings per share and net earnings); earnings before interest, taxes and depreciation; earnings before interest, taxes, depreciation and amortization; total stockholder return; return on equity or average stockholder's equity; return on assets, investment, or capital employed; stock price; margin (including gross margin); income (before or after taxes); operating income; operating income after taxes; pre-tax profit; operating cash flow; sales or revenue targets; increases in revenue or product revenue; expenses and cost reduction goals; improvement in or attainment of working capital levels; economic value added (or an equivalent metric); market share; cash flow; cash flow per share; share price performance; debt reduction; customer satisfaction; stockholders' equity; capital expenditures; debt levels; operating profit or net operating profit; workforce diversity; growth of net income or operating income; billings; preclinical development related compound goals; financing; regulatory milestones, including approval of a compound; stockholder liquidity; corporate governance and compliance; product commercialization; intellectual property; personnel matters; progress of internal research or clinical programs; progress of partnered programs; partner satisfaction; budget management; clinical achievements; completing phases of a clinical trial (including the treatment phase); announcing or presenting preliminary or final data from clinical trials, in each case, whether on particular timelines or generally; timely completion of clinical trials; submission of INDs and NDAs and other regulatory achievements; partner or collaborator achievements; internal controls, including those related to the Sarbanes-Oxley Act of 2002; research progress, including the development of programs; investor relations, analysts and communication; manufacturing achievements (including obtaining particular yields from manufacturing runs and other measurable objectives related to process development activities); strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property); establishing relationships with commercial entities with respect to the marketing, distribution and sale of the Company's products (including with group purchasing organizations, distributors and other vendors); supply chain achievements (including establishing relationships with manufacturers or suppliers of active pharmaceutical ingredients and other component materials and manufacturers of the Company's products); co-development, co-marketing, profit sharing, joint venture or other similar arrangements; individual performance goals; corporate development and planning goals; and other measures of performance selected by the Board or Committee.

(vv) "Performance Goals" means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of Common Stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles. In addition, the Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for such Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Award Agreement or the written terms of a Performance Award.

(ww) "*Performance Period*" means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to vesting or exercise of an Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(xx) "*Plan*" means this Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan, as amended from time to time.

(yy) "*Plan Administrator*" means the person, persons, and/or third-party administrator designated by the Company to administer the day-to-day operations of the Plan and the Company's other equity incentive programs.

(zz) "*Post-Termination Exercise Period*" means the period following termination of a Participant's Continuous Service within which an Option or SAR is exercisable, as specified in Section 4(h).

(aaa) "*Prospectus*" means the document containing the Plan information specified in Section 10(a) of the Securities Act.

(bbb) "*Restricted Stock Award*" means an Award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

(ccc) "*Restricted Stock Award Agreement*" means a written or electronic agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. The Restricted Stock Award Agreement includes the Grant Notice for the Restricted Stock Award and the agreement containing the written summary of the general terms and conditions applicable to the Restricted Stock Award and which is provided including by electronic means, to a Participant along with the Grant Notice. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ddd) "**RSU** Award" or "**RSU**" means an Award of restricted stock units representing the right to receive an issuance of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

(eee) "*RSU Award Agreement*" means a written or electronic agreement between the Company and a holder of an RSU Award evidencing the terms and conditions of an RSU Award grant. The RSU Award Agreement includes the Grant Notice for the RSU Award and the agreement containing the written summary of the general terms and conditions applicable to the RSU Award and which is provided, including by electronic means, to a Participant along with the Grant Notice. Each RSU Award Agreement will be subject to the terms and conditions of the Plan.

(fff) "*Rule 16b-3*" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(ggg) "Rule 405" means Rule 405 promulgated under the Securities Act.

(hhh) "*SAR Agreement*" means a written or electronic agreement between the Company and a holder of a SAR evidencing the terms and conditions of a SAR grant. The SAR Agreement includes the Grant Notice for the SAR and the agreement containing the written summary of the general terms and conditions applicable to the SAR and which is provided, including by electronic means, to a Participant along with the Grant Notice. Each SAR Agreement will be subject to the terms and conditions of the Plan.

(iii) "Section 409A" means Section 409A of the Code and the regulations and other guidance thereunder.

(jjj) "Section 409A Change in Control" means a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets, as provided in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(kkk) "Securities Act" means the Securities Act of 1933, as amended.

(III) "*Share Reserve*" means the number of shares available for issuance under the Plan as set forth in Section 2(a).

(mmm) "*Stock Appreciation Right*" or "*SAR*" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 4.

(nnn) "*Subsidiary*" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(000) "*Ten Percent Stockholder*" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate.

(ppp) "*Trading Policy*" means the Company's policy permitting certain individuals to sell Company shares only during certain "window" periods and/or otherwise restricts the ability of certain individuals to transfer or encumber Company shares, as in effect from time to time.

ANNEX E

TVARDI THERAPEUTICS, INC.

2025 EMPLOYEE STOCK PURCHASE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: [] APPROVED BY THE STOCKHOLDERS: []

1. GENERAL; PURPOSE.

(a) The Plan provides a means by which Eligible Employees of the Company and certain Designated Companies may be given an opportunity to purchase shares of Common Stock. The Plan permits the Company to grant a series of Purchase Rights to Eligible Employees under an Employee Stock Purchase Plan. In addition, the Plan permits the Company to grant a series of Purchase Rights to Eligible Employees that do not meet the requirements of an Employee Stock Purchase Plan.

(b) The Plan includes two components: a 423 Component and a Non-423 Component. The Company intends (but makes no undertaking or representation to maintain) the 423 Component to qualify as an Employee Stock Purchase Plan. The provisions of the 423 Component, accordingly, will be construed in a manner that is consistent with the requirements of Section 423 of the Code. In addition, this Plan authorizes grants of Purchase Rights under the Non-423 Component that do not meet the requirements of an Employee Stock Purchase Plan. Except as otherwise provided in the Plan or determined by the Board, the Non-423 Component will operate and be administered in the same manner as the 423 Component. In addition, the Company may make separate Offerings which vary in terms (provided that such terms are not inconsistent with the provisions of the Plan or the requirements of an Employee Stock Purchase Plan to the extent the Offering is made under the 423 Component), and the Company will designate which Designated Company is participating in each separate Offering.

(c) The Company, by means of the Plan, seeks to retain the services of Eligible Employees, to secure and retain the services of new Employees and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Related Corporations.

2. ADMINISTRATION.

(a) The Board will administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 2(c). References herein to the Board shall be deemed to refer to the Committee except where context dictates otherwise.

(b) The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine how and when Purchase Rights will be granted and the provisions of each Offering (which need not be identical).

(ii) To designate from time to time (A) which Related Corporations will be eligible to participate in the Plan as Designated 423 Companies, (B) which Related Corporations or Affiliates will be eligible to participate in the Plan as Designated Non-423 Companies, (C) which Affiliates or Related Corporations may be excluded from participation in the Plan, and (D) which Designated Companies will participate in each separate Offering (to the extent that the Company makes separate Offerings).

(iii) To construe and interpret the Plan and Purchase Rights, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, in a manner and to the extent it deems necessary or expedient to make the Plan fully effective.

(iv) To settle all controversies regarding the Plan and Purchase Rights granted under the Plan.

(v) To suspend or terminate the Plan at any time as provided in Section 12.

(vi) To amend the Plan at any time as provided in Section 12.

(vii) Generally, to exercise such powers and to perform such acts as it deems necessary or expedient to promote the best interests of the Company and its Related Corporations and to carry out the intent that the Plan be treated as an Employee Stock Purchase Plan with respect to the 423 Component.

(viii) To adopt such rules, procedures and sub-plans as are necessary or appropriate to permit or facilitate participation in the Plan by Employees who are non-U.S. nationals or employed or located outside the United States. Without limiting the generality of, and consistent with, the foregoing, the Board specifically is authorized to adopt rules, procedures, and sub-plans regarding, without limitation, eligibility to participate in the Plan, the definition of eligible "earnings," handling and making of Contributions, establishment of bank or trust accounts to hold Contributions, payment of interest, conversion of local currency, obligations to pay payroll tax, determination of beneficiary designation requirements, withholding procedures and handling of share issuances, any of which may vary according to applicable requirements, and which, if applicable to a Designated Non-423 Company, do not have to comply with the requirements of Section 423 of the Code.

(c) The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee any of the administrative powers the Committee is authorized to exercise (and references in this Plan and any applicable Offering Document to the Board will thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. Further, to the extent not prohibited by Applicable Law, the Board or Committee may, from time to time, delegate some or all of its authority under the Plan to one or more Officers or other persons or groups of persons as it deems necessary, appropriate or advisable under conditions or limitations that it may set at or after the time of the delegation. The Board may retain the authority to concurrently administer the Plan with the Committee (or its delegate) and may, at any time, revest in the Board some or all of the powers previously delegated. Whether or not the Board has delegated administration of the Plan to a Committee (or a delegate of the Committee), the Board will have the final power to determine all questions of policy and expediency that may arise in the administration of the Plan.

(d) All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

3. SHARES OF COMMON STOCK SUBJECT TO THE PLAN.

(a) Subject to the provisions of Section 11(a) relating to Capitalization Adjustments, the maximum number of shares of Common Stock that may be issued under the Plan will not exceed [] shares of Common Stock (the "*Initial Share Reserve*"),¹ plus the number of shares of Common Stock that are automatically added on January 1st of each year for a period of up to ten years, commencing on January 1, 2026 and ending on (and including) January 1, 2035 in an amount equal to the lesser of (x) one percent (1%) of the total number of shares of Fully Diluted Common Stock outstanding on December 31st of the preceding calendar year, and (y) a number of shares equal to three times the Initial Share Reserve. Notwithstanding the foregoing, the Board may act prior to the first day of any calendar year to provide that there will be no January 1st increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence. For the avoidance of doubt, up to the maximum number of shares of Common Stock reserved under this Section 3(a) may be used to satisfy purchases of Common Stock under the 423 Component and any remaining portion of such maximum number of shares may be used to satisfy purchases of Common Stock under the Non-423 Component.

¹ NTD: Equal to 1% of the total number of shares of common stock issued and outstanding immediately after the Effective Time.



(b) If any Purchase Right granted under the Plan terminates without having been exercised in full, the shares of Common Stock not purchased under such Purchase Right will again become available for issuance under the Plan.

(c) The stock purchasable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market.

4. GRANT OF PURCHASE RIGHTS; OFFERING.

(a) The Board may from time to time grant or provide for the grant of Purchase Rights to Eligible Employees under an Offering (consisting of one or more Purchase Periods) on an Offering Date or Offering Dates selected by the Board. Each Offering will be in such form and will contain such terms and conditions as the Board will deem appropriate, and with respect to the 423 Component, will comply with the requirement of Section 423(b)(5) of the Code that all Employees granted Purchase Rights will have the same rights and privileges. The terms and conditions of an Offering shall be incorporated by reference into the Plan and treated as part of the Plan. The provisions of separate Offerings need not be identical, but each Offering will include (through incorporation of the provisions of this Plan by reference in the document comprising the Offering or otherwise) the period during which the Offering will be effective, which period will not exceed 27 months beginning with the Offering Date, and the substance of the provisions contained in Sections 5 through 8, inclusive.

(b) If a Participant has more than one Purchase Right outstanding under the Plan, unless such Participant otherwise indicates in forms delivered to the Company or a third party designated by the Company (each, a "*Company Designee*"): (i) each form will apply to all of such Participant's Purchase Rights under the Plan, and (ii) a Purchase Right with a lower exercise price (or an earlier-granted Purchase Right, if different Purchase Rights have identical exercise prices) will be exercised to the fullest possible extent before a Purchase Right with a higher exercise price (or a later-granted Purchase Right if different Purchase Rights have identical exercise price (or a later-granted Purchase Right if different Purchase Rights have identical exercise) will be exercised.

(c) The Board will have the discretion to structure an Offering so that if the Fair Market Value of a share of Common Stock on the first Trading Day of a new Purchase Period within that Offering is less than or equal to the Fair Market Value of a share of Common Stock on the Offering Date for that Offering, then (i) that Offering will terminate immediately as of that first Trading Day, and (ii) the Participants in such terminated Offering will be automatically enrolled in a new Offering beginning on the first Trading Day of such new Purchase Period.

5. ELIGIBILITY.

(a) Purchase Rights may be granted only to Employees of the Company or, as the Board may designate in accordance with Section 2(b), to Employees of a Related Corporation or an Affiliate. Except as provided in Section 5(b) or as required by Applicable Law, an Employee will not be eligible to be granted Purchase Rights unless, on the Offering Date, the Employee has been in the employ of the Company, the Related Corporation or the Affiliate, as the case may be, for such continuous period preceding such Offering Date as the Board may (unless prohibited by Applicable Law) require, but in no event will the required period of continuous employment be equal to or greater than two years. In addition, the Board may provide (unless prohibited by Applicable Law) that no Employee's customary employment with the Company, the Related Corporation or the Affiliate is more than 20 hours per week and more than five months per calendar year or such other criteria as the Board may determine consistent with Section 423 of the Code with respect to the 423 Component. The Board may also exclude (unless prohibited by Applicable Law) from participation in the Plan or any Offering Employees who are "highly compensated employees" (within the meaning of Section 423(b)(4)(D) of the Code) of the Company, a Related Corporation or an Affiliate, or a subset of such highly compensated employees.

(b) The Board may provide that each person who, during the course of an Offering, first becomes an Eligible Employee will, on a date or dates specified in the Offering which coincides with the day on which such person becomes an Eligible Employee or which occurs thereafter, receive a Purchase Right under that

Offering, which Purchase Right will thereafter be deemed to be a part of that Offering. Such Purchase Right will have the same characteristics as any Purchase Rights originally granted under that Offering, as described herein, except that:

(i) the date on which such Purchase Right is granted will be the "Offering Date" of such Purchase Right for all purposes, including determination of the exercise price of such Purchase Right;

(ii) the period of the Offering with respect to such Purchase Right will begin on its Offering Date and end coincident with the end of such Offering; and

(iii) the Board may provide that if such person first becomes an Eligible Employee within a specified period of time before the end of the Offering, such individual will not receive any Purchase Right under that Offering.

(c) No Employee will be eligible for the grant of any Purchase Rights under the 423 Component if, immediately after any such Purchase Rights are granted, such Employee owns stock possessing five percent or more of the total combined voting power or value of all classes of stock of the Company or of any Related Corporation. For purposes of this Section 5(c), the rules of Section 424(d) of the Code will apply in determining the stock ownership of any Employee, and stock which such Employee may purchase under all outstanding Purchase Rights and options will be treated as stock owned by such Employee.

(d) As specified by Section 423(b)(8) of the Code, an Eligible Employee may be granted Purchase Rights under the 423 Component only if such Purchase Rights, together with any other rights granted under all Employee Stock Purchase Plans of the Company and any Related Corporations, do not permit such Eligible Employee's rights to purchase stock of the Company or any Related Corporation to accrue at a rate which, when aggregated, exceeds \$25,000 of Fair Market Value of such stock (determined at the time such rights are granted, and which, with respect to the Plan, will be determined as of their respective Offering Dates) for each calendar year in which such rights are outstanding at any time.

(e) Officers of the Company and any Designated Company, if they are otherwise Eligible Employees, will be eligible to participate in Offerings under the Plan. Notwithstanding the foregoing, the Board may (unless prohibited by Applicable Law) provide in an Offering that Employees who are highly compensated Employees within the meaning of Section 423(b)(4)(D) of the Code will not be eligible to participate.

(f) Notwithstanding anything in this Section 5 to the contrary, in the case of an Offering under the Non-423 Component, an Eligible Employee (or group of Eligible Employees) may be excluded from participation in the Plan or an Offering if the Board has determined, in its sole discretion, that participation of such Eligible Employee(s) is not advisable or practical for any reason.

6. PURCHASE RIGHTS; PURCHASE PRICE.

(a) On each Offering Date, each Eligible Employee, pursuant to an Offering made under the Plan, will be granted a Purchase Right to purchase up to that number of shares of Common Stock purchasable either with a percentage of earnings (as defined by the Board in each Offering) or with a maximum dollar amount, as designated by the Board, but in either case not exceeding 15% of such Employee's earnings (as defined by the Board in each Offering), during the period that begins on the Offering Date (or such later date as the Board determines for a particular Offering) and ends on the date stated in the Offering, which date will be no later than the end of the Offering.

(b) The Board will establish one or more Purchase Dates during an Offering on which Purchase Rights granted for that Offering will be exercised and shares of Common Stock will be purchased in accordance with such Offering.

(c) In connection with each Offering made under the Plan, the Board may specify (i) a maximum number of shares of Common Stock that may be purchased by any Participant on any Purchase Date during such Offering, (ii) a maximum aggregate number of shares of Common Stock that may be purchased by all Participants pursuant to such Offering and/or (iii) a maximum aggregate number of shares of Common Stock that may be purchased by all Participants on any Purchase Date under the Offering. If the aggregate purchase of shares of Common Stock issuable upon exercise of Purchase Rights granted under the

Offering would exceed any such maximum aggregate number, then, in the absence of any Board action otherwise, a pro rata (based on each Participant's accumulated Contributions) allocation of the shares of Common Stock (rounded down to the nearest whole share) available will be made in as nearly a uniform manner as will be practicable and equitable.

(d) The purchase price of shares of Common Stock acquired pursuant to Purchase Rights will be no less than the lesser of:

(i) an amount equal to 85% of the Fair Market Value of the shares of Common Stock on the Offering Date; or

(ii) an amount equal to 85% of the Fair Market Value of the shares of Common Stock on the applicable Purchase Date.

7. PARTICIPATION; WITHDRAWAL; TERMINATION.

(a) An Eligible Employee may elect to participate in an Offering and authorize payroll deductions as the means of making Contributions by completing and delivering to the Company or a Company Designee, within the time specified in the Offering, an enrollment form provided by the Company or a Company Designee. The enrollment form will specify the amount of Contributions not to exceed the maximum amount specified by the Board. Each Participant's Contributions will be credited to a bookkeeping account for such Participant under the Plan and will be deposited with the general funds of the Company except where Applicable Law requires that Contributions be deposited with a third party. If permitted in the Offering, a Participant may begin such Contributions with the first payroll occurring on or after the Offering Date (or, in the case of a payroll date that occurs after the end of the prior Offering but before the Offering Date of the next new Offering, Contributions from such payroll will be included in the new Offering). If permitted in the Offering, a Participant may thereafter reduce (including to zero) or increase such Participant's Contributions. If required under Applicable Law or if specifically provided in the Offering and to the extent permitted by Section 423 of the Code with respect to the 423 Component, in addition to or instead of making Contributions by payroll deductions, a Participant may make Contributions through the payment by cash, check or wire transfer prior to a Purchase Date.

(b) During an Offering, a Participant may cease making Contributions and withdraw from the Offering by delivering to the Company or a Company Designee a withdrawal form provided by the Company. The Company may impose a deadline before a Purchase Date for withdrawing. Upon such withdrawal, such Participant's Purchase Right in that Offering will immediately terminate and the Company will distribute as soon as practicable to such Participant all of such Participant's accumulated but unused Contributions and such Participant's Purchase Right in that Offering shall thereupon terminate. A Participant's withdrawal from that Offering will have no effect upon such Participant's eligibility to participate in any other Offerings under the Plan, but such Participant will be required to deliver a new enrollment form to participate in subsequent Offerings.

(c) Unless otherwise required by Applicable Law, Purchase Rights granted pursuant to any Offering under the Plan will terminate immediately if the Participant either (i) is no longer an Employee for any reason or for no reason (subject to any post-employment participation period required by Applicable Law) or (ii) is otherwise no longer eligible to participate. The Company will distribute as soon as practicable to such individual all of such individual's accumulated but unused Contributions.

(d) Unless otherwise determined by the Board, a Participant whose employment transfers or whose employment terminates with an immediate rehire (with no break in service) by or between the Company and a Designated Company or between Designated Companies will not be treated as having terminated employment for purposes of participating in the Plan or an Offering; however, if a Participant transfers from an Offering under the 423 Component to an Offering under the Non-423 Component, the exercise of the Participant's Purchase Right will be qualified under the 423 Component only to the extent such exercise complies with Section 423 of the Code. If a Participant transfers from an Offering under the Non-423 Component to an Offering under the 423 Component, the exercise of the Purchase Right will remain non-qualified under the Non-423 Component. The Board may establish different and additional rules

governing transfers between separate Offerings within the 423 Component and between Offerings under the 423 Component and Offerings under the Non-423 Component.

(e) During a Participant's lifetime, Purchase Rights will be exercisable only by such Participant. Purchase Rights are not transferable by a Participant, except by will, by the laws of descent and distribution, or, if permitted by the Company, by a beneficiary designation as described in Section 10.

(f) Unless otherwise specified in the Offering or required by Applicable Law, the Company will have no obligation to pay interest on Contributions.

8. EXERCISE OF PURCHASE RIGHTS.

(a) On each Purchase Date, each Participant's accumulated Contributions will be applied to the purchase of shares of Common Stock, up to the maximum number of shares of Common Stock permitted by the Plan and the applicable Offering, at the purchase price specified in the Offering. No fractional shares will be issued unless specifically provided for in the Offering.

(b) Unless otherwise provided in the Offering, if any amount of accumulated Contributions remains in a Participant's account after the purchase of shares of Common Stock and such remaining amount is less than the amount required to purchase one share of Common Stock on the final Purchase Date of an Offering, then such remaining amount will be held in such Participant's account for the purchase of shares of Common Stock under the next Offering under the Plan, unless such Participant withdraws from or is not eligible to participate in such next Offering, in which case such amount will be distributed to such Participant after the final Purchase Date without interest (unless the payment of interest is otherwise required by Applicable Law). If the amount of Contributions remaining in a Participant's account after the purchase of shares of an Offering, then such remaining amount will be distributed in full to such Participant after the final Purchase Date of an Offering, then such remaining amount will be distributed in full to such Participant after the final Purchase Date of an Offering, then such remaining amount will be distributed in full to such Participant after the final Purchase Date of such Offering without interest (unless otherwise required by Applicable Law).

(c) No Purchase Rights may be exercised to any extent unless the shares of Common Stock to be issued upon such exercise under the Plan are covered by an effective registration statement pursuant to the Securities Act and the Plan is in material compliance with all applicable U.S. and non-U.S. federal, state and other securities, exchange control and other laws applicable to the Plan. If on a Purchase Date the shares of Common Stock are not so registered or the Plan is not in such compliance, no Purchase Rights will be exercised on such Purchase Date, and, subject to Section 423 of the Code with respect to the 423 Component, the Purchase Date will be delayed until the shares of Common Stock are subject to such an effective registration statement and the Plan is in material compliance, except that the Purchase Date will in no event be more than 27 months from the Offering Date. If, on the Purchase Date, as delayed to the maximum extent permissible, the shares of Common Stock are not registered and the Plan is not in material compliance with all Applicable Laws, as determined by the Company in its sole discretion, no Purchase Rights will be exercised and all accumulated but unused Contributions will be distributed to the Participants without interest (unless the payment of interest is otherwise required by Applicable Law).

9. COVENANTS OF THE COMPANY.

The Company will seek to obtain from each U.S. and non-U.S. federal, state or other regulatory commission, agency or other Governmental Body having jurisdiction over the Plan such authority as may be required to grant Purchase Rights and issue and sell shares of Common Stock thereunder unless the Company determines, in its sole discretion, that doing so is not practical or would cause the Company to incur costs that are unreasonable. If, after commercially reasonable efforts, the Company is unable to obtain the authority that counsel for the Company deems necessary for the grant of Purchase Rights or the lawful issuance and sale of Common Stock under the Plan, and at a commercially reasonable cost, the Company will be relieved from any liability for failure to grant Purchase Rights and/or to issue and sell Common Stock upon exercise of such Purchase Rights.

10. DESIGNATION OF BENEFICIARY.

(a) The Company may, but is not obligated to, permit a Participant to submit a form designating a beneficiary who will receive any shares of Common Stock and/or Contributions from the Participant's

account under the Plan if the Participant dies before such shares and/or Contributions are delivered to the Participant. The Company may, but is not obligated to, permit the Participant to change such designation of beneficiary. Any such designation and/or change must be on a form approved by the Company.

(b) If a Participant dies, and in the absence of a valid beneficiary designation, the Company will deliver any shares of Common Stock and/or Contributions to the executor or administrator of the estate of the Participant. If no executor or administrator has been appointed (to the knowledge of the Company), the Company, in its sole discretion, may deliver such shares of Common Stock and/or Contributions, without interest (unless the payment of interest is otherwise required by Applicable Law), to the Participant's spouse, dependents or relatives, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.

11. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; CORPORATE TRANSACTIONS.

(a) In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities by which the share reserve is to increase automatically each year pursuant to Section 3(a), (iii) the class(es) and number of securities subject to, and the purchase price applicable to outstanding Offerings and Purchase Rights, and (iv) the class(es) and number of securities that are the subject of the purchase limits under each ongoing Offering. The Board will make these adjustments, and its determination will be final, binding and conclusive.

(b) In the event of a Corporate Transaction, then: (i) any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue outstanding Purchase Rights or may substitute similar rights (including a right to acquire the same consideration paid to the stockholders in the Corporate Transaction) for outstanding Purchase Rights, or (ii) if any surviving or acquiring corporation (or its parent company) does not assume or continue such Purchase Rights or does not substitute similar rights for such Purchase Rights, then the Participants' accumulated Contributions will be used to purchase shares of Common Stock (rounded down to the nearest whole share) within ten business days (or such other period specified by the Board) prior to the Corporate Transaction under the outstanding Purchase Rights, and the Purchase Rights will terminate immediately after such purchase.

12. AMENDMENT, TERMINATION OR SUSPENSION OF THE PLAN.

(a) The Board may amend the Plan at any time in any respect the Board deems necessary or advisable. However, except as provided in Section 11(a) relating to Capitalization Adjustments, stockholder approval will be required for any amendment of the Plan for which stockholder approval is required by Applicable Law.

(b) The Board may suspend or terminate the Plan at any time. No Purchase Rights may be granted under the Plan while the Plan is suspended or after it is terminated.

(c) Any benefits, privileges, entitlements and obligations under any outstanding Purchase Rights granted before an amendment, suspension or termination of the Plan will not be materially impaired by any such amendment, suspension or termination except (i) with the consent of the person to whom such Purchase Rights were granted, (ii) as necessary to facilitate compliance with any laws, listing requirements, or governmental regulations (including, without limitation, the provisions of Section 423 of the Code and the regulations and other interpretive guidance issued thereunder relating to Employee Stock Purchase Plans) including without limitation any such regulations or other guidance that may be issued or amended after the date the Plan is adopted by the Board, or (iii) as necessary to obtain or maintain favorable tax, listing, or regulatory treatment. To be clear, the Board may amend outstanding Purchase Rights without a Participant's consent if such amendment is necessary to ensure that the Purchase Right and/or the Plan complies with the requirements of Section 423 of the Code with respect to the 423 Component or with respect to other Applicable Laws. Notwithstanding anything in the Plan or any Offering Document to the contrary, the Board will be entitled to: (i) establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars; (ii) permit Contributions in excess of the amount designated by a Participant in order to adjust for mistakes in the Company's processing of properly completed Contribution elections; (iii) establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that

amounts applied toward the purchase of Common Stock for each Participant properly correspond with amounts withheld from the Participant's Contributions; (iv) amend any outstanding Purchase Rights or clarify any ambiguities regarding the terms of any Offering to enable the Purchase Rights to qualify under and/or comply with Section 423 of the Code with respect to the 423 Component; and (v) establish other limitations or procedures as the Board determines in its sole discretion advisable that are consistent with the Plan. The actions of the Board pursuant to this paragraph will not be considered to alter or impair any Purchase Rights granted under an Offering as they are part of the initial terms of each Offering and the Purchase Rights granted under each Offering.

13. TAX QUALIFICATION; TAX WITHHOLDING.

(a) Although the Company may endeavor to (i) qualify a Purchase Right for special tax treatment under the laws of the United States or jurisdictions outside of the United States or (ii) avoid adverse tax treatment, the Company makes no representation to that effect and expressly disavows any covenant to maintain special or to avoid unfavorable tax treatment, notwithstanding anything to the contrary in this Plan. The Company will be unconstrained in its corporate activities without regard to the potential negative tax impact on Participants.

(b) Each Participant will make arrangements, satisfactory to the Company and any applicable Related Corporation, to enable the Company or the Related Corporation to fulfill any withholding obligation for Tax-Related Items. Without limitation to the foregoing, in the Company's sole discretion and subject to Applicable Law, such withholding obligation may be satisfied in whole or in part by (i) withholding from the Participant's salary or any other cash payment due to the Participant from the Company or a Related Corporation; (ii) withholding from the proceeds of the sale of shares of Common Stock acquired under the Plan, either through a voluntary sale or a mandatory sale arranged by the Company; or (iii) any other method deemed acceptable by the Board. The Company shall not be required to issue any shares of Common Stock under the Plan until such obligations are satisfied.

(c) The 423 Component is exempt from the application of Section 409A of the Code, and any ambiguities herein shall be interpreted to so be exempt from Section 409A of the Code. The Non-423 Component is intended to be exempt from the application of Section 409A of the Code under the short-term deferral exception and any ambiguities shall be construed and interpreted in accordance with such intent. In furtherance of the foregoing and notwithstanding any provision in the Plan to the contrary, if the Committee determines that an option granted under the Plan may be subject to Section 409A of the Code or that any provision in the Plan would cause an option under the Plan to be subject to Section 409A, the Committee may amend the terms of the Plan and/or of an outstanding option granted under the Plan, or take such other action the Committee determines is necessary or appropriate, in each case, without the Participant's consent, to exempt any outstanding option or future option that may be granted under the Plan from or to allow any such options to comply with Section 409A of the Code, but only to the extent any such amendments or action by the Committee would not violate Section 409A of the Code. Notwithstanding the foregoing, the Company shall have no liability to a Participant or any other party if the option under the Plan that is intended to be exempt from or compliant with Section 409A of the Code is not so exempt or compliant or for any action taken by the Committee with respect thereto.

14. EFFECTIVE DATE OF PLAN.

The Plan will become effective immediately prior to and contingent upon the Effective Date. No Purchase Rights will be exercised unless and until the Plan has been approved by the stockholders of the Company, which approval must be within 12 months before or after the date the Plan is adopted (or if required under Section 12(a) above, materially amended) by the Board.

15. MISCELLANEOUS PROVISIONS.

(a) Proceeds from the sale of shares of Common Stock pursuant to Purchase Rights will constitute general funds of the Company.

(b) A Participant will not be deemed to be the holder of, or to have any of the rights of a holder with respect to, shares of Common Stock subject to Purchase Rights unless and until the Participant's shares of Common Stock acquired upon exercise of Purchase Rights are recorded in the books of the Company (or its transfer agent).

(c) The Plan and Offering do not constitute an employment contract. Nothing in the Plan or in the Offering will in any way alter the at will nature of a Participant's employment or amend a Participant's employment contract, if applicable, or be deemed to create in any way whatsoever any obligation on the part of any Participant to continue in the employ of the Company or a Related Corporation or an Affiliate, or on the part of the Company, a Related Corporation or an Affiliate to continue the employment of a Participant.

(d) The provisions of the Plan will be governed by the laws of the State of Delaware without resort to that state's conflict of laws rules.

(e) If any particular provision of the Plan is found to be invalid or otherwise unenforceable, such provision will not affect the other provisions of the Plan, but the Plan will be construed in all respects as if such invalid provision were omitted.

(f) If any provision of the Plan does not comply with Applicable Law, such provision shall be construed in such a manner as to comply with Applicable Law.

16. DEFINITIONS.

As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "423 Component" means the part of the Plan, which excludes the Non-423 Component, pursuant to which Purchase Rights that satisfy the requirements for an Employee Stock Purchase Plan may be granted to Eligible Employees.

(b) "*Affiliate*" means any entity, other than a Related Corporation, whether now or subsequently established, which is at the time of determination, a "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 promulgated under the Securities Act. The Board may determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(c) "*Applicable Law*" means the Code and any applicable U.S. and non-U.S. securities, exchange control, tax, federal, state, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, listing rule, regulation, judicial decision, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (or under the authority of the New York Stock Exchange, Nasdaq Stock Market or the Financial Industry Regulatory Authority).

(d) "Board" means the Board of Directors of the Company.

(e) "*Capitalization Adjustment*" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Purchase Right after the date the Plan is adopted by the Board without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) "*Code*" means the U.S. Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(g) "*Committee*" means a committee of one or more members of the Board to whom authority has been delegated by the Board in accordance with Section 2(c).

(h) "Common Stock" means the common stock of the Company.

(i) "Company" means Tvardi Therapeutics, Inc., a Delaware corporation.

(j) *"Contributions"* means the payroll deductions and other additional payments specifically provided for in the Offering that a Participant contributes to fund the exercise of a Purchase Right. A Participant may make additional payments into his or her account if specifically provided for in the Offering, and then only if the Participant has not already had the maximum permitted amount withheld during the Offering through payroll deductions and, with respect to the 423 Component, to the extent permitted by Section 423.

(k) "*Corporate Transaction*" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its subsidiaries;

(ii) a sale or other disposition of more than 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(1) "*Designated 423 Company*" means any Related Corporation selected by the Board as participating in the 423 Component.

(m) "*Designated Company*" means any Designated Non-423 Company or Designated 423 Company, provided, however, that at any given time, a Related Corporation participating in the 423 Component shall not be a Related Corporation participating in the Non-423 Component.

(n) "*Designated Non-423 Company*" means any Related Corporation or Affiliate selected by the Board as participating in the Non-423 Component.

(o) "Director" means a member of the Board.

(p) "*Effective Date*" means the effective date of this Plan, which is the date of the closing of the transactions contemplated by Merger Agreement.

(q) "Effective Time" shall have the meaning set forth in the Merger Agreement.

(r) "*Eligible Employee*" means an Employee who meets the requirements set forth in the document(s) governing the Offering for eligibility to participate in the Offering, provided that such Employee also meets the requirements for eligibility to participate set forth in the Plan.

(s) "*Employee*" means any person, including an Officer or Director, who is "employed" for purposes of Section 423(b)(4) of the Code by the Company or a Related Corporation or solely with respect to the Non-423 Component, an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(t) "*Employee Stock Purchase Plan*" means a plan that grants Purchase Rights intended to be options issued under an "employee stock purchase plan," as that term is defined in Section 423(b) of the Code.

(u) "*Exchange Act*" means the U.S. Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder.

(v) "Fair Market Value" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by

the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in such source as the Board deems reliable. Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing sales price on the last preceding date for which such quotation exists.

(ii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith in compliance with Applicable Laws and regulations and, to the extent applicable as determined in the sole discretion of the Board, in a manner that complies with Sections 409A of the Code.

(w) "*Fully Diluted Common Stock*" means the number of shares of Common Stock, determined as of the applicable time of measurement, equal to the sum of (i) the total number of shares of Common Stock issued and outstanding and (ii) the total number of shares of Common Stock subject to securities that are convertible into or exercisable for shares of Common Stock (whether vested or unvested).

(x) "*Governmental Body*" means any: (i) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (ii) U.S. or non-U.S. federal, state, local, municipal or other government; (iii) governmental or regulatory body, or quasi-governmental body of any nature (including any governmental division, department, administrative agency or bureau, commission, authority, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or entity and any court or other tribunal, and for the avoidance of doubt, any tax authority) or other body exercising similar powers or authority; or (iv) self-regulatory organization (including the New York Stock Exchange, the Nasdaq Stock Market and the Financial Industry Regulatory Authority).

(y) "*Merger Agreement*" means that certain Agreement and Plan of Merger and Reorganization, dated as of December 17, 2024, by and among Cara Therapeutics, Inc., CT Convergence Merger Sub, Inc. and Tvardi Therapeutics, Inc.

(z) "*Non-423 Component*" means the part of the Plan, which excludes the 423 Component, pursuant to which Purchase Rights that are not intended to satisfy the requirements for an Employee Stock Purchase Plan may be granted to Eligible Employees.

(aa) "*Offering*" means the grant to Eligible Employees of Purchase Rights, with the exercise of those Purchase Rights automatically occurring at the end of one or more Purchase Periods. The terms and conditions of an Offering will generally be set forth in the "*Offering Document*" approved by the Board for that Offering.

(bb) "Offering Date" means a date selected by the Board for an Offering to commence.

(cc) "*Officer*" means a person who is an officer of the Company or a Related Corporation within the meaning of Section 16 of the Exchange Act.

(dd) "Participant" means an Eligible Employee who holds an outstanding Purchase Right.

(ee) "*Plan*" means this Tvardi Therapeutics, Inc. 2025 Employee Stock Purchase Plan, as amended from time to time, including both the 423 Component and the Non-423 Component.

(ff) "*Purchase Date*" means one or more dates during an Offering selected by the Board on which Purchase Rights will be exercised and on which purchases of shares of Common Stock will be carried out in accordance with such Offering.

(gg) "*Purchase Period*" means a period of time specified within an Offering, generally beginning on the Offering Date or on the first Trading Day following a Purchase Date, and ending on a Purchase Date. An Offering may consist of one or more Purchase Periods.

(hh) "*Purchase Right*" means an option to purchase shares of Common Stock granted pursuant to the Plan.

(ii) "*Related Corporation*" means any "parent corporation" or "subsidiary corporation" of the Company whether now or subsequently established, as those terms are defined in Sections 424(e) and (f), respectively, of the Code.

(jj) "Securities Act" means the U.S. Securities Act of 1933, as amended.

(kk) "*Tax-Related Items*" means any income tax, social insurance, payroll tax, fringe benefit tax, payment on account or other tax-related items arising out of or in relation to a Participant's participation in the Plan, including, but not limited to, the exercise of a Purchase Right and the receipt of shares of Common Stock or the sale or other disposition of shares of Common Stock acquired under the Plan.

(ll) "*Trading Day*" means any day on which the exchange(s) or market(s) on which shares of Common Stock are listed, including but not limited to the New York Stock Exchange, Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market or any successors thereto, is open for trading.

TABLE OF CONTENTS

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ANNEX F

FORM OF CERTIFICATE OF AMENDMENT TO AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF CARA THERAPEUTICS, INC.

Cara Therapeutics, Inc. (the "*Company*"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "*DGCL*"), does hereby certify that:

FIRST: The name of this corporation is Cara Therapeutics, Inc., and the date on which the Certificate of Incorporation of this corporation was originally filed with the Secretary of State of the State of Delaware was July 2, 2004, under the original name Cara Therapeutics, Inc.

SECOND: The Board of Directors of the Company (the "*Board*"), acting in accordance with the provisions of Sections 141 and 242 of the DGCL, adopted resolutions amending its Certificate of Incorporation (the "*Certificate of Incorporation*"), as follows:

Effective as of the effective time of [5:00 p.m.], Eastern Time, on [***DATE***]⁽¹⁾ (the "*Effective* Time"), each [•] shares of the Company's Common Stock, par value \$0.001 per share, issued and outstanding immediately prior to the Effective Time shall, automatically and without any action on the part of the Company or the respective holders thereof, be combined into one (1) share of Common Stock without increasing or decreasing the par value of each share of Common Stock (the "Reverse Split"); provided, however, no fractional shares of Common Stock shall be issued as a result of the Reverse Split and, in lieu thereof, upon receipt after the Effective Time by the exchange agent selected by the Company of a properly completed and duly executed transmittal letter and, where shares are held in certificated form, the surrender of the stock certificate(s) formerly representing shares of pre-Reverse Split Common Stock, any stockholder who would otherwise be entitled to a fractional share of post-Reverse Split Common Stock as a result of the Reverse Split, following the Effective Time (after taking into account all fractional shares of post-Reverse Split Common Stock otherwise issuable to such stockholder), shall be entitled to receive a cash payment (without interest) equal to the fractional share of post-Reverse Split Common Stock to which such stockholder would otherwise be entitled multiplied by the average of the closing sales prices of a share of the Company's Common Stock (as adjusted to give effect to the Reverse Split) on The Nasdaq Stock Market for the date immediately preceding the Effective Time. Each stock certificate that, immediately prior to the Effective Time, represented shares of pre-Reverse Split Common Stock shall, from and after the Effective Time, automatically and without any action on the part of the Company or the respective holders thereof, represent that number of whole shares of post-Reverse Split Common Stock into which the shares of pre-Reverse Split Common Stock represented by such certificate shall have been combined (as well as the right to receive cash in lieu of any fractional shares of post-Reverse Split Common Stock as set forth above); provided, however, that each holder of record of a certificate that represented shares of pre-Reverse Split Common Stock shall receive, upon surrender of such certificate, a new certificate representing the number of whole shares of post-Reverse Split Common Stock into which the shares of pre-Reverse Split Common Stock represented by such certificate shall have been combined pursuant to the Reverse Split, as well as any cash in lieu of fractional shares of post-Reverse Split Common Stock to which such holder may be entitled as set forth above. The Reverse Split shall be effected on a record holder-by-record holder basis, such that any fractional shares of post-Reverse Split Common Stock resulting from the Reverse Split and held by a single record holder shall be aggregated.

THIRD: The foregoing amendment to the Certificate of Incorporation was duly approved by the Board.

FOURTH: Thereafter, pursuant to a resolution of the Board, this Certificate of Amendment was submitted to the stockholders of the Company for their approval, and was duly adopted in accordance with the provisions of Section 242 of the DGCL.

(1) Insert next business day after filing with the Secretary of State of the State of Delaware.

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FIFTH: This amendment to the Certificate of Incorporation shall be effective on and as of as of the effective time of [5:00 p.m.], Eastern Time, on $[***DATE^{***}]^{(2)}$.

[SIGNATURE PAGE FOLLOWS]

⁽²⁾ Insert next business day after filing with the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, Cara Therapeutics, Inc. has caused this Certificate of Amendment to be executed by its Chief Executive Officer as of [***DATE***].

By:

Christopher Posner Chief Executive Officer

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ANNEX G

FORM OF CERTIFICATE OF AMENDMENT TO AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF CARA THERAPEUTICS, INC.

Cara Therapeutics, Inc. (the "*Company*"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "*DGCL*"), does hereby certify that:

FIRST: The name of this corporation is Cara Therapeutics, Inc., and the date on which the Certificate of Incorporation of this corporation was originally filed with the Secretary of State of the State of Delaware was July 2, 2004, under the original name Cara Therapeutics, Inc.

SECOND: The Board of Directors of the Company (the "*Board*"), acting in accordance with the provisions of Sections 141 and 242 of the DGCL, adopted resolutions amending its Certificate of Incorporation (the "*Certificate of Incorporation*") to provide that Section A of Article IV of the Certificate of Incorporation is amended and restated to read in its entirety as follows:

"A. This Company is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Company is authorized to issue is $[\bullet]$ ($[\bullet]$) shares. $[\bullet]$ ($[\bullet]$) shares shall be Common Stock, each having a par value of one-tenth of one cent (\$0.001). Five million (5,000,000) shares shall be Preferred Stock, each having a par value of one-tenth of one cent (\$0.001)."

THIRD: The foregoing amendment to the Certificate of Incorporation was duly approved by the Board.

FOURTH: Thereafter, pursuant to a resolution of the Board, this Certificate of Amendment was submitted to the stockholders of the Company for their approval, and was duly adopted in accordance with the provisions of Section 242 of the DGCL.

[SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, Cara Therapeutics, Inc. has caused this Certificate of Amendment to be executed by its Chief Executive Officer as of [***DATE***].

By:

Christopher Posner Chief Executive Officer

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PART II INFORMATION NOT REQUIRED IN PROXY STATEMENT/PROSPECTUS

Item 20 — Indemnification of Directors and Officers

We are incorporated under the laws of the State of Delaware. Section 102 of the DGCL permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the DGCL, our Restated Certificate and Bylaws provide that: (i) we are required to indemnify our directors to the fullest extent permitted by the DGCL; (ii) we may, in our discretion, indemnify our officers, employees and agents as set forth in the DGCL; (iii) we are required, upon satisfaction of certain conditions, to advance all expenses incurred by our directors in connection with certain legal proceedings; (iv) the rights conferred in the Bylaws are not exclusive; and (v) we are authorized to enter into indemnification agreements with our directors, officers, employees and agents.

We have entered into agreements with our directors that require us to indemnify them against expenses, judgments, fines, settlements and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director or officer of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder. At present, no litigation or proceeding is pending that involves any of our directors or officers regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

Cara has purchased and intends to maintain insurance on behalf of any person who is or was a director or officer of Cara against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The Merger Agreement provides that, subject to certain limitations as set forth in the Merger Agreement, from the Effective Time through the sixth anniversary of the date on which the Effective Time occurs, Cara and the surviving corporation will indemnify each person who is, has been at any time prior to the date of the Merger Agreement, or who becomes prior to the Effective Time, a director, officer, fiduciary or agent of Cara or Tvardi or their respective subsidiaries. The Merger Agreement also provides that the provisions

relating to the indemnification, advancement of expenses and exculpation of present and former directors and officers of Cara or any of its subsidiaries set forth in the organizational documents of Cara or any of its subsidiaries will not be amended, modified or repealed for a period of six years from the Effective Time in any manner that would adversely affect the rights of individuals who, at or prior to the Effective Time, were officers or directors of Cara or any of its subsidiaries, unless required by applicable law. After Closing, the organizational documents of the surviving corporation will contain provisions at least as favorable as the provisions relating to the indemnification, advancement of expenses and exculpation of present and former directors and officers presently set forth in Cara's organizational documents as of the date of the Merger Agreement.

From and after the Effective Time, (i) the Surviving Corporation shall fulfill and honor in all respects the obligations of the Tvardi to each person who is or has served as a director or officer of Tvardi as of immediately prior to the Closing pursuant to any indemnification provisions under Tvardi's amended and restated certificate of incorporation and bylaws and pursuant to any indemnification agreements between Tvardi and such directors and officers, with respect to claims arising out of matters occurring at or prior to the Closing pursuant to any indemnification of Cara or any of its subsidiaries to each person who is or has served as a director or officer of Cara as of immediately prior to the Closing pursuant to any indemnification provisions under Cara's amended and restated certificate of incorporation and amended and restated bylaws or any of its subsidiaries and pursuant to any indemnification agreements between Cara or any of its subsidiaries and such directors and officers, with respect to claims arising out of matters occurring at or prior to the Closing pursuant to any indemnification provisions under Cara's amended and restated certificate of incorporation and amended and restated bylaws or any of its subsidiaries and pursuant to any indemnification agreements between Cara or any of its subsidiaries and such directors and officers, with respect to claims arising out of matters occurring at or prior to the Effective Time.

From the Effective Time through the sixth (6th) anniversary of the date on which the Effective Time occurs, Cara shall maintain directors' and officers' liability insurance policies, with an effective date as of the Closing Date, on commercially available terms and conditions and with coverage limits customary for companies similarly situated to Cara.

From and after the Effective Time, Cara shall pay all expenses, including reasonable attorneys' fees, that are incurred by indemnified persons in connection with their successful enforcement of the rights provided to such persons in the Merger Agreement. The director and officer indemnification provisions of the Merger Agreement are intended to be in addition to the rights otherwise available to the current and former officers and directors of Cara and Tvardi by law, charter, statute, bylaw or agreement, and shall operate for the benefit of, and shall be enforceable by, each of such indemnified persons, their heirs and their representatives.

In the event Cara or the Surviving Corporation or any of their respective successors or assigns (i) consolidates with or merges into any other person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfers all or substantially all of its properties and assets to any person, then, and in each such case, proper provision shall be made so that the successors and assigns of Cara or the Surviving Corporation, as the case may be, shall succeed to the indemnification obligations set forth in the Merger Agreement. Cara shall cause the Surviving Corporation to perform all of the director and officer indemnification obligations of the Surviving Corporation under the Merger Agreement.

In the event Cara or the Surviving Corporation or any of their respective successors or assigns (i) consolidates with or merges into any other person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfers all or substantially all of its properties and assets to any person, then, and in each such case, proper provision shall be made so that the successors and assigns of Cara or the Surviving Corporation, as the case may be, shall succeed to the indemnification obligations set forth in the Merger Agreement. Cara shall cause the Surviving Corporation to perform all of the director and officer indemnification obligations of the Surviving Corporation under the Merger Agreement.

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Item 21 — Exhibits and Financial Statement Schedules

(a) The following exhibits are filed herewith or incorporated herein by reference:

Incorporated by Reference

		meorporateu by reference					
Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith	To be Filed by Amendment	Previously Filed
2.1†	Agreement and Plan of Merger and Reorganization, dated December 17, 2024, by and among Cara Therapeutics, Inc., CT Convergence Merger Sub, Inc. and Tvardi Therapeutics, In.	8-K	12/18/2024	2.1			
2.2†	<u>Asset Purchase Agreement,</u> <u>dated December 17, 2024, by</u> <u>and among Cara Therapeutics,</u> <u>Inc., Cara Royalty Sub, LLC</u> <u>and Vifor Fresenius Medical</u> <u>Care Renal Pharma, Ltd.</u>	8-K	12/18/2024	10.4			
3.1	Amended and Restated Certificate of Incorporation of Cara Therapeutics, Inc.	8-K	02/07/2014	3.1			
3.2	Amended and Restated Bylaws of Cara Therapeutics, Inc.	8-K	02/07/2014	3.2			
4.1	Form of Common Stock Certificate of Cara Therapeutics, Inc.	S-1/A	01/17/2014	4.1			
4.2†	Securities Purchase Agreement, dated October 15, 2020, by and between Cara Therapeutics, Inc. and Vifor (International) Ltd. Opinion of Mintz, Levin, Cohn,	10-K	02/25/2021	4.4		X	
5.1	Ferris, Glovsky and Popeo, P.C.					Λ	
10.1#	Form of Indemnity Agreement	S-1/A	01/17/2014	10.1			
10.2#	2014 Equity Incentive Plan	S-1/A	01/17/2014	10.3			
10.2.1	Form of Stock Option Agreement under 2014 Equity Incentive Plan	S-1/A	01/17/2014	10.3.1			
10.2.2	Form of Restricted Stock Unit Award under 2014 Equity Incentive Plan	S-1/A	01/17/2014	10.3.2			
10.3*	License Agreement dated April 4, 2013 by and between the Registrant and Maruishi Pharmaceutical Co., Ltd.	S-1	11/08/2013	10.7			
10.4*	License and API Supply Agreement effective as of April 16, 2012 by and between the Registrant and Chong Kun Dang Pharmaceutical Corp.	S-1	11/08/2013	10.8			

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Exhibit Number	Exhibit Description	Incorporated by Reference					
		Form	Date	Number	Filed Herewith	To be Filed by Amendment	Previously Filed
10.5	Amendment to License and API Supply Agreement effective as of May 1, 2012 by and between the Registrant and Chong Kun Dang Pharmaceutical Corp.	S-1	11/08/2013	10.9			
10.6†	<u>API Commercial Supply</u> <u>Agreement between Cara</u> <u>Therapeutics, Inc. and</u> <u>Polypeptide Laboratories S.A.</u>	10-Q	11/08/2021	10.1			
10.7#	Employment Agreement with Christopher Posner	8-K	11/03/2021	10.1			
10.8#	<u>Offer Letter with Ryan</u> <u>Maynard</u>	8-K	09/12/2022	10.1			
10.9#	Form of Retention Agreement	10 - K	03/01/2022	10.13			
10.10#	Cara Therapeutics, Inc. Severance Plan and Form of Participation Agreement	10-K	03/01/2022	10.14			
10.11#	Amended and Restated Non- Employee Director Compensation Policy	10-Q	08/07/2023	10.2			
10.12	Lease Agreement dated December 21, 2015 between the Registrant and Four Stamford Plaza Owner L.L.C.	8-K	12/23/2015	10.1			
10.13	Amendment to Lease Agreement between the Registrant and Four Stamford Plaza Owner L.L.C. Stamford Lease, dated June 23, 2020	10-Q	08/10/2020	10.2			
10.14†	License Agreement by and between Cara Therapeutics, Inc. and Vifor Fresenius Medical Care Renal Pharma Ltd.	10-Q	08/08/2022	10.2			
10.15†	Master Manufacturing Services Agreement between the Registrant and Patheon UK Limited and related Product Agreements	10-Q	08/07/2019	10.2			
10.16†	Non-Exclusive License Agreement, dated August 20, 2019, between the Registrant and Enteris Biopharma, Inc.	10-Q	11/05/2019	10.1			
10.17#	2019 Inducement Plan	8-K	11/20/2019	10.1			
10.18	Form of Stock Option Grant Notice under 2019 Inducement Plan	8-K	11/20/2019	10.2			

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		Incorporated by Reference					
Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith	To be Filed by Amendment	Previously Filed
10.19	Form of Restricted Stock Unit Notice under 2019 Inducement Plan	8-K	11/20/2019	10.3			
10.20†	License Agreement, dated October 15, 2020, by and between Cara Therapeutics, Inc. and Vifor (International) Ltd.	10-K	02/25/2021	10.21			
10.21	Open Market Sale Agreement, dated March 1, 2022, between the Registrant and Jefferies LLC	S-3	03/01/2022	1.2			
10.22	Agreement of Lease dated May 11, 2023 by and between 400 Atlantic Joint Venture LLC and SLJ Atlantic Stamford LLC (tenants-in-common) and Cara Therapeutics, Inc.	10-Q	08/07/2023	10.1			
10.23†	Purchase and Sale Agreement dated November 1, 2023 by and between Cara Royalty Sub, LLC and HCRX Investments Holdco, L.P. and Healthcare Royalty Partners IV, L.P.	10-K	03/06/2024	10.25			
10.24#	<u>Tvardi Therapeutics, Inc. 2018</u> <u>Stock Incentive Plan, as</u> <u>amended.</u>				Х		
10.25#	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Tvardi Therapeutics, Inc. 2018 Stock Incentive Plan.				Х		
10.26#	Form of Restricted Stock Agreement under the Tvardi Therapeutics, Inc. 2018 Stock Incentive Plan.				Х		
10.27#	Offer Letter by and between Imran Alibhai, Ph.D. and Tvardi Therapeutics, Inc.				Х		
10.28#	Offer Letter by and between Dan Conn and Tvardi Therapeutics, Inc.				Х		
10.29#	Offer Letter by and between John Kauh, M.D. and Tvardi Therapeutics, Inc.				Х		
10.30#	Offer Letter by and between Jeffrey Larson, Ph.D., DABT and Tvardi Therapeutics, Inc.				Х		

Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith	To be Filed by Amendment	Previously Filed
10.31#	Offer Letter by and between				Х		
	<u>Yixin "Joseph" Chen, Ph.D. and</u> Tvardi Therapeutics, Inc.						
10.32†	Exclusive License Agreement by and between the StemMed,				Х		
10.33†	Ltd. (f/k/a Stem Med Limited Partnership) and Baylor College of Medicine, dated July 16, 2012, as amended April 26, 2015, subject to Notice of Assignment from Stem Med Limited Partnership to Tvardi Therapeutics, Inc. dated January 14, 2018, and as further amended August 13, 2019. Exclusive License Agreement by and between the StemMed, Ltd. and Baylor College of Medicine, dated June 19, 2015, subject to Notice of Assignment from Stem Med Limited				Х		
	Partnership to Tvardi Therapeutics, Inc. dated February 22, 2018, and as amended on June 18, 2019 and April 6, 2023.						
21.1	Subsidiaries of the registrant.				Х		
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.				Х		
23.2	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.				Х		
23.3	Consent of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (included in Exhibit 5.1).					Х	
24.1	Power of Attorney (included on the signature page to this Registration Statement on Form S-4).				Х		
99.1	Consent of Sujal Shah to be named as a director.				Х		
99.2	Consent of Wallace Hall to be named as a director.				Х		
99.3	Consent of Imran Alibhai, Ph.D, to be named as a director.				Х		

Incorporated by Reference

		Inc	orporated by Refe	rence			
Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith	To be Filed by Amendment	Previously Filed
99.4	Consent of Shaheen Wirk,				Х		
	M.D., to be named as a director.						
99.5	Consent of Michael S. Wyzga				Х		
<i>)).</i> 5	to be named as a director.				1		
00 (v		
99.6	Proposed Amendment to				Х		
	<u>Amended and Restated</u> <u>Certificate of Incorporation of</u>						
	the registrant (included as						
	Annex F to the proxy						
	statement/prospectus forming a						
	part of this Registration						
	Statement).						
99.7	Proposed Amendment to				Х		
<i>JJ</i> .1	Amended and Restated				Λ		
	<u>Certificate of Incorporation of</u>						
	the registrant (included as						
	Annex G to the proxy						
	statement/prospectus forming a						
	part of this Registration						
	Statement).						
99.8	Form of Proxy Card for Special					Х	
	Meeting of Cara Therapeutics,						
	Inc.						
101	The following materials from	10 - K	03/06/2024	101			
	the registrant's Annual Report	10-Q	05/13/2024	101			
	on Form 10-K for the year						
	ended December 31, 2023, the	10-Q	08/24/2024	101			
	registrant's <u>Quarterly Report on</u> Form 10-Q for the quarter	10-Q	11/14/2024	101			
	ending March 31, 2024, the						
	registrant's <u>Quarterly Report on</u>						
	Form 10-Q for the quarter						
	ending June 30, 2024, and the						
	registrant's <u>Quarterly Report on</u>						
	Form 10-Q for the guarter						
	ending September 30, 2024						
	formatted in Extensible						
	Business Reporting Language						
	(XBRL) includes: (i) Balance						
	Sheets at September 30, 2024,						
	June 30, 2024, March 31, 2024						
	and December 31, 2023,						
	(ii) Statements of						
	Comprehensive Loss for the						
	Three Months Ended March 31,						
	2024 and 2023, Six Months						
	Ended June 30, 2024 and 2023 and for the Nine Months ended						
	September 30, 2024 and 2023,						
	(iii) Statements						
	(iii) Statements						

Incorporated by Reference

Incorporated by Reference

Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith	To be Filed by Amendment	Previously Filed
	of Stockholders' Equity for the						
	Three Months Ended March 31,						
	2024 and 2023, the Six Months						
	Ended June 30, 2023 and 2022						
	and Nine Months Ended						
	September, 2024 and 2023,						
	(iv) Statements of Cash Flows						
	for the Three Months Ended						
	March 31, 2024 and 2023, the						
	Six Months Ended June 30,						
	2024 and 2023 and Nine						
	Months Ended September, 2024						
	and 2023 and (v) Notes to						
	Financial Statements						
107							
107	<u>Filing Fee Table</u>				Х		

Management contracts or compensatory plans or arrangements.

* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

- [†] Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and is the type of information that the Company treats as private or confidential.
- (b) Financial Statement Schedules

Not Applicable.

(d) Filing Fee

See Exhibit 107.

Item 22 — Undertakings

- (a) The undersigned registrant hereby undertakes as follows:
 - (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act;
 - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement; notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and



- (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act, each such posteffective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act, if the registrant is subject to Rule 430C (§ 230.430C of this chapter), each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§ 230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (6) That, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (7) To deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report, to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Exchange Act; and, where interim financial information required to be presented by Article 3 of Regulation S-X is not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

- (8) That prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the issuer undertakes that such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.
- (9) That every prospectus (i) that is filed pursuant to paragraph (8) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (10) To respond to requests for information that is incorporated by reference into this proxy statement/ prospectus pursuant to Items 4, 10(b), 11, or 13 of this form, within one (1) business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means; this includes information contained in documents filed subsequent to the effective date of this registration statement through the date of responding to the request.
- (11) To supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in this registration statement when it became effective.
- (12) Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event a claim of indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in a successful defense of any action, suit or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-4 and has duly caused this Registration Statement to be signed on its behalf by the undersigned thereunto duly authorized, in the city of Stamford, State of Connecticut, on this 18th day of December, 2024.

CARA THERAPEUTICS, INC.

By: /s/ Christopher Posner

Christopher Posner President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each of the persons whose names appear below constitutes and appoints Christopher Posner and Ryan Maynard, and each of them, such person's true and lawful attorney in fact and agent, with full power of substitution and re-substitution, for such person and in his or her name, place and stead, in any and all capacities, to execute any and all amendments (including post-effective amendments) to this Registration Statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the U.S. Securities Act of 1933), and to file the same, together with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, and such other agencies, offices and persons as may be required by applicable law, granting unto said attorney in fact and agent, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date	
/s/ Christopher Posner Christopher Posner	President and Chief Executive Officer and Director (Principal Executive Officer)	December 18, 2024	
/s/ Ryan Maynard Ryan Maynard	Chief Financial Officer (Principal Financial and Accounting Officer)	December 18, 2024	
/s/ Martin Vogelbaum Martin Vogelbaum	Chairman of the Board	December 18, 2024	
/s/ Helen Boudreau Helen Boudreau	Director	December 18, 2024	
/s/ Jeffrey Ives, Ph.D. Jeffrey Ives, Ph.D.	Director	December 18, 2024	

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Lisa von Moltke, M.D.	Director	December 18, 2024
Lisa von Moltke, M.D.		
/s/ Susan Shiff, Ph.D.	Director	December 18, 2024
Susan Shiff, Ph.D.		

OF

TVARDI THERAPEUTICS, INC.

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2018 STOCK INCENTIVE PLAN

OF

TVARDI THERAPEUTICS, INC.

1. Purpose

The purpose of this 2018 Stock Incentive Plan (the "**Plan**") of Tvardi Therapeutics, Inc., a Delaware corporation (the "**Company**"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "**Company**" shall include any of the Company's present and future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "**Code**") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "**Board**"); *provided, however*, that such other business ventures shall be limited to entities that, where required by Section 409A of the Code, are eligible issuers of service recipient stock (as defined in Treas. Reg. Section 1.409A-1(b)(5)(iii)(E), or applicable successor regulation).

2. <u>Eligibility</u>

All of the Company's employees, officers and directors, as well as consultants and advisors to the Company (as such terms consultants and advisors are defined and interpreted for purposes of Rule 701 under the Securities Act of 1933, as amended (the "Securities Act") (or any successor rule)) are eligible to be granted Awards under the Plan. Each person who is granted an Award under the Plan is deemed a "Participant." "Award" means Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Stock (as defined in Section 7), Restricted Stock Units (as defined in Section 7) and Other Stock-Based Awards (as defined in Section 8).

3. Administration and Delegation

(a) <u>Administration by the Board</u>. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All actions and decisions by the Board with respect to the Plan and any Awards shall be made in the Board's discretion and shall be final and binding on all Participants and any other persons having or claiming any interest in the Plan or in any Award.

(b) <u>Appointment of Committees</u>. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (each, a "**Committee**"). All references in the Plan to the "**Board**" shall mean the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

4. Stock Available for Awards

(a) <u>Number of Shares</u>. Subject to adjustment under Section 9, Awards may be made under the Plan for up to 3,000,000 shares of common stock, \$0.001 par value per share, of the Company (the "**Common Stock**"), any or all of which Awards may be in the form of Incentive Stock Options (as defined in Section 5(b)). If any Award expires or is terminated, surrendered or canceled without having been fully exercised, is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right), or results in any Common Stock not being issued, the unused Common Stock subject to such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock tendered to the Company by a Participant to exercise an Award or to satisfy tax withholding obligations arising with respect to an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options, the two immediately preceding sentences shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(b) <u>Substitute Awards</u>. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a), except as may be required by reason of Section 422 and related provisions of the Code.

5. Stock Options

(a) <u>General</u>. The Board may grant options to purchase Common Stock (each, an "**Option**") and determine the number of shares of Common Stock to be subject to each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable.

(b) <u>Incentive Stock Options</u>. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "**Incentive Stock Option**") shall only be granted to employees of the Company, any of the Company's present and future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. An Option that is not intended to be an Incentive Stock Option shall be designated non-statutory stock option (a "**Nonstatutory Stock Option**)." The Company shall have no liability to a Participant, or any other person, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or if the Company converts an Incentive Stock Option to a Nonstatutory Stock Option.

(c) <u>Exercise Price</u>. The Board shall establish the exercise price of each Option and specify the exercise price in the applicable Option agreement. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) of the Common Stock on the date the Option is granted; provided that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall not be less than 100% of the Grant Date Fair Market Value on such future date. The "**Grant Date Fair Market Value**" of a share of Common Stock for purposes of the Plan will be determined as follows:

(1) if the Common Stock is not publicly traded, the Board will determine the Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise;

(2) if the Common Stock is listed on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

(3) if the Common Stock is not listed on any such exchange, the average of the closing bid and asked prices as reported by an authorized OTCBB market data vendor as listed on the OTCBB website (otcbb.com) on the date of grant.

For any date that is not a trading day, the Grant Date Fair Market Value of a share of Common Stock for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

The Board has discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the applicable Participant's agreement that the Board's determination is conclusive and binding even though others might make a different determination.

(d) <u>Duration of Options</u>. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement; *provided, however*, that no Option will be granted with a term in excess of 10 years.

(e) Exercise of Options.

Options may be exercised by delivery to the Company of a notice of exercise in a form of notice (which may be electronic) approved by the Company, together with payment in full (in the manner specified in Section 5(f)) of the exercise price for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.

- (f) <u>Payment Upon Exercise</u>. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:
 - (1) in cash or by check, payable to the order of the Company;

(2) when the Common Stock is registered under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), except as may otherwise be provided in the applicable Option agreement or approved by the Board, in its discretion, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) when the Common Stock is registered under the Exchange Act and to the extent provided for in the applicable Option agreement or approved by the Board, in its discretion, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board), *provided* (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board in its discretion and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent provided for in the applicable Nonstatutory Stock Option agreement or approved by the Board in its discretion, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;

(5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board, in its discretion, by (i) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (ii) payment of such other lawful consideration as the Board may determine; or

(6) by any combination of the above permitted forms of payment.

6. Stock Appreciation Rights

(a) <u>General</u>. The Board may grant Awards consisting of stock appreciation rights ("**SARs**") entitling the Participant, upon exercise, to receive an amount of Common Stock or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of Common Stock (valued in the manner determined by (or in a manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.

(b) <u>Measurement Price</u>. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of a share of Common Stock on the date the SAR is granted; *provided*, that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall not be less than 100% of the Grant Date Fair Market Value on such future date.

(c) <u>Duration of SARs</u>. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided*, *however*, that no SAR will be granted with a term in excess of 10 years.

(d) <u>Exercise of SARs</u>. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.

7. Restricted Stock; Restricted Stock Units

(a) <u>General</u>. The Board may grant Awards entitling Participants to acquire shares of Common Stock ("**Restricted Stock**"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the Participant in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction periods established by the Board for such Award. The Board may also grant Awards entitling the Participant to receive shares of Common Stock or cash to be delivered at the time such Award vests ("**Restricted Stock Units**") (Restricted Stock and Restricted Stock Units are each referred to herein as a "**Restricted Stock Award**").

(b) <u>Terms and Conditions for All Restricted Stock Awards</u>. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted Stock.

(1) <u>Dividends</u>. Unless otherwise provided in the applicable Award agreement, any dividends (whether paid in cash, stock or property) declared and paid by the Company with respect to shares of Restricted Stock ("Accrued Dividends") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Accrued Dividends will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Stock.

(2) <u>Stock Certificates</u>. The Company may require that any stock certificates issued in respect of shares of Restricted Stock, as well as dividends or distributions paid on such Restricted Stock, shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to Participant's Designated Beneficiary. "**Designated Beneficiary**" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, "**Designated Beneficiary**" means the Participant's estate.

(d) Additional Provisions Relating to Restricted Stock Units.

(1) <u>Settlement</u>. Upon the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each Restricted Stock Unit, the Participant shall be entitled to receive from the Company the number of shares of Common Stock specified in the Award agreement or (if so provided in the applicable Award agreement or otherwise determined by the Board) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of shares of Common Stock or a combination thereof. The Board may, in its discretion, provide that settlement of Restricted Stock Units shall be deferred, on a mandatory basis or at the election of the Participant in a manner that complies with Section 409A of the Code.

(2) <u>Voting Rights</u>. A Participant shall have no voting rights with respect to any Restricted Stock Units.

(3) <u>Dividend Equivalents</u>. The Award agreement for Restricted Stock Units may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of Common Stock ("**Dividend Equivalents**"). Dividend Equivalents may be paid currently or credited to an account for the Participants, may be settled in cash and/or shares of Common Stock and may be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which paid, in each case to the extent provided in the applicable Award agreement.

8. Other Stock-Based Awards

(a) <u>General</u>. The Board may grant other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property ("**Other Stock-Based Awards**"). Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine.

(b) <u>Terms and Conditions</u>. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price applicable thereto.

9. Adjustments for Changes in Common Stock and Certain Other Events

(a) <u>Changes in Capitalization</u>. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the number and class of securities and exercise price per share of each outstanding Option, (iii) the share and per-share provisions and the measurement price of each outstanding SAR, (iv) the number of shares subject to and the repurchase price per share subject to each outstanding Award of Restricted Stock and (v) the share and per-share-related provisions and the purchase price, if any, of each outstanding Award of Restricted Stock Unit and each outstanding Other Stock-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) <u>Reorganization Events</u>.

(1) <u>Definition</u>. A "**Reorganization Event**" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

(2) <u>Consequences of a Reorganization Event on Awards Other than Restricted Stock.</u>

In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (i) (or any portion of) outstanding Awards other than Restricted Stock on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unexercised and/or unvested Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable, or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of shares of Common Stock subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 9(b)(2), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(ii) Notwithstanding the terms of Section 9(b)(2)(i), in the case of outstanding Restricted Stock Units that are subject to Section 409A of the Code: (i) if the applicable Restricted Stock Unit agreement provides that the Restricted Stock Units shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 9(b)(2)(i) and the Restricted Stock Units shall instead be settled in accordance with the terms of the applicable Restricted Stock Unit agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 9(b)(2)(i) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A of the Code; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A of the Code, and the acquiring or succeeding corporation does not assume or substitute the Restricted Stock Units pursuant to clause (i) of Section 9(b)(2)(i), then the unvested Restricted Stock Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(iii) For purposes of Section 9(b)(2)(i), an Award (other than Restricted Stock) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each share of Common Stock subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determined to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

(3) <u>Consequences of a Reorganization Event on Restricted Stock</u>. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Stock; *provided, however*, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, either initially or by amendment, or provide for forfeiture of such Restricted Stock if issued at no cost. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock then outstanding shall automatically be deemed terminated or satisfied.

10. General Provisions Applicable to Awards.

(a) <u>Transferability of Awards</u>. Awards (or any interest in an Award, including, prior to exercise, any interest in shares of Common Stock issuable upon exercise of an Option or SAR) shall not be sold, assigned, transferred (including by establishing any short position, put equivalent position (as defined in Rule 16a-1 issued under the Exchange Act) or call equivalent position (as defined in Rule 16a-1 issued under the Exchange Act) or call equivalent position (as defined in Rule 16a-1 issued under the Exchange Act)), pledged, hypothecated or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, and, during the life of the Participant, shall be exercisable only by the Participant; except that Awards, other than Awards subject to Section 409A of the Code, may be transferred to family members (as defined in Rule 701(c)(3) under the Securities Act) through gifts or (other than Incentive Stock Options) domestic relations orders or to an executor or guardian upon the death or disability of the Participant. The Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall deliver to the Company a written instrument, as a condition to such transfer, in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 10(a) shall be deemed to restrict a transfer to the Company.

(b) <u>Documentation</u>. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) <u>Board Discretion</u>. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) <u>Termination of Status</u>. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.

Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding (e) obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price unless the Company determines otherwise. If provided for in an Award or approved by the Board in its discretion, a Participant may satisfy such tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain shares of Common Stock having a fair market value (valued in the manner determined by (or in a manner approved by) the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of shares of Common Stock (up to the number of shares having a fair market value (valued in the manner determined by (or in a manner approved by) the Company) equal to the maximum individual statutory rate of tax) as the Company shall determine in its discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(f) Amendment of Award.

(1) The Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 9.

(2) The Board may, without stockholder approval, amend any outstanding Award granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Award. The Board may also, without stockholder approval, cancel any outstanding award (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled award.

(g) <u>Conditions on Delivery of Stock</u>. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) <u>Acceleration</u>. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

11. Miscellaneous.

(a) <u>No Right To Employment or Other Status</u>. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) <u>No Rights As Stockholder</u>. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares.

(c) <u>Effective Date and Term of Plan</u>. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the expiration of 10 years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date.

(d) <u>Amendment of Plan</u>. The Board may amend, suspend or terminate the Plan or any portion thereof at any time; *provided* that if at any time the approval of the Company's stockholders is required as to any modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Stock Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 11(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan.

(e) <u>Authorization of Sub-Plans (including Grants to non-U.S. Employees)</u>. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) <u>Compliance with Section 409A of the Code</u>. If and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with Participant's employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A of the Code and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that the Participant is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A of the Code) (the "**New Payment Date**"), except as Section 409A of the Code may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A of the Code but do not to satisfy the conditions of that section.

(g) <u>Limitations on Liability</u>. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee, or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument such individual executes in such individual's capacity as a director, officer, other employee, or agent of the Company. The Company will indemnify and hold harmless each director, officer, other employee, or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) <u>Governing Law</u>. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.



TVARDI THERAPEUTICS, INC. 2018 STOCK INCENTIVE PLAN

CALIFORNIA SUPPLEMENT

Pursuant to Section 11(e) of the Plan, the Board has adopted this supplement for purposes of satisfying the requirements of Section 25102(o) of the California Law:

Any Awards granted under the Plan to a Participant who is a resident of the State of California on the date of grant (a "California Participant") shall be subject to the following additional limitations, terms and conditions:

1. Additional Limitations on Options.

(a) <u>Maximum Duration of Options</u>. No Options granted to California Participants shall have a term in excess of 10 years measured from the Option grant date.

(b) <u>Minimum Exercise Period Following Termination</u>. Unless a California Participant's employment is terminated for cause (as defined by applicable law, the terms of the Plan or option grant or a contract of employment), in the event of termination of employment of such Participant, such Participant shall have the right to exercise an Option, to the extent that such Participant is entitled to exercise such Option on the date employment terminated, until the earlier of: (i) at least six months from the date of termination, if termination was caused by such Participant's death or disability, (ii) at least 30 days from the date of termination was caused other than by such Participant's death or disability and (iii) the Option expiration date.

2. <u>Additional Limitations for Other Stock-Based Awards</u>. The terms of all Awards granted to a California Participant under Section 8 of the Plan shall comply, to the extent applicable, with Section 260.140.46 of the California Code of Regulations.

3. <u>Additional Limitations on Timing of Awards</u>. No Award granted to a California Participant shall become exercisable, vested or realizable, as applicable to such Award, unless the Plan has been approved by the holders of a majority of the Company's outstanding voting securities by the later of (i) within 12 months before or after the date the Plan was adopted by the Board, or (ii) prior to or within 12 months of the granting of any Award to a California Participant.

4. <u>Additional Restriction Regarding Recapitalizations, Stock Splits, Etc.</u> For purposes of Section 9 of the Plan, in the event of a stock split, reverse stock split, stock dividend, recapitalization, combination, reclassification or other distribution of the Company's securities underlying the Award without the receipt of consideration by the Company, the number of securities purchasable, and in the case of Options, the exercise price of such Options, shall be proportionately adjusted.

5. <u>Additional Limitations on Transferability of Awards.</u> Notwithstanding the provisions of Section 10(a) of the Plan, an Award granted to a California Participant may not be transferred to an executor or guardian upon the disability of the Participant.

* * * *

TVARDI THERAPEUTICS, INC.

STOCK OPTION AGREEMENT GRANTED UNDER 2018 STOCK INCENTIVE PLAN

This Stock Option Agreement (this "Agreement") is made between Tvardi Therapeutics, Inc., a Delaware corporation (the "Company"), and the Participant pursuant to the 2018 Stock Incentive Plan (the "Plan").

NOTICE OF GRANT

I. Participant Information

Participant:	
Participant Address:	

II. Grant Information

Grant Date:	
Number of Shares:	
Exercise Price Per Share:	
Vesting Commencement Date:	
Type of Option:	[Incentive Stock Option][Nonstatutory Stock Option]

III. Vesting Table

Vesting Date	Shares that Vest ⁽¹⁾
First anniversary of the Vesting Commencement Date	25% of the Shares
End of each successive one month period following the first anniversary of the Vesting	2.0833% of Shares
Commencement Date until the fourth anniversary of the Vesting Commencement Date	

(1) The number of shares is subject to adjustment for any changes in the Company's capitalization as set forth in Section 9 of the Plan.

IV. Final Exercise Date

5:00 pm Eastern time on Date:	[Date is ten years minus one day from Grant Date]
5.00 pm Eastern time on Date.	[Date is ten years minus one day nom Grant Date]

This Agreement includes this Notice of Grant and the following Exhibits, which are expressly incorporated by reference in their entirety herein:

Exhibit A – General Terms and Conditions

Exhibit B - Notice of Stock Option Exercise

Exhibit C - Tvardi Therapeutics, Inc. 2018 Stock Incentive Plan

IN WITNESS WHEREOF, the parties hereto have executed this Agreement.

TVARDI THERAPEUTICS, INC.	PARTICIPANT	SPOUSAL CONSENT ¹
Name: Title:	Name:	Name:

¹ If the Participant resides in a community property state, it is desirable to have the Participant's spouse also accept the option. The following are community property states: Arizona, California, Idaho, Louisiana, Nevada, New Mexico, Texas, and Washington. Although Wisconsin is not formally a community property state, it has laws governing the division of marital property similar to community property states and it may be desirable to have a Wisconsin Participant's spouse accept the option.

Stock Option Agreement 2018 Stock Incentive Plan

Ехнівіт А

GENERAL TERMS AND CONDITIONS

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. <u>Grant of Option</u>. This Agreement evidences the grant by the Company, on the grant date (the "**Grant Date**") set forth in the Notice of Grant that forms part of this Agreement (the "**Notice of Grant**"), to the Participant of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2018 Stock Incentive Plan (the "**Plan**"), the number of shares set forth in the Notice of Grant (the "**Shares**") of common stock, \$0.001 par value per share, of the Company ("**Common Stock**") at the exercise price per Share set forth in the Notice of Grant (the "**Exercise Price**"). Unless earlier terminated, this option shall expire at the time and on the date set forth in the Notice of Grant (the "**Final Exercise Date**").

It is intended that the option evidenced by this Agreement shall be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "**Code**") solely to the extent set forth in the Notice of Grant. To the extent not designated as an incentive stock option, or to the extent that the option does not qualify as an incentive stock option, the option shall be a nonstatutory stock option.

Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. <u>Vesting Schedule</u>.

This option will become exercisable ("vest") in accordance with the Vesting Table set forth in the Notice of Grant.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) <u>Form of Exercise</u>. Each election to exercise this option shall be accompanied by a completed Notice of Stock Option Exercise in the form attached hereto as <u>Exhibit B</u>, signed by the Participant, and received by the Company at its principal office, accompanied by this Agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of Shares covered hereby, provided that no partial exercise of this option may be for any fractional share or for fewer than ten whole shares (unless the number of Shares that remain subject to this option at the time of exercise is less than ten whole shares, in which case the Participant may purchase the total number of whole shares that remain subject to this option).

(b) <u>Continuous Relationship with the Company Required</u>. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee, officer or director of, or consultant or advisor to, the Company or any parent or subsidiary of the Company as defined in Section 424(e) or (f) of the Code or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) <u>Termination of Relationship with the Company</u>. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) <u>Exercise Period Upon Death or Disability</u>. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such service relationship for "**cause**" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) <u>Termination for Cause</u>. If, prior to the Final Exercise Date, the Participant's service relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his or her service relationship by the Company for Cause, and the effective date of such termination is subsequent to the date of the delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service relationship shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination). If the Participant is party to an employment, consulting or severance agreement with the Company or subject to a severance plan maintained by the Company (including, without limitation, breach by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Company), as determined by the Company, and the company), as determined by the Company, which determination shall be conclusive. The Participant's service relationship shall be considered to have been terminated for "Cause" if the Company determines, within 30 days after the Participant's termination of service, that termination for Cause was warranted.

4. <u>Company Right of First Refusal</u>.

(a) <u>Notice of Proposed Transfer</u>. If the Participant proposes to sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively, "**transfer**") any Shares acquired upon exercise of this option, then the Participant shall first give written notice of the proposed transfer (the "**Transfer Notice**") to the Company. The Transfer Notice shall name the proposed transferee and state the number of such Shares the Participant proposes to transfer (the "**Offered Shares**"), the price per share and all other material terms and conditions of the transfer.

(b) <u>Company Right to Purchase</u>. For 30 days following its receipt of such Transfer Notice, the Company shall have the option to purchase all or part of the Offered Shares at the price and upon the terms set forth in the Transfer Notice. In the event the Company elects to purchase all or part of the Offered Shares, it shall give written notice of such election to the Participant within such 30-day period. Within 10 days after his or her receipt of such notice, the Participant shall tender to the Company at its principal offices the certificate or certificates representing the Offered Shares to be purchased by the Company, duly endorsed in blank by the Participant or with duly endorsed stock powers attached thereto, all in a form suitable for transfer of the Offered Shares to the Company. Promptly following receipt of such certificate or certificates, the Company shall deliver or mail to the Participant a check in payment of the purchase price for such Offered Shares; provided that if the terms of payment set forth in the Transfer Notice; and provided further that any delay in making such payment shall not invalidate the Company's exercise of its option to purchase the Offered Shares.

(c) <u>Shares Not Purchased By Company</u>. If the Company does not elect to acquire all of the Offered Shares, the Participant may, within the 30-day period following the expiration of the option granted to the Company under subsection (b) above, transfer the Offered Shares which the Company has not elected to acquire to the proposed transferee, <u>provided that</u> such transfer shall not be on terms and conditions more favorable to the transferee than those contained in the Transfer Notice. Notwithstanding any of the above, all Offered Shares transferred pursuant to this Section 4 shall remain subject to the right of first refusal set forth in this Section 4 and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Section 4.

(d) <u>Consequences of Non-Delivery</u>. After the time at which the Offered Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Offered Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Offered Shares, but shall, insofar as permitted by law, treat the Company as the owner of such Offered Shares.

(e) <u>Exempt Transactions</u>. The following transactions shall be exempt from the provisions of this Section 4:

(1) any transfer of Shares to or for the benefit of any spouse, child or grandchild of the Participant, or to a trust for their benefit;

(2) any transfer pursuant to an effective registration statement filed by the Company under the Securities Act of 1933, as amended (the "Securities Act"); and

(3) the sale of all or substantially all of the outstanding shares of capital stock of the Company (including pursuant to a merger or consolidation);

provided, however, that in the case of a transfer pursuant to clause (1) above, such Shares shall remain subject to the right of first refusal set forth in this Section 4.

(f) <u>Assignment of Company Right</u>. The Company may assign its rights to purchase Offered Shares in any particular transaction under this Section 4 to one or more persons or entities.

(g) <u>Termination</u>. The provisions of this Section 4 shall terminate upon the earlier of the following events:

(1) the closing of the sale of shares of Common Stock in an underwritten public offering pursuant to an effective registration statement filed by the Company under the Securities Act; or

(2) the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of the Company's voting securities immediately prior to such transaction beneficially own, directly or indirectly, more than 50% (determined on an as-converted basis) of the outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction).

(h) <u>No Obligation to Recognize Invalid Transfer</u>. The Company shall not be required (1) to transfer on its books any of the Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Section 4, or (2) to treat as owner of such Shares or to pay dividends to any transfere to whom any such Shares shall have been so sold or transferred.

(i) <u>Legends</u>. The certificate representing Shares shall bear a legend substantially in the following form (in addition to, or in combination with, any legend required by applicable federal and state securities laws and agreements relating to the transfer of the Company securities):

"The shares represented by this certificate are subject to a right of first refusal in favor of the Company, as provided in a certain stock option agreement with the Company."

5. <u>Agreement in Connection with Initial Public Offering</u>.

The Participant agrees, in connection with the initial underwritten public offering of the Common Stock pursuant to a registration statement under the Securities Act, (i) not to (a) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any other securities of the Company or (b) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of shares of Common Stock or other securities of the Company, whether any transaction described in clause (a) or (b) is to be settled by delivery of securities, in cash or otherwise, during the period beginning on the date of the filing of such registration statement with the Securities and Exchange Commission and ending 180 days after the date of the final prospectus relating to the offering (plus up to an additional 34 days to the extent requested by the managing underwriters for such offering in order to address NASD Rule 2711(f)(4) or NYSE Rule 472(f)(4) or any similar successor provision), and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering. The Company may impose stop-transfer instructions with respect to the shares of Common Stock or other securities subject to the foregoing restriction until the end of the "lock-up" period.

6. <u>Tax Matters</u>.

(a) <u>Withholding</u>. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

(b) <u>Disqualifying Disposition</u>. If this option satisfies the requirements to be treated as an incentive stock option under the Code and the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

7. <u>Transfer Restrictions</u>.

(a) This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

(b) The Participant agrees that he or she will not transfer any Shares issued pursuant to the exercise of this option unless the transferee, as a condition to such transfer, delivers to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of Section 4 and Section 5; provided that such a written confirmation shall not be required with respect to (1) Section 4 after such provision has terminated in accordance with Section 4(g) or (2) Section 5 after the completion of the lock-up period in connection with the Company's initial underwritten public offering.

8. <u>Provisions of the Plan</u>.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is attached hereto as <u>Exhibit C</u>.

[Remainder of Page Intentionally Left Blank]

Ехнівіт В

NOTICE OF STOCK OPTION EXERCISE

[DATE]¹

Tvardi Therapeutics, Inc. 7000 Fannin Street Suite 1960M Houston, TX 77030

Attention: Treasurer Dear Sir or Madam:

I am the holder of $[_]^2$ Stock Option granted to me under the Tvardi Therapeutics, Inc. (the "**Company**") 2018 Stock Incentive Plan on $[_]^3$ for the purchase of $[_]^4$ shares of Common Stock of the Company at a purchase price of $[_]^5$ per share.

I hereby exercise my option to purchase [$]^6$ shares of Common Stock (the "Shares"), for which I have enclosed [$]^7$ in the amount of [$]^8$. Please register my stock certificate as follows:

 Name(s):
 9

 Address:
 9

1 Enter date of exercise.

3 Enter the date of grant.

4 Enter the total number of shares of Common Stock for which the option was granted.

5 Enter the option exercise price per share of Common Stock.

6 Enter the number of shares of Common Stock to be purchased upon exercise of all or part of the option.

7 Enter "cash", "personal check" or if permitted by the option or Plan, "stock certificates No. XXXX and XXXX".

8 Enter the dollar amount (price per share of Common Stock times the number of shares of Common Stock to be purchased), or the number of shares tendered. Fair market value of shares tendered, together with cash or check, must cover the purchase price of the shares issued upon exercise.

9 Enter name(s) to appear on stock certificate in one of the following formats: (a) your name only (i.e., John Doe); (b) your name and other name (i.e., John Doe and Jane Doe, Joint Tenants with Right to Survivorship); or for Nonstatutory Stock Options only, (c) a child's name, with you as custodian (i.e. Jane Doe, Custodian for Tommy Doe). Note: There may be income and/or gift tax consequences for registering shares in a child's name.

² Enter either "an Incentive" or "a Nonstatutory" or both.

I represent, warrant and covenant as follows:

1. I am purchasing the Shares for my own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act of 1933 (the "Securities Act"), or any rule or regulation under the Securities Act.

2. I have had such opportunity as I have deemed adequate to obtain from representatives of the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company.

3. I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.

4. I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period.

5. I understand that (i) the Shares have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least six months and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

Very truly yours,

[Name]

TVARDI THERAPEUTICS, INC.

RESTRICTED STOCK AGREEMENT GRANTED UNDER 2018 STOCK INCENTIVE PLAN

This Restricted Stock Agreement (the "A	Agreement") is made this [] day of [], 20[], between Tvardi Therapeutics, Inc., a
Delaware corporation (the "Company"), and [] (the " Pa	rticipant").	

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. <u>Purchase of Shares</u>.

The Company shall issue and sell to the Participant, and the Participant shall purchase from the Company, subject to the terms and conditions set forth in this Agreement and in the Company's 2018 Stock Incentive Plan (the "**Plan**"), [____] shares (the "**Shares**") of common stock, \$0.001 par value, of the Company ("**Common Stock**"), at a purchase price of \$[___] per share. The aggregate purchase price for the Shares shall be paid by the Participant by check payable to the order of the Company or such other method as may be acceptable to the Company. Upon receipt by the Company of payment for the Shares, the Company shall issue to the Participant one or more certificates in the name of the Participant for that number of Shares purchased by the Participant. The Participant agrees that the Shares shall be subject to the purchase options set forth in Sections 3 and 6 of this Agreement and the restrictions on transfer set forth in Section 5 of this Agreement.

2. <u>Certain Definitions</u>.

(a) "**Change in Control**" shall mean the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of the Company's voting securities immediately prior to such transaction beneficially own, directly or indirectly, more than 50% (determined on an as-converted basis) of the outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction).

(b) "Service" shall mean employment by or the provision of services to the Company or a parent or subsidiary thereof as an advisor, officer, consultant or member of the Board of Directors.

(c) "Vesting Commencement Date" shall mean [_____].

3. <u>Purchase Option</u>.

(a) In the event that the Participant ceases to provide Service for any reason or no reason, with or without cause, prior to the fourth (4th) anniversary of the Vesting Commencement Date, the Company shall have the right and option (the "**Purchase Option**") to purchase from the Participant, for a sum of $[_]$ per share (the "**Option Price**"), some or all of the Shares as set forth herein.

(b) All of the Shares shall initially be subject to the Purchase Option. The Participant shall acquire a vested interest in, and the Company's Purchase Option shall accordingly lapse with respect to, (i) twenty-five percent (25%) of the Shares upon Participant's completion of one (1) year of Service measured from the Vesting Commencement Date and (ii) the balance of the Shares in a series of successive equal monthly installments of 1/48 of the Shares upon Participant's completion of each additional month of Service over the thirty-six (36)-month period measured from the first anniversary of the Vesting Commencement Date.

4. Exercise of Purchase Option and Closing.

(a) The Company may exercise the Purchase Option by delivering or mailing to the Participant (or the Participant's estate), within 180 days after the termination of the Service of the Participant, a written notice of exercise of the Purchase Option. Such notice shall specify the number of Shares to be purchased. If and to the extent the Purchase Option is not so exercised by the giving of such a notice within such 180-day period, the Purchase Option shall automatically expire and terminate effective upon the expiration of such 180-day period.

(b) Within ten (10) days after delivery to the Participant of the Company's notice of the exercise of the Purchase Option pursuant to subsection (a) above, the Participant (or the Participant's estate) shall, pursuant to the provisions of the Joint Escrow Instructions referred to in Section 8 below, tender to the Company at its principal offices the certificate or certificates representing the Shares that the Company has elected to purchase in accordance with the terms of this Agreement, duly endorsed in blank or with duly endorsed stock powers attached thereto, all in form suitable for the transfer of such Shares to the Company. Promptly following its receipt of such certificate or certificates, the Company shall pay to the Participant the aggregate Option Price for such Shares (provided that any delay in making such payment shall not invalidate the Company's exercise of the Purchase Option with respect to such Shares).

(c) After the time at which any Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Shares, but shall, in so far as permitted by law, treat the Company as the owner of such Shares.

(d) The Option Price may be payable, at the option of the Company, in cancellation of all or a portion of any outstanding indebtedness of the Participant to the Company or in cash (by check) or both.

(e) The Company shall not purchase any fraction of a Share upon exercise of the Purchase Option, and any fraction of a Share resulting from a computation made pursuant to Section 3 of this Agreement shall be rounded to the nearest whole Share (with any one-half Share being rounded upward).

(f) The Company may assign its Purchase Option to one or more persons or entities.

5. <u>Restrictions on Transfer</u>.

(a) The Participant shall not sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively "**transfer**") any Shares, or any interest therein, that are subject to the Purchase Option, except that the Participant may transfer such Shares (i) to or for the benefit of any spouse, children, parents, uncles, aunts, siblings, grandchildren and any other relatives approved by the Board of Directors (collectively, "**Approved Relatives**") or to a trust established solely for the benefit of the Participant and/or Approved Relatives, <u>provided</u> that such Shares shall remain subject to this Agreement (including without limitation the restrictions on transfer set forth in this Section 5, the Purchase Option and the right of first refusal set forth in Section 6) and such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Agreement or (ii) as part of the sale of all or substantially all of the shares of capital stock of the Company (including pursuant to a merger or consolidation), <u>provided</u> that, in accordance with the Plan, the securities or other property received by the Participant in connection with such transaction shall remain subject to this Agreement.

(b) The Participant shall not transfer any Shares, or any interest therein, that are no longer subject to the Purchase Option, except in accordance with Section 6 below.

6. <u>Right of First Refusal</u>.

(a) If the Participant proposes to transfer any Shares that are no longer subject to the Purchase Option (either because they are free from the Purchase Option pursuant to Section 3 or because the Purchase Option expired unexercised pursuant to Section 4), then the Participant shall first give written notice of the proposed transfer (the "**Transfer Notice**") to the Company. The Transfer Notice shall name the proposed transferee and state the number of such Shares the Participant proposes to transfer (the "**Offered Shares**"), the price per share and all other material terms and conditions of the transfer.

(b) For 30 days following its receipt of such Transfer Notice, the Company shall have the option to purchase all or part of the Offered Shares at the price and upon the terms set forth in the Transfer Notice. In the event the Company elects to purchase all or part of the Offered Shares, it shall give written notice of such election to the Participant within such 30-day period. Within 10 days after the Participant's receipt of such notice, the Participant shall tender to the Company at its principal offices the certificate or certificates representing the Offered Shares to be purchased by the Company, duly endorsed in blank by the Participant or with duly endorsed stock powers attached thereto, all in a form suitable for transfer of the Offered Shares to the Company. Promptly following receipt of such certificate or certificates, the Company shall deliver or mail to the Participant a check in payment of the purchase price for such Offered Shares; provided that if the terms of payment set forth in the Transfer Notice; and provided further that any delay in making such payment shall not invalidate the Company's exercise of its option to purchase the Offered Shares.

(c) If the Company does not elect to acquire all of the Offered Shares, the Participant may, within the 30-day period following the expiration of the option granted to the Company under subsection (b) above, transfer the Offered Shares which the Company has not elected to acquire to the proposed transferee, provided that such transfer shall not be on terms and conditions more favorable to the transferee than those contained in the Transfer Notice. Notwithstanding any of the above, all Offered Shares transferred pursuant to this Section 6 shall remain subject to this Agreement (including without limitation the restrictions on transfer set forth in Section 5 and the right of first refusal set forth in this Section 6) and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Agreement.

(d) After the time at which the Offered Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Offered Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Offered Shares, but shall, insofar as permitted by law, treat the Company as the owner of such Offered Shares.

(e) The following transactions shall be exempt from the provisions of this

Section 6:

(1) a transfer of Shares to or for the benefit of any Approved Relatives,

or to a trust established solely for the benefit of the Participant and/or Approved Relatives;

(2) any transfer pursuant to an effective registration statement filed by the Company under the Securities Act of 1933, as amended (the "Securities Act"); and

(3) the sale of all or substantially all of the outstanding shares of capital stock of the Company (including pursuant to a merger or consolidation);

<u>provided</u>, however, that in the case of a transfer pursuant to clause (1) above, such Shares shall remain subject to this Agreement (including without limitation the restrictions on transfer set forth in Section 5 and the right of first refusal set forth in this Section 6) and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Agreement.

(f) The Company may assign its rights to purchase Offered Shares in any particular transaction under this Section 6 to one or more persons or entities.

(g) The provisions of this Section 6 shall terminate upon the earlier of the following events:

(1) the closing of the sale of shares of Common Stock in an underwritten public offering pursuant to an effective registration statement filed by the Company under the Securities Act; or

(2) a Change in Control.

(h) The Company shall not be required (1) to transfer on its books any of the Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Agreement, or (2) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

7. <u>Agreement in Connection with Initial Public Offering</u>.

The Participant agrees, in connection with the initial underwritten public offering of the Common Stock pursuant to a registration statement under the Securities Act, (i) not to (a) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock or (b) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of shares of Common Stock, whether any transaction described in clause (a) or (b) is to be settled by delivery of shares of Common Stock or other securities, in cash or otherwise, during the period beginning on the date of the filing of such registration statement with the Securities and Exchange Commission and ending 180 days from the date of the final prospectus relating to the offering (plus up to an additional 34 days to the extent requested by the managing underwriters for such offering in order to address NASD Rule 2711(f) (4) or NYSE Rule 472(f)(4) or any similar successor provision), and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering. The Company may impose stop-transfer instructions with respect to the shares of Common Stock or other securities subject to the foregoing restriction until the end of the "lock-up" period.

8. <u>Escrow</u>.

The Participant shall, upon the execution of this Agreement, execute Joint Escrow Instructions in the form attached to this Agreement as <u>Exhibit A</u>. The Joint Escrow Instructions shall be delivered to the Secretary of the Company, as escrow agent thereunder. The Participant shall deliver to such escrow agent a stock assignment duly endorsed in blank, in the form attached to this Agreement as <u>Exhibit B</u>, and hereby instructs the Company to deliver to such escrow agent, on behalf of the Participant, the certificate(s) evidencing the Shares issued hereunder. Such materials shall be held by such escrow agent pursuant to the terms of such Joint Escrow Instructions.

9. <u>Restrictive Legends</u>.

All certificates representing Shares shall have affixed thereto legends in substantially the following form, in addition to any other legends that may be required under federal or state securities laws:

"The shares of stock represented by this certificate are subject to restrictions on transfer and an option to purchase set forth in a certain Restricted Stock Agreement between the corporation and the registered owner of these shares (or such owner's predecessor in interest), and such Agreement is available for inspection without charge at the office of the Secretary of the corporation." "The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended, and may not be sold, transferred or otherwise disposed of in the absence of an effective registration statement under such Act or an opinion of counsel satisfactory to the corporation to the effect that such registration is not required."

10. <u>Provisions of the Plan</u>.

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

11. Investment Representations.

The Participant represents, warrants and covenants as follows:

(a) The Participant is purchasing the Shares for Participant's own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act, or any rule or regulation under the Securities Act.

(b) The Participant has had such opportunity as Participant has deemed adequate to obtain from representatives of the Company such information as is necessary to permit him to evaluate the merits and risks of Participant's investment in the Company.

(c) The Participant has sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.

(d) The Participant can afford a complete loss of the value of the Shares and is able to bear the economic risk of holding such Shares for an indefinite period.

(e) The Participant understands that (i) the Shares have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act; (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least one year and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

12. <u>Withholding Taxes; Section 83(b) Election</u>.

(a) The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state or local taxes of any kind required by law to be withheld with respect to the purchase of the Shares by the Participant or the lapse of the Purchase Option.

(b) The Participant has reviewed with the Participant's own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement. The Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement. The Participant understands that it may be beneficial in many circumstances to elect to be taxed at the time the Shares are granted by the Company rather than when and as the Company's Purchase Option expires by filing an election under Section 83(b) of the Internal Revenue Code of 1986 with the I.R.S. within 30 days from the date of grant by the Company.

THE PARTICIPANT ACKNOWLEDGES THAT IT IS SOLELY THE PARTICIPANT'S RESPONSIBILITY AND NOT THE COMPANY'S TO FILE TIMELY THE ELECTION UNDER SECTION 83(b), EVEN IF THE PARTICIPANT REQUESTS THE COMPANY OR ITS REPRESENTATIVES TO MAKE THIS FILING ON THE PARTICIPANT'S BEHALF.

13. <u>Miscellaneous</u>.

(a) <u>No Rights to Employment</u>. The Participant acknowledges and agrees that the vesting of the Shares pursuant to Section 3 hereof is earned only by the Participant's continuous Service (not through the act of being hired or purchasing the Shares hereunder). The Participant further acknowledges and agrees that the transactions contemplated hereunder and the vesting schedule set forth herein do not constitute an express or implied promise of continued engagement as an employee or consultant for the vesting period, for any period, or at all.

(b) <u>Severability</u>. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, and each other provision of this Agreement shall be severable and enforceable to the extent permitted by law.

(c) <u>Waiver</u>. Any provision for the benefit of the Company contained in this Agreement may be waived, either generally or in any particular instance, by the Board of Directors of the Company.

(d) <u>Binding Effect</u>. This Agreement shall be binding upon and inure to the benefit of the Company and the Participant and their respective heirs, executors, administrators, legal representatives, successors and assigns, subject to the restrictions on transfer set forth in Sections 5 and 6 of this Agreement.

(e) <u>Notice</u>. All notices required or permitted hereunder shall be in writing and deemed effectively given upon personal delivery or five days after deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed to the other party hereto at the address shown beneath his or her or its respective signature to this Agreement, or at such other address or addresses as either party shall designate to the other in accordance with this Section 13(e).

(f) <u>Pronouns</u>. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns and pronouns shall include the plural, and vice versa.

(g) <u>Entire Agreement</u>. This Agreement and the Plan constitute the entire agreement between the parties, and supersedes all prior agreements and understandings, relating to the subject matter of this Agreement.

(h) <u>Amendment</u>. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Participant.

(i) <u>Governing Law</u>. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflict of law principles.

(j) <u>Participant's Acknowledgments</u>. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is fully aware of the legal and binding effect of this Agreement; and (v) understands that the law firm of WilmerHale is acting as counsel to the Company in connection with the transactions contemplated by the Agreement, and is not acting as counsel for the Participant.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed the Restricted Stock Agreement as of the date and year first above written. The Participant hereby agrees to the terms and conditions thereof. The Participant hereby acknowledges receipt of a copy of the Company's 2018 Stock Incentive Plan.

COMPANY:

TVARDI THERAPEUTICS, INC.

By:		
Name		
Title:		
Address:	7000 Fannin Street	
	Suite 1960M	
	Houston, TX 77030	
PARTICI	PANT:	
By:		
Name	:	
Address:	[
	[
SPOUSA	L CONSENT:	
By:		
Name	::	
Address:	[
	L	
	-	

SIGNATURE PAGE TO RESTRICTED STOCK AGREEMENT GRANTED UNDER STOCK INCENTIVE PLAN

Ехнівіт А

JOINT ESCROW INSTRUCTIONS

TVARDI THERAPEUTICS, INC.

JOINT ESCROW INSTRUCTIONS

[_____, 20__]

Tvardi Therapeutics, Inc. 7000 Fannin Street Suite 1960M Houston, TX 77030

Attention: Secretary Dear Secretary:

As Escrow Agent for Tvardi Therapeutics, Inc., a Delaware corporation (the "Company"),

and its successors in interest under the Restricted Stock Agreement (the "Agreement") of even date herewith, to which a copy of these Joint Escrow Instructions is attached, and the undersigned person ("Holder"), you are hereby authorized and directed to hold the documents delivered to you pursuant to the terms of the Agreement in accordance with the following instructions:

1. <u>Appointment</u>. Holder irrevocably authorizes the Company to deposit with you any certificates evidencing Shares (as defined in the Agreement) to be held by you hereunder and any additions and substitutions to said Shares. For purposes of these Joint Escrow Instructions, "**Shares**" shall be deemed to include any additional or substitute property. Holder does hereby irrevocably constitute and appoint you as his or her attorney-in-fact and agent for the term of this escrow to execute with respect to such Shares all documents necessary or appropriate to make such Shares negotiable and to complete any transaction herein contemplated. Subject to the provisions of this Section 1 and the terms of the Agreement, Holder shall exercise all rights and privileges of a stockholder of the Company while the Shares are held by you.

2. <u>Closing of Purchase</u>.

(a) Upon any purchase by the Company of the Shares pursuant to the Agreement, the Company shall give to Holder and you a written notice specifying the number of Shares to be purchased, the purchase price for the Shares, as determined pursuant to the Agreement, and the time for a closing hereunder (the "**Closing**") at the principal office of the Company. Holder and the Company hereby irrevocably authorize and direct you to close the transaction contemplated by such notice in accordance with the terms of said notice.

(b) At the Closing, you are directed (i) to date the stock assignment form or forms necessary for the transfer of the Shares, (ii) to fill in on such form or forms the number of Shares being transferred, and (iii) to deliver the same, together with the certificate or certificates evidencing the Shares to be transferred, to the Company against the simultaneous delivery to you of the purchase price for the Shares being purchased pursuant to the Agreement.

3. <u>Withdrawal</u>. The Holder shall have the right to withdraw from this escrow any Shares as to which the Purchase Option (as defined in the Agreement) has terminated or expired.

4. <u>Duties of Escrow Agent</u>.

(a) Your duties hereunder may be altered, amended, modified or revoked only by a writing signed by all of the parties hereto.

(b) You shall be obligated only for the performance of such duties as are specifically set forth herein and may rely and shall be protected in relying or refraining from acting on any instrument reasonably believed by you to be genuine and to have been signed or presented by the proper party or parties. You shall not be personally liable for any act you may do or omit to do hereunder as Escrow Agent or as attorney-in-fact of Holder while acting in good faith and in the exercise of your own good judgment, and any act done or omitted by you pursuant to the advice of your own attorneys shall be conclusive evidence of such good faith.

(c) You are hereby expressly authorized to disregard any and all warnings given by any of the parties hereto or by any other person or entity, excepting only orders or process of courts of law, and are hereby expressly authorized to comply with and obey orders, judgments or decrees of any court. If you are uncertain of any actions to be taken or instructions to be followed, you may refuse to act in the absence of an order, judgment or decrees of a court. In case you obey or comply with any such order, judgment or decree of any court, you shall not be liable to any of the parties hereto or to any other person or entity, by reason of such compliance, notwithstanding any such order, judgment or decree being subsequently reversed, modified, annulled, set aside, vacated or found to have been entered without jurisdiction.

(d) You shall not be liable in any respect on account of the identity, authority or rights of the parties executing or delivering or purporting to execute or deliver the Agreement or any documents or papers deposited or called for hereunder.

(e) You shall be entitled to employ such legal counsel and other experts as you may deem necessary properly to advise you in connection with your obligations hereunder and may rely upon the advice of such counsel.

(f) Your rights and responsibilities as Escrow Agent hereunder shall terminate if (i) you cease to be Secretary of the Company or (ii) you resign by written notice to each party. In the event of a termination under clause (i), your successor as Secretary shall become Escrow Agent hereunder; in the event of a termination under clause (ii), the Company shall appoint a successor Escrow Agent hereunder.

(g) If you reasonably require other or further instruments in connection with these Joint Escrow Instructions or obligations in respect hereto, the necessary parties hereto shall join in furnishing such instruments.

(h) It is understood and agreed that if you believe a dispute has arisen with respect to the delivery and/or ownership or right of possession of the securities held by you hereunder, you are authorized and directed to retain in your possession without liability to anyone all or any part of said securities until such dispute shall have been settled either by mutual written agreement of the parties concerned or by a final order, decree or judgment of a court of competent jurisdiction after the time for appeal has expired and no appeal has been perfected, but you shall be under no duty whatsoever to institute or defend any such proceedings.

(i) These Joint Escrow Instructions set forth your sole duties with respect to any and all matters pertinent hereto and no implied duties or obligations shall be read into these Joint Escrow Instructions against you.

(j) The Company shall indemnify you and hold you harmless against any and all damages, losses, liabilities, costs, and expenses, including attorneys' fees and disbursements, (including without limitation the fees of counsel retained pursuant to Section 4(e) above, for anything done or omitted to be done by you as Escrow Agent in connection with this Agreement or the performance of your duties hereunder, except such as shall result from your gross negligence or willful misconduct.

5. <u>Notice</u>. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail with postage and fees prepaid, addressed to each of the other parties thereunto entitled at the following addresses, or at such other addresses as a party may designate by ten days' advance written notice to each of the other parties hereto.

COMPANY:	Notices to the Company shall be sent to the address set forth in the salutation hereto, Attn: President
HOLDER:	Notices to Holder shall be sent to the address set forth below Holder's signature below.
ESCROW AGENT:	Notices to the Escrow Agent shall be sent to the address set forth in the salutation hereto.

6. <u>Miscellaneous</u>.

(a) By signing these Joint Escrow Instructions, you become a party hereto only for the purpose of said Joint Escrow Instructions, and you do not become a party to the Agreement.

(b) This instrument shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed these Joint Escrow Instructions as of the day and year first above written.

Very truly yours,	
COMPANY:	
TVARDI THERAPEUTICS, INC.	

By:	
Name:	
Title:	
HOLDER:	
By:	
Name:	
Address:	[]
ESCROW	AGENT:
Ву:	
Name:	
Title:	Secretary
SIGNATURE PAGE TO JOINT ESCROV	VINSTRUCTIONS

Exhibit B

STOCK ASSIGNMENT SEPARATE FROM CERTIFICATE

STOCK ASSIGNMENT SEPARATE FROM CERTIFICATE

Dated:

PARTICIPANT:

[Name]

Name of Spouse (if any):

Instructions to Participant: Please do <u>not</u> fill in any blanks other than the signature line(s). The purpose of the Stock Assignment Separate from Certificate is to enable the Company to acquire the Shares upon exercise of its Right of First Refusal and/or Purchase Option without requiring additional signatures on the part of the Participant or Participant's spouse, if any. The signature(s) to this assignment must correspond with the name as written upon the face of the certificate, in every particular, without alteration, enlargement, or any change whatever.

NOTICE ON 83(B) ELECTIONS

IF YOU WISH TO MAKE A SECTION 83(B) ELECTION, THE FILING OF SUCH ELECTION IS YOUR RESPONSIBILITY.

THE FORM FOR MAKING THIS SECTION 83(B) ELECTION IS ATTACHED TO THIS AGREEMENT. YOU MUST FILE THIS FORM WITHIN 30 DAYS OF THE GRANT DATE.

YOU (AND NOT THE COMPANY, ANY OF ITS AGENTS OR ANY OTHER PERSON) SHALL BE SOLELY RESPONSIBLE FOR FILING SUCH FORM WITH THE IRS, EVEN IF YOU REQUEST THE COMPANY, ITS AGENTS OR ANY OTHER PERSON TO MAKE THIS FILING ON YOUR BEHALF AND EVEN IF THE COMPANY, ANY OF ITS AGENTS OR ANY OTHER PERSON HAS PREVIOUSLY MADE THIS FILING ON YOUR BEHALF.

The 83(b) election should be filed by mailing a signed election form by certified mail, return receipt requested to the IRS Service Center where you file your tax returns. See <u>www.irs.gov</u>.

SECTION 83(B) ELECTION

The undersigned hereby makes an election pursuant to Section 83(b) of the Internal Revenue Code of 1986, as amended, with respect to the property described below and supplies the following information in accordance with Treas. Reg. § 1.83-2:

1. The name, address, and taxpayer identification number of the undersigned are:

[Name] [Address] [City, State Zip]

Taxpayer Identification Number:

- 2. The property with respect to which this election is being made is [____] shares of common stock, \$0.001 par value per share, of Tvardi Therapeutics, Inc., a Delaware corporation (the "**Company**").
- 3. The date on which the property was transferred or the date on which the restrictions on such property were imposed, whichever is later, is______, 20[_] and the taxable year for which this election is being made is the calendar year 20[_]
- 4. The property is subject to vesting provisions and may be forfeited under the terms of a stock restriction agreement executed between the undersigned and the Company.
- 5. The fair market value of the property at the time of the transfer or the date on which the restrictions on such property were imposed, whichever is later, (determined without regard to any lapse restriction, as defined in Treas. Reg. § 1.83-3(i)) is \$[____], equal to a fair market value of \$[____] per share.
- 6. The amount paid for the property by the undersigned is $[_]^{12}$, equal to a purchase price of $[_]$ per share.
- 7. This statement is executed on_____, 20[__].

In accordance with Treas. Reg. § 1.83-2(d) & (e)(7), a copy of this statement has been furnished to the Company.

1 If restrictions are being added to previously unrestricted stock, the following language is to be used: "[____] shares of the Company, having a fair market value of \$[____],"

² If the shares were issued in exchange for an assignment of intellectual property rights, the following language is to be used: "Intellectual property having a fair market value of $[_____],$ "

SECTION 83(B) ELECTION

BACKGROUND INFORMATION

Section 83(b) of the Internal Revenue Code permits persons who receive restricted property, such as restricted stock, in connection with the performance of services to include the value of such property in their gross income for the year the property is received. Such persons who purchase stock of the company subject to a stock restriction agreement providing for the vesting of such stock over a period of time are entitled to make this election. Any person who makes a timely Section 83(b) election will recognize compensation income on the date of grant (the date listed in item 3 of the election form) equal to the difference, if any, between the fair market value of the stock and the amount paid for the stock. A person who pays taxes in connection with an election and subsequently forfeits the stock, however, will not receive a refund or other tax benefit for the taxes previously paid.

Any person who does not make the election will be required to include the value of the stock in gross income in the year in which the stock vests. In particular, when the stock vests, the person will recognize compensation income in an amount equal to the difference between the fair market value of the stock on the vesting date and the amount paid for the stock. As a result, if the value of the stock increases, a person who does not make a timely Section 83(b) election will have compensation income at the time each installment of stock vests.

Each person should consult with his or her tax or legal advisor regarding the advisability and timing of filing the election. The original, signed and dated Section 83(b) election must be filed within 30 days of the grant date but may be filed prior to the grant date. The election should be filed by certified mail, return receipt requested, with the Internal Revenue Service at the service center where the electing person ordinarily files his or her annual tax return. A copy of the Section 83(b) election must also be included with the person's federal income tax return for the year of grant (each person should check with his or her tax preparer regarding this and any state, local, foreign or other filing requirements).

Please also note that the certified mailing receipt for the Section 83(b) election should be retained. This receipt is essential if the Internal Revenue Service does not receive the Section 83(b) election and challenges the election.

Imran Alibhai 4323 Cozac Lane Sugar Land, TX 77479

Dear Imran:

On behalf of Tvardi Therapeutics, Inc. (the "Company"), I am pleased to offer you employment with the Company. The purpose of this letter agreement (the "Agreement") is to set forth the terms of your employment with the Company, should you accept our offer.

1. You will be employed to serve as the Company's Chief Executive Officer, effective as of December 1, 2018 (the "Effective Date"). You will be a full-time employee of the Company, and you will report to the Board of Directors (the "Board") and have such duties and responsibilities as are customary for such positions. You agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. Upon your commencement of employment with the Company, and so long as you are employed by the Company as its Chief Executive Officer (in either an interim or non-interim capacity), you shall serve as a member of the Board, with no additional remuneration payable for such service. Upon your separation from employment with the Company or your otherwise no longer serving as the Company's Chief Executive Officer (in either an interim or non-interim capacity), you shall, at the Board's request, resign from the Board. The Company agrees that, following prior approval by the Board (which such determination shall be made by the Board in good faith), you may participate as a member of a board of directors or scientific advisory board of two non-profit organizations and one company other than the Board of the Company, so long as your service does not individually or in the aggregate materially interfere with the performance of your duties, create a potential business or fiduciary conflict, and/or violate any restrictive covenant agreement by and between you and the Company. You agree to abide by the rules, regulations, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company. You shall work out of the Company's office in Houston.

2. Your base salary will be at the rate of \$26,666.67 per monthly pay period (equivalent to an annualized base salary of \$320,000), subject to tax and other withholdings as required by law. The Board may elect to further increase your base salary periodically based on your performance and/or industry standards for similarly situated executives.

3. Following the end of each fiscal year and subject to the approval of the Company's Board (or a committee thereof), you will be eligible for a retention and performance bonus, targeted at 50% (\$160,000 for 2019) of your annualized base salary as determined by the Board (or a committee thereof) in good faith based on your individual performance and the Company's performance during the applicable fiscal year, including, without limitation, based on the completion of or progress towards the deliverables listed in Attachment A as it relates to 2019; provided, however, you will not be eligible for a 2018 bonus based on your start date. The Company will in good faith consider a request by you to advance you 25% of your targeted 2019 bonus (\$40,000) within ninety (90) days after the Effective Date (but not before January 1, 2019), based on your performance and the Company's performance at the time of such request. This amount is not refundable but is creditable against your 2019 bonus or against severance that would otherwise be payable in 2019. You must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn a bonus award, as it also serves as an incentive to remain employed by the Company, provided that the Company will award and pay any bonus for a calendar year before March 15th of the next calendar year.

4. You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, may be changed by the Company at any time without advance notice (other than as required by such programs or under law). Until and unless the Company adopts a group health plan that applies to all Company employees, the Company will bear the cost of health insurance for you and your immediate family, provided, however, that such amount shall be subject to applicable taxes and withholdings. You will also be entitled to indemnification by the Company with respect to your service as an officer and director of the Company pursuant to an Indemnification Agreement substantially similar in substance to the NVCA form agreement. The Company will pay your legal fees and expenses of up to \$3,000 incurred in connection with the review and negotiation of this Agreement within thirty days of receipt of an invoice for such charges.

5. You are eligible for four (4) weeks of vacation per calendar year to be taken at such times as will not materially interfere with the performance of your duties. The number of vacation days for which you are eligible shall accrue at the rate of 1.66 days per month that you are employed during such calendar year.

6. Subject to the approval of the Board of Directors, the Company will grant to you a stock option (the "Initial Option Grant") under the Company's 2018 Stock Incentive Plan (the "Stock Plan") to purchase an aggregate number of shares of common stock of the Company as shall equal 5% of the fully diluted shares of the Company's common stock (which shall give effect to the conversion to common stock of all outstanding shares of preferred stock and to the shares available for issuance or outstanding under the Company's Stock Plan) (the "Fully Diluted Shares"), at an exercise price equal to the fair market value of the common stock on the date of grant, as determined by the Board. The Initial Option Grant will be evidenced in writing by, and subject to the terms of the Stock Plan and a stock option agreement provided by the Company, which agreement will specify that (a) the options subject to the Initial Option Grant ("Options") will vest, subject to your continued service, (x) as to 25% of the underlying shares on the first anniversary of the Effective Date, and (y) as to the balance in equal 1/36t^h monthly installments thereafter until the fourth anniversary of the Effective Date; and (b) the right to exercise the Options shall terminate one (1) year after the cessation of your providing services to the Company. Furthermore, the Board may elect to grant you additional stock options based on your performance, a material increase in the number of Fully Diluted Shares and/or industry standards for similarly situated executives.

Without otherwise limiting the "at-will" nature of your employment, if your employment is terminated by the Company without Cause or by you for Good Reason (each as defined below), and provided you execute and allow to become effective (within 60 days following the termination or such shorter period (of not less than twenty-one (21) days) as may be directed by the Company) a severance and release of claims agreement in a form prescribed by the Company (which will include, at a minimum, a release of all releasable claims and post-employment confidentiality, non-disparagement, non-competition, non-solicitation and cooperation obligations) (the "Release Agreement"), (i) the Company will pay you as severance pay an aggregate amount equivalent to six (6) months of your then current base salary plus one additional month for each full year of employment you have completed with the Company (the "Severance Period") (provided, however, that in no event shall the Severance Period (other than in connection with a Change in Control, as set forth below) exceed ten (10) months), less all applicable taxes and withholdings, which severance pay will be paid ratably in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance pay shall begin no earlier than January 1 of such subsequent calendar year; (ii) should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will, for the Severance Period, pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage (the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation); and (iii) the next twenty four months of the unvested portion of the Initial Option Grant and any other equity grant from the Company to you (collectively, the "Equity Grants") will fully vest as of the date of your separation from the Company, provided, however, that: (x) no shares may be transferred and no stock option exercised (in each case with respect to the portion of the Equity Grants accelerating pursuant to this section) until the Release Agreement has become enforceable and irrevocable; and if the Release Agreement does not become enforceable and irrevocable in accordance with this offer letter, the portions of the Equity Grants that have vested as a result of this provision shall be cancelled effective as of the date of your separation from employment. Additionally, if within three (3) months before or twelve (12) months following a Change of Control, your employment by the Company is terminated by the Company without Cause or by you for Good Reason, the Severance Period shall be extended to twelve (12) months and the vesting schedule for your outstanding Equity Grants will be accelerated in full such that 100% of such Equity Grants that are not then vested will be accelerated and become vested and exercisable effective upon the termination; provided, however, that all such benefits are conditioned on the Release Agreement requirements and other terms and conditions set forth in this Section 7.



8. For purposes of this Agreement:

"Cause" means any of: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Board in its sole discretion that you have (i) engaged in dishonesty, willful misconduct or gross negligence that has a material adverse effect on the Company, (ii) committed an act that materially injures the reputation, business or business relationships of the Company, (iii) materially breached the terms of any invention and non-disclosure agreement or non-competition and nonsolicitation agreement with the Company which breach is not cured within ten days written notice thereof; or (iv) failed or refused to comply in any material respect with the Company's material policies or procedures and in a manner that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, provided that in the case of (iv) that you were given written notice of such violation or failure by the Board and a period of 30 days to cure (provided that the Board determines that such violation or failure is curable).

"Change of Control" shall mean, regardless of form thereof, consummation of (a) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (b) a merger, reorganization or consolidation in which the outstanding shares of capital stock of the Company are converted into or exchanged for securities of the successor entity and the holders of the Company's outstanding voting power immediately prior to such transaction do not own a majority of the outstanding capital stock of the Company to an unrelated person or entity or (d) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the successor entity immediately upon completion of the transaction in which the owners of the Successor entity immediately upon completion of the transaction in which the owners of the Successor entity immediately upon completion of the successor in the owners of the Successor entity immediately upon completion of the transaction in which the owners of the Successor entity immediately upon completion of the transaction do not own at least a majority of the outstanding voting power of the successor entity immediately upon completion of the transaction; provided, however, that "Change of Control" shall not include any financing transaction of the Company (whether public or private) that would otherwise be and/or trigger a "Change of Control" under (c) and/or (d) above.

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"Good Reason" shall mean (i) any action by the Company which results in a material diminution in such position, authority, duties or responsibilities, (ii) a material reduction in the aggregate of your base compensation and benefits, other than (x) a reduction in monthly base salary of no more than twenty percent (20%) as a result of across-the-board reductions or terminations affecting employees of the Company generally or (y) the Company's adopting of a group health plan for its employees, (iii) the Company's material breach of Section 3 of this Agreement; or (iv) a requirement that you, without your prior consent, regularly report to work at a location that is fifty (50) miles or more away from your then current place of work; provided, however, that the conditions described immediately above in clauses (i) through (iv) shall not give rise to a termination for Good Reason, unless you have notified the Company in writing within thirty (30) days of the first occurrence of the facts and circumstances claimed to provide a basis for the termination for Good Reason, the Company has failed to correct the condition within thirty (30) days after the Company's receipt of such written notice, and you actually terminate employment with the Company within sixty (60) days of the first occurrence of the condition. For the avoidance of doubt, your required travel on the Company's business shall not be deemed a relocation of your principal office under clause (iii), above.

9. You will be required to execute an Invention and Non-Disclosure Agreement and a Non-Competition and Non-Solicitation Agreement in the forms attached as <u>Attachment B</u> and <u>Attachment C</u>, as a condition of employment.

10. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this letter.

11. You agree to provide to the Company, within three days of your hire date, documentation of your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need to obtain a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

12. This letter shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Board of Directors, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter other than Paragraph 7 shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company.

13. The Company's offer of at-will employment is contingent upon your authorization and successful completion of background and reference checks. You will be required to execute authorizations for the Company to obtain consumer reports and/or investigative consumer reports and use them in conducting background checks as a condition to your employment. The Company may obtain background reports both pre-employment and from time to time during your employment with the Company, as necessary.

14. The Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

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15. This offer letter is your formal offer of employment and supersedes any and all prior or contemporaneous agreements, discussions and understandings, whether written or oral, relating to the subject matter of this letter or your employment with the Company. The resolution of any disputes under this letter will be governed by the laws of the State of Delaware.

* * *

If you agree with the provisions of this letter, please sign the enclosed duplicate of this letter in the space provided below and return it to me, by November 23, 2018. If you do not accept this offer by November 23, 2018, this offer will be revoked.

Very Truly Yours,

By: /s/ David J. Tweardy

Name: David J. Tweardy Title: President The foregoing correctly sets forth the terms of my employment by Tvardi Therapeutics, Inc. I am not relying on any representations pertaining to my employment other than those set forth above.

/s/ Imran Alibhai Name: Imran Alibhai

Date: 11/20/2018 2:02:29 PM PST

Attachment A

Bonus Factors

The Company's determination of the amount of bonus for which you shall be eligible for the 2019 calendar year shall include a review of your and the Company's performance with respect to the following deliverables:

- Successful reformulation of TTI-101 (aka C188-9) to reduce pill burden in the ongoing trial
- Execution of the Phase 1 clinical trial with new formulation of TTI-101
- Successful submission of several grants including CPRIT and SBIR grants
- Successful acquisition of a CPRIT (at least \$10M) or other grants e.g. NIH BBIR grants (\$2M per grant) or other grant (at least \$2M).
- Successful IV formulation of TTI-101 and completion of 14-week safety studies in rats to enable an IND assuming the company is adequately funded to pursue an IV formulation of TTI-101
- Successful completion of formulation and safety studies to enable cancer or non-cancer indication for TTI-102 assuming the company is adequately funded to pursue TTI-102
- In the absence of non-dilutive grant, significant progress toward a subsequent financing
- · Completion of hiring of necessary leadership to advance key clinical objectives
- Installation of accounting, IT and HR systems
- Generation of electronic systems for compliance and electronic data room for fundraising

Attachment B

Invention and Non-Disclosure Agreement

Attachment C

Non-Competition and Non-Solicitation Agreement

TVARDI THERAPEUTICS, INC.

NON-COMPETITION AND NON-SOLICITATION AGREEMENT

This Non-Competition and Non-Solicitation Agreement (this "Agreement") made this 1st day of December, 2018, is by and between Tvardi Therapeutics, Inc., a Delaware corporation (the "Company"), and Imran Alibhai (the "Employee").

For good consideration and in consideration of the employment or continued employment of the Employee by the Company, the Employee and the Company agree as follows:

1. Non-Competition and Non-Solicitation.

(a) <u>Non-Competition and Non-Solicitation</u>. While the Employee is employed by the Company and for a period of one (1) year after the termination or cessation of such employment for any reason, the Employee will not directly or indirectly:

(i) in the geographical areas that the Company does business or has done business at the time of the Employee's termination, engage or assist others in engaging in any business or enterprise (whether as owner, partner, officer, director, employee, consultant, investor, lender or otherwise, except as the holder of not more than 1% of the outstanding stock of a publicly-held company) that is competitive with the Company's business of developing small-molecule inhibitors of STAT family and its pathway molecules modulating STAT protein activity in cancer, inflammation, and fibrosis;" or

(ii) either alone or in association with others, solicit, divert or take away, or attempt to divert or take away, the business or patronage of any of the actual or prospective clients, customers, accounts or business partners of the Company which were contacted, solicited, or served by the Company during the Employee's employment with the Company; or

(iii) either alone or in association with others (i) solicit, induce or attempt to induce, any employee or independent contractor of the Company to terminate his or her employment or other engagement with the Company, or (ii) hire or recruit, or attempt to hire or recruit, or engage or attempt to engage as an independent contractor, any person who was employed or otherwise engaged by the Company at any time during the term of the Employee's employment with the Company; <u>provided</u>, that this clause (ii) shall not apply to the recruitment or hiring or other engagement of any individual whose employment or other engagement with the Company has been terminated for a period of six months or longer.

(b) <u>Extension</u>. If the Employee violates the provisions of any of the preceding paragraphs of this Section 1, the Employee shall continue to be bound by the restrictions set forth in such paragraph until a period of one (1) year has expired without any violation of such provisions.

2. Miscellaneous.

(a) <u>Equitable Remedies</u>. The Employee acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach or threatened breach of this Agreement is likely to cause the Company substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies which may be available, shall have the right to seek an injunction from a court restraining such a breach or threatened breach without posting a bond and the right to specific performance of the provisions of this Agreement.

(b) <u>Obligations to Third Parties</u>. The Employee represents that, except as the Employee has disclosed in writing to the Company, the Employee is not bound by the terms of any agreement with any previous employer or other party to refrain from competing, directly or indirectly, with the business of such previous employer or any other party, or to refrain from soliciting employees, customers or suppliers of such previous employer or other party. The Employee further represents that his/her performance of all the terms of this Agreement and the performance of his/her duties as an employee of the Company does not and will not conflict with or breach any agreement with any prior employer or other party (including, without limitation, any non-competition agreement).

(c) <u>Disclosure of this Agreement</u>. For a period of one year after the termination or cessation of the Employee's employment for any reason, the Employee agrees to notify any potential, prospective employer or prospective business associate, of the terms and existence of this Agreement and the Employee's continuing obligations to the Company hereunder.

(d) <u>Not Employment Contract</u>. The Employee acknowledges that this Agreement does not constitute a contract of employment, does not imply that the Company will continue his/her employment for any period of time and does not change the at-will nature of his/her employment.

(e) <u>Successors and Assigns</u>. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of the Employee are personal and shall not be assigned by him or her. The Employee expressly consents to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employ the Employee may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

(f) <u>Interpretation</u>. If any restriction set forth in Section 1 is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

(g) <u>Severability</u>. In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

(h) <u>Waivers</u>. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(i) <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware (without reference to the conflicts of laws provisions thereof). Any action, suit, or other legal proceeding which is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the State of Delaware (or, if appropriate, a federal court located within Delaware), and the Company and the Employee each consents to the jurisdiction of such a court. The Company and the Employee each hereby irrevocably waive any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

(j) <u>Entire Agreement; Amendment</u>. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by the Employee and the Company. The Employee agrees that any change or changes in his/her duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

(k) <u>Captions</u>. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed the Non-Competition and Non-Solicitation Agreement as of the date and year first above written.

COMPANY:

TVARDI THERAPEUTICS, INC.

By: /s/ David Tweardy

Name:David J. TweardyTitle:President

EMPLOYEE:

/s/ Irman Alibhai Name: Irman Alibhai

SIGNATURE PAGE TO NON-COMPETITION AND NON-SOLICITATION AGREEMENT



January 12, 2022

Dan Conn 205 East 69th Street, #10C New York, NY 10021

Dear Dan:

Breakthrough Medicines for Cancer, Chronic Inflammation & Fibrosis

On behalf of Tvardi Therapeutics, Inc. (the "Company"), I am pleased to offer you employment with the Company. The purpose of this letter agreement (the "Agreement") is to set forth the terms of your employment with the Company, should you accept our offer.

You will be employed to serve as the Company's Chief Financial Officer, effective as of January 12, 2022 (the "Effective Date"). You will be a full-1 time employee of the Company, and you will report to the Company's Chief Executive Officer ("CEO") and have such duties and responsibilities as are customary for such positions. You agree to devote your full business time, commercially reasonable efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as a Chief Financial Officer of the Company. The Company agrees that, following prior approval by the CEO (which such determination shall be made by the CEO in good faith), you may participate as a member of a board of directors of one non-profit organization and up to two companies other than the Company, so long as your service does not individually or in the aggregate materially interfere with the performance of your duties, create a potential business or fiduciary conflict, and/or violate any restrictive covenant agreement by and between you and the Company. In addition, the Company agrees that you may provide consulting services to Christie's International Real Estate, its affiliated entities and licensees, and you may serve on the Board of a real estate brand licensing business, so long as such work does not individually or in the aggregate materially interfere with the performance of your duties, create a potential business or fiduciary conflict, and/or violate any restrictive covenant agreement by and between you and the Company. You agree to abide by the rules, regulations, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company. This is primarily a remote position, with the majority of your time being spent in New York unless otherwise agreed in writing, but you will work out of the Company's office in Houston, and travel for business, from time to time as needed, provided that you shall not be required to work out of the Company's Houston office for more than six business days in any calendar month. The consulting agreement between you and the Company terminates by mutual agreement effective upon the start of your employment with the Company.

2. Your base salary will be at the rate of \$28,333.33 per monthly pay period (equivalent to an annualized base salary of \$340,000, subject to tax and other withholdings as required by law. The Company may elect to increase your base salary periodically based on your performance and/or industry standards for similarly-situated executives.

3. Following the end of each fiscal year and subject to the approval of the Company's Board (or a committee thereof), you will be eligible for a retention and performance bonus, targeted at 30% of your annualized base salary as determined by the Company in its sole discretion based on your individual performance and the Company's performance during the applicable fiscal year. You must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn a bonus award, as it also serves as an incentive to remain employed by the Company, provided that the Company will award and pay any bonus for a calendar year before March 15th of the next calendar year. Notwithstanding the foregoing, you will be entitled to severance entitlements pursuant to Section 7 if you are terminated other than for Cause or you resign for Good Reason.

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2450 Holcombe Blvd, Suite X, Houston, Texas 77021

4. You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, may be changed by the Company at any time without advance notice (other than as required by such programs or under law).

5. You are eligible for a maximum of four (4) weeks of vacation per calendar year to be taken at such times as may be approved by the CEO. The number of vacation days for which you are eligible shall accrue at the rate of 1.66 days per month that you are employed during such calendar year.

6. The Company will grant to you a stock option (the "Initial Option Grant") under the Company's 2018 Stock Incentive Plan (the "Stock Plan") to purchase an aggregate number of shares of common stock of the Company as shall equal 1.2% of the fully diluted shares of the Company's common stock (which shall give effect to the conversion to common stock of all outstanding shares of preferred stock and to the shares available for issuance or outstanding under the Company's Stock Plan) (the "Fully Diluted Shares"), at an exercise price equal to the fair market value of the common stock on the date of grant, as determined by the Board. The Initial Option Grant will be evidenced in writing by, and subject to the terms of the Stock Plan (a copy of which has been provided) and a stock option agreement in substantially the form previously provided by the Company (as modified to give effect to your continued service, (x) as to 25% of the underlying shares on the first anniversary of the Effective Date and (y) as to the balance in equal 1/36th monthly installments thereafter until the fourth anniversary of the Effective Date; and (b) the right to exercise the Options shall terminate one (1) year after the cessation of your providing services to the Company. Furthermore, the Board may elect to grant you additional stock options based on your performance and/or industry standards for similarly situated executives.

Without otherwise limiting the "at-will" nature of your employment, if your employment is terminated by the Company without Cause or by you for 7. Good Reason (each as defined below), and provided you execute and allow to become effective (within 60 days following the termination or such shorter period (of not less than twenty-one (21) days) as may be directed by the Company) a severance and release of claims agreement in a form mutually agreed by you and the Company, both acting reasonably (which will include, at a minimum, a release of all releasable claims and post-employment confidentiality, mutual non-disparagement, non-competition, non-solicitation and cooperation obligations) (the "Release Agreement"), (i) the Company will pay you as severance pay, starting in the first pay period after execution of the Release Agreement and expiration of any applicable revocation period an aggregate amount equivalent to six (6) months of your then current base salary plus one additional month for each full year of employment you have completed with the Company (the "Severance Period") (provided, however, that in no event shall the Severance Period (other than in connection with a Change in Control, as set forth in Paragraph 8 below) exceed ten (10) months), less all required withholdings, which severance pay will be paid ratably during the Severance Period in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; plus (x) any pay in lieu of any unused portion of your accrued vacation; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance pay shall begin no earlier than January 1 of such subsequent calendar year; (ii) should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will for a period of six (6) months following your termination, plus one month for each year of your employment at the Company, continue to pay the percentage of the premium for such coverage that is paid by the Company under the health care plan as of the termination date of your employment for active C-level employees (and family members, if applicable) who receive the same type of coverage (the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation); and (iii) the unvested portion of the Initial Option Grant and any other equity grant from the Company to you that would have vested on the schedule set forth in Paragraph 6 had your employment continued until the end of the Severance Period (collectively, the "Equity Grants") will fully vest as of the date of your separation from the Company, provided, however, that: (x) no shares may be transferred and no stock option exercised (in each case with respect to the portion of the Equity Grants accelerating pursuant to this section until the Release Agreement has become enforceable and irrevocable; and if the Release Agreement does not become enforceable and irrevocable in accordance with this offer letter, the portions of the Equity Grants that have vested as a result of this provision shall be cancelled effective as of the date of your separation from employment).

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8. If, within three (3) months before or twelve (12) months following a Change of Control, your employment by the Company is terminated by the Company or its successor without Cause or by you for Good Reason, (i) the Severance Period shall be extended to twelve (12) months, and (ii) the vesting schedule for your outstanding Equity Grants will be accelerated in full such that 100% of such Equity Grants that are not then vested will be accelerated and become vested and exercisable upon the effective date of such Change of Control or, if later, upon the termination of your employment by the Company or its successor without Cause or by you for Good Reason following such Change of Control; provided, however, that all such benefits are conditioned on the Release Agreement requirements and other terms and conditions set forth in Sections 7 and 8 hereof.

9. If, after twelve (12) months following the effective date of a Change of Control, your employment by the Company is terminated by the Company or its successor without Cause or you resign for Good Reason, you shall be entitled to severance and accelerated equity vesting on the terms set forth in Section 7 hereof.

10. For purposes of this Agreement:

"Cause" means any of: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Board in its sole discretion, after due consideration of all the relevant facts and circumstances, that you have (i) engaged in dishonesty willful misconduct or gross negligence that, in each case, has a material adverse effect on the Company, (ii) committed an act that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, (iii) materially breached the terms of any invention and non-disclosure agreement or non-competition and non-solicitation agreement with the Company, which breach is not cured within ten days written notice thereof; or (iv) failed or refused to comply in any material respect with the Company's material, published policies or procedures and in a manner that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, provided that in the case of (iv) that you were given written notice of such violation or failure by the Board and a period of 30 days to cure (provided that the Board determines that such violation or failure is curable).

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"Change of Control" shall mean, regardless of form thereof, consummation of (a) the sale of all or substantially all of the assets of the Company to an unrelated person or entity, (b) a merger, reorganization or consolidation in which the outstanding shares of capital stock of the Company are converted into or exchanged for securities of the successor entity and the holders of the Company's outstanding voting power immediately prior to such transaction do not own a majority of the outstanding capital stock of the Company to an unrelated person or entity or (d) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the successor entity immediately prior to such transaction do not own at least a majority of the outstanding voting power of the successor entity immediately upon completion of the transaction; provided, however, that "Change of Control" shall not include any financing transaction of the Company (whether public or private) that would otherwise be and/or trigger a "Change of Control" under (c) and/or (d) above.

"Good Reason" shall mean (i) a material breach by the Company of this Agreement or any equity agreement which remains uncured, if curable, following thirty days notice provided by you of such breach, (ii) [omitted], (iii) any action by the Company which results in a material diminution in your authority, duties or responsibilities, (iv) a reduction in your base compensation except to the extent that any such benefit is replaced with a comparable cash benefit of equal or greater value, or a reduction in scope or value thereof, other than as a result of across-the board reductions affecting other C-level employees of the Company that does not exceed 15% of your base compensation, or (v) a requirement that you, without your prior consent, regularly report to work at a location that is fifty (50) miles or more away from your place of residence (provided, however, that the conditions described immediately above in clauses (i) through (v) shall not give rise to a termination for Good Reason, unless you have notified the Company in writing within sixty (60) days of the first occurrence of the facts and circumstances claimed to provide a basis for the termination for Good Reason, the Company has failed to correct the condition within thirty (30) days after the Company's receipt of such written notice, and you actually terminate employment with the Company within sixty (60) days of the first occurrence of the first occurrence of the condition. For the avoidance of doubt, your required travel on the Company's business shall not be deemed a relocation of your principal office under clause (iii), above.

11. You will be required to execute an Invention and Non-Disclosure Agreement and a Non-Competition and Non-Solicitation Agreement in the forms attached as <u>Attachment A</u> and <u>Attachment B</u>, as a condition of employment.

12. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this letter, other than any agreement with Christie's International Real Estate, its affiliates or licensees that might require you to provide consulting services, as noted above.

13. You agree to provide to the Company, within three days of your hire date, documentation of your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need to obtain a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

14. This letter agreement is binding upon and shall inure to the benefit of your heirs and representatives and the Company, its successors and assigns, including any Acquiror.

15. This letter shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Board of Directors, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as provided in Sections 7, 8 and 9 above.

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16. The Company's offer of at-will employment is contingent upon your authorization and successful completion of background and reference checks. You will be required to execute authorizations for the Company to obtain consumer reports and/or investigative consumer reports and use them in conducting background checks as a condition to your employment. The Company may obtain background reports both pre-employment and from time to time during your employment with the Company, as necessary.

17. The Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

18. This offer letter is your formal offer of employment and supersedes any and all prior or contemporaneous agreements, discussions and understandings, whether written or oral, relating to the subject matter of this letter or your employment with the Company. The resolution of any disputes under this letter will be governed by the laws of the State of Delaware.

* * *

If you agree with the provisions of this letter, please sign the enclosed duplicate of this letter in the space provided below and return it to me, by January 20, 2022. If you do not accept this offer by January 20, 2022, this offer will be revoked.

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Very Truly Yours,

By: /s/ Imran Alibhai Imran Alibhai Chief Executive Officer

The foregoing correctly sets forth -tie terms of my employment by Tvardi Therapeutics, Inc. I am not relying on any representations pertaining-to my employment other than those set forth above.

/s/ Dan Conn	Date:	1/12/2022
Name: Dan Conn		
Tvardi Therapeutics	6	www.tvardi.com

Attachment A

Invention and Non-Disclosure Agreement

www.tvardi.com

Attachment B

Non-Competition and Non-Solicitation Agreement

www.tvardi.com

December 5, 2022

John Kauh 19 Woodwild Way Berkeley Heights, NJ 07922

Dear John:

On behalf of Tvardi Therapeutics, Inc. (the "Company"), I am pleased to offer you employment with the Company. The purpose of this letter agreement (the "Agreement") is to set forth the terms of your employment with the Company, should you accept our offer.

1. You will be employed to serve as the Company's Chief Medical Officer, effective as of _January 30, 2023 (the "Effective Date"). You will be a full-time employee of the Company, and you will report to the Company's Chief Executive Officer and have such duties and responsibilities as are customary for such positions. You agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. Prior written approval from the Company's Chief Executive Officer is required for you to serve on any Board of Directors. You agree to abide by the rules, regulations, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company. This is primarily a remote position, but you will work out of the Company's office in Houston and travel for business from time to time as needed.

2. Your base salary will be at the rate of \$400,000.00, subject to tax and other withholdings as required by law. The Company may elect to increase your base salary periodically based on your performance and/or industry standards for similarly situated executives.

3. Following the end of each fiscal year and subject to the approval of the Company's Board (or a committee thereof), you will be eligible for a retention and performance bonus, targeted at 30% (\$120,000) of your annualized base salary as determined by the Company in its sole discretion based on your individual performance and the Company's performance during the applicable fiscal year. You must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn a bonus award, as it also serves as an incentive to remain employed by the Company, provided that the Company will award and pay any bonus for a calendar year before March 15th of the next calendar year.

4. The Company will provide you a Sign-on Advance in the amount of \$25,000, less customary deductions and tax withholdings (the "Advance"). The Company will pay this Advance to you during your first 45-days of employment. You will earn the full amount of the Advance if you remain employed with the Company for a total of one year. Accordingly, you acknowledge and agree that if you voluntarily resign or are terminated for cause by the Company within a year of service, you are required to pay back the Company on a prorated basis, calculated based on your employment termination date and taking into account the number of days you were employed by the Company. You will be required to repay that prorated amount of the Advance within thirty days of your employment separation date.

5. You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, may be changed by the Company at any time without advance notice (other than as required by such programs or under law).

6. You are eligible for a maximum of four (4) weeks of vacation per calendar year to be taken at such times as may be approved by the Company. The number of vacation days for which you are eligible shall accrue at the rate of 1.66 days per month that you are employed during such calendar year.

7. Subject to the approval of the Board of Directors, the Company will grant to you a stock option (the "Initial Option Grant") under the Company's 2018 Stock Incentive Plan (the "Stock Plan") to purchase an aggregate number of shares of common stock of the Company as shall equal 1.0% of the fully diluted shares of the Company's common stock at the date of the grant (which shall give effect to the conversion to common stock of all outstanding shares of preferred stock and to the shares available for issuance or outstanding under the Company's Stock Plan) (the "Fully Diluted Shares"), at an exercise price equal to the fair market value of the common stock on the date of grant, as determined by the Board. The Initial Option Grant will be evidenced in writing by, and subject to the terms of the Stock Plan and a stock option agreement provided by the Company, which agreement will specify that (a) the options subject to the Initial Option Grant ("Options") will vest, subject to your continued service, (x) as to 25% of the underlying shares on the first anniversary of the Effective Date and (y) as to the balance in equal 1/36th monthly installments thereafter until the fourth anniversary of the Effective Date; and (b) the right to exercise the Options shall terminate one (1) year after the cessation of your providing services to the Company. Furthermore, the Board may elect to grant you additional stock options based on your performance and/or industry standards for similarly situated executives.

Without otherwise limiting the "at-will" nature of your employment, if your employment is terminated by the Company without Cause or by you for Good Reason (each as defined below), and provided you execute and allow to become effective (within 60 days following the termination or such shorter period (of not less than twenty-one (21) days) as may be directed by the Company) a severance and release of claims agreement in a form prescribed by the Company (which will include, at a minimum, a release of all releasable claims and post-employment confidentiality, non-disparagement, non-competition, non-solicitation and cooperation obligations) (the "Release Agreement"), (i) the Company will pay you as severance pay an aggregate amount equivalent to six (6) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid ratably in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance pay shall begin no earlier than January 1 of such subsequent calendar year; (ii) should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will for a period of six (6) months following your termination continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage (the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation); and (iii) twelve and one-half percent (12.5%) of the unvested portion of the Initial Option Grant and any other equity grant from the Company to you (collectively, the "Equity Grants") will fully vest as of the date of your separation from the Company, provided, however, that: (x) no shares may be transferred and no stock option exercised (in each case with respect to the portion of the Equity Grants accelerating pursuant to this section until the Release Agreement has become enforceable and irrevocable; and if the Release Agreement does not become enforceable and irrevocable in accordance with this offer letter, the portions of the Equity Grants that have vested as a result of this provision shall be cancelled effective as of the date of your separation from employment. Additionally, if within three (3) months before or twelve (12) months following a Change of Control, your employment by the Company is terminated by the Company without Cause or by you for Good Reason, the Severance Period shall be extended to twelve (12) months and the vesting schedule for your outstanding Equity Grants will be accelerated in full such that 100% of such Equity Grants that are not then vested will be accelerated and become vested and exercisable effective upon the termination; provided, however, that all such benefits are conditioned on the Release Agreement requirements and other terms and conditions set forth in this Section 7

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9. For purposes of this Agreement:

"Cause" means any of: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Board in its sole discretion that you have (i) engaged in dishonesty, willful misconduct or gross negligence that has a material adverse effect on the Company, (ii) committed an act that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, (iii) materially breached the terms of any invention and nondisclosure agreement or non-competition and non-solicitation agreement with the Company, which breach is not cured within ten days written notice thereof; or (iv) failed or refused to comply in any material respect with the Company's material policies or procedures and in a manner that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, business or business relationships of the Company be expected to materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, provided that in the case of (iv) that you were given written notice of such violation or failure by the Board and a period of 30 days to cure (provided that the Board determines that such violation or failure is curable).

"Change of Control" shall mean, regardless of form thereof, consummation of (a) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (b) a merger, reorganization or consolidation in which the outstanding shares of capital stock of the Company are converted into or exchanged for securities of the successor entity and the holders of the Company's outstanding voting power immediately prior to such transaction do not own a majority of the outstanding capital stock of the Company to an unrelated person or entity or (d) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own a tleast a majority of the outstanding voting power of the successor entity immediately prior to such transaction do not own at least a majority of the outstanding voting power of the transaction of own at least a majority of the outstanding voting power of the transaction; provided, however, that "Change of Control" shall not include any financing transaction of the Company (whether public or private) that would otherwise be and/or trigger a "Change of Control" under (c) and/or (d) above.

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"Good Reason" shall mean (i) any action by the Company which results in a material diminution in such position, authority, duties or responsibilities, (ii) a material reduction in your base compensation except to the extent that any such benefit is replaced with a comparable benefit, or a reduction in scope or value thereof, other than as a result of across-the board reductions or terminations affecting employees of the Company generally, or (iii) a requirement that you, without your prior consent, regularly report to work at a location that is fifty (50) miles or more away from your then current place of work; provided, however, that the conditions described immediately above in clauses (i) through (iii) shall not give rise to a termination for Good Reason, unless you have notified the Company in writing within thirty (30) days of the first occurrence of the facts and circumstances claimed to provide a basis for the termination for Good Reason, the Company has failed to correct the condition within thirty (30) days after the Company's receipt of such written notice, and you actually terminate employment with the Company within sixty (60) days of the first occurrence of the condition. For the avoidance of doubt, your required travel on the Company's business shall not be deemed a relocation of your principal office under clause (iii), above.

10. You will be required to execute an Invention and Non-Disclosure Agreement and a Non-Competition and Non-Solicitation Agreement in the forms attached as <u>Attachment A</u> and <u>Attachment B</u>, as a condition of employment.

11. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this letter.

12. You agree to provide to the Company, within three days of your hire date, documentation of your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need to obtain a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

13. This letter shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Board of Directors, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company.

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14. The Company's offer of at-will employment is contingent upon your authorization and successful completion of background and reference checks. You will be required to execute authorizations for the Company to obtain consumer reports and/or investigative consumer reports and use them in conducting background checks as a condition to your employment. The Company may obtain background reports both pre-employment and from time to time during your employment with the Company, as necessary.

15. The Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all interne and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

16. This offer letter is your formal offer of employment and supersedes any and all prior or contemporaneous agreements, discussions and understandings, whether written or oral, relating to the subject matter of this letter or your employment with the Company. The resolution of any disputes under this letter will be governed by the laws of the State of Delaware.

* * *

If you agree with the provisions of this letter, please sign the enclosed duplicate of this letter in the space provided below and return it to me, by December 15, 2022. If you do not accept this offer by December 15, 2022, this offer will be revoked.

Very Truly Yours,

By: /s/ Imran Alibhai Imran Alibhai Chief Executive Officer

The foregoing correctly sets forth the terms of my employment by Tvardi Therapeutics, Inc. I am not relying on any representations pertaining to my employment other than those set forth above.

/S/ .	Johi	1 Kau	ıh
Na	me:	John	Kauh

Date: 14 Dec 2022

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Attachment A

Invention and Non-Disclosure Agreement

Attachment B

Non-Competition and Non-Solicitation Agreement



October 26, 2020

Dr. Jeffrey L. Larson

RE: Senior Vice President – Research and Development (R&D) with Tvardi Therapeutics, Inc.

Dear Jeff,

It has been a pleasure to work with you as a consultant here at Tvardi Therapeutics. Based on our recent discussions, I would like to offer you the position of Senior Vice-President of R&D at Tvardi Therapeutics, Inc. reporting into the CEO. Your position will be multifaceted which will drive various aspects of research and development in the company.

Your annual starting salary will be \$200,000. You will be eligible for a yearly bonus target of up to 10% of your base salary based on your individual as well as the company's performance. The Company will also pay you a one-time sign-on bonus of \$20,000. The Sign-on bonus shall be paid with the payroll following 45 days of employment with the company. This sign-on bonus is required to be paid back to the company, on a pro-rata basis, in case you voluntarily terminate your employment with the company or are terminated for cause by the company within a year from your start date. In addition, the Company will grant to you an incentive stock option award under the Company's 2018 Stock Incentive Plan to purchase 125,000 shares of the Company's common stock. Your bonus and stock option grants are contingent on approval by the board of directors. The company also offers a competitive benefits package which includes:

- · Fully covered medical, vision, and dental insurance
- 3 weeks of vacation, increasing by an additional week after 12 months of employment
- 10 designated Company holidays
- 401K program
- A flex health spending account, discount program, and 24/7 online support administered by Insperity

The intended start date for your employment would be November 9, 2020. We look forward to you joining the team!

Sincerely,

/s/ Imran Alibhai Imran Alibhai, PhD Chief Executive Officer /s/ Jeffrey L. Larson

Confirmation of acceptance via signature

Printed Name:

Date:

Tvardi Therapeutics

2450 Holcombe Blvd, Suite X, Houston, TX 77021

www.tvardi.com



September 8, 2021

Yixin Chen, PhD yjc999@gmail.com

Via e-mail

Dear Yixin,

I am very excited to invite you to join Tvardi Therapeutics, Inc. (the "Company") as we continue to develop breakthrough medicines for cancer, chronic inflammation, and fibrosis. In this letter, I would like to set forth the terms and conditions of your employment relationship with the Company.

Title and Location. I am pleased to offer you a full-time position as Vice President, CMC working at our corporate offices in Houston, TX. Your employment with the Company shall be subject to the terms and conditions of this letter and accompanying Invention and Non-Disclosure Agreement and will commence on October 1, 2021. You will report to me.

Compensation. As an exempt employee, you will initially receive an annual base salary of **\$205,000**, which will be paid in accordance with the Company's normal payroll procedures and are subject to the usual required deductions and tax withholdings.

Bonus Program. The Company's Bonus Program is currently under review by the Board of Directors and has not been approved. If approved by the Board of Directors, you will be eligible to participate in the Company's incentive bonus program. It is being recommended that the *projected* annual target bonus for your position is **20%** of your annual base salary, pending approval by the Board of Directors. Any award would be based upon both the Company's achievement, in the discretion of the Company, of its performance goals, determined by the Company's Board of Directors (the "Board") and/or the CEO, and your achievement of your personal goals to be set by me. The actual award, if any, will be prorated from your date of hire for your first year of employment and will be subject to the usual required deductions and tax withholdings. In order to be eligible to receive the bonus payment, you must be employed by the Company at the time of payment of the bonus.

Benefit Plans. At this time, the Company utilizes Insperity, a Professional Employer Organization (the "PEO"), which serves in a co-employer relationship for payroll processing and benefit programs. As an employee, you will be eligible to participate in the employee benefit plans currently and hereafter maintained by Insperity of general applicability that is provided to other employees of the Company. Where a particular benefit is subject to a formal plan (for example, medical or life insurance), eligibility to participate in and receive any particular benefit from the plan is governed solely by the applicable plan document.

Paid Time Off. You will be entitled to paid time off benefits in accordance with the Company's Paid Time Off ("PTO") policy. Currently, the Company offers full-time employees 15 days of accrued PTO annually for your first year of service, and then increases to 20 days of accrued PTO annually for consecutive years of service. Of course, the Company may change this policy from time to time in its sole discretion.

Equity Awards. In addition to the compensation and benefits set forth above, if you decide to join the Company, it will be recommended that you be granted **85,000** stock options under the Company's **2018 Stock Incentive Plan**, subject to the approval of the Company's Board of Directors or its Compensation Committee, to purchase shares of the Company's Common Stock (the "Option"). If approved and provided that you remain in continuous service to the Company on each date, 25% of the Option shares shall vest and become exercisable on the one-year anniversary of your employment commencement date and an additional 1/48th of the Option shares shall vest and become exercisable on a monthly basis thereafter over the following 36 months, as described in the applicable Plan and your Option grant documents.

2450 Holcombe Blvd, Suite X, Houston,		
Tvardi Therapeutics	TX 77021	www.tvardi.com

At-will Employment. We are excited to have you join the Company and look forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes an at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause and with or without notice. No provision of this offer letter shall be construed to create an express or implied employment contract, or a promise of employment for any specific period of time.

Authorization to Work. For the purposes of federal immigration law, you will be required to provide sufficient evidence of your authorization to work in the United States and your identity sufficient to allow the Company to complete the Form 1-9 required by law. Such documentation must be provided within (3) business days of your date of hire, or our employment relationship with you will be terminated. Additionally, this offer is contingent upon satisfactory completion of a background and reference check. You agree to assist as needed and to complete any documentation at the Company's request to meet these conditions.

No Conflicting Agreements or Obligations. We also ask that, if you have not already done so, you disclose to the Company and all agreements relating to your prior employment that may affect your eligibility to be employed by the company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing your duties of your position and you represent that such is the case. Moreover, you agree that, during the term of employment with the Company, you will not engage in other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third-party confidential information to the Company, including that of your former employer or other person to whom you have an obligation of confidentiality, and that in performing your duties for the Company you will not in any way utilize any such information.

Company Policies. As an employee of the Company, you will be expected to abide by the Company's rules and policies and acknowledge in writing that you have read and will comply with the Company's Employee Handbook. Consequently, as a condition of your employment, you are also required to sign and fully comply with the Invention and Non-Disclosure Agreement.

Conflicting Outside Employment. While employed by the Company, you may not work as an employee or consultant of any other organization or engage in any other activities which conflict or interfere with your employment obligations to the Company, including working for a competitive organization, or undertaking any activities that could create a conflict of interest.

Invention and Non-Disclosure Agreement. As a condition of your employment, you are also required to sign and comply with the Company's standard Invention and Non-Disclosure Agreement that, among other things, requires the assignment to the Company of the intellectual property rights to any invention made during your employment at the Company, and prohibits you from disclosing confidential or proprietary information of the Company.

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Offer Acceptance. If you accept this offer, please sign below to indicate your acceptance, along with the Invention and Non-Disclosure Agreement. This offer of employment will expire on September 10, 2021, unless accepted by you in writing prior to such date.

We look forward to your favorable reply and we are thrilled at the prospect of having you join us in our efforts in treating patients with an unmet need.

Sincerely,

/s/ Imran Alibhai

Imran Alibhai, PhD Chief Executive Officer

Enclosures: Invention and Non-Disclosure Agreement

ACCEPTANCE OF EMPLOYMENT OFFER

Tvardi Therapeutics

I have read, understand, and accept employment on the terms and conditions outlined in this offer letter. I am not relying on any representation made to me by anyone other than as set forth above. I also acknowledge and understand the "at-will" provision, in that it may not be modified or amended except by written agreement signed by me or an authorized representative of the Company.

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Signature:	/s/ Yixin Chen
Printed Name:	Yixin Chen
Date:	<u>08 Sept. 2021</u>

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CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE TVARDI THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO TVARDI THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

EXCLUSIVE LICENSE AGREEMENT

Re: BCM BLG # [***] Entitled "Chemical Probes That Competitively and Selectively Inhibit Stat3 Activation", developed by [***]

This Exclusive License Agreement (hereinafter called "Agreement"), to be effective as of the 16th day of July, 2012 (hereinafter called "Agreement Date"), is by and between Baylor College of Medicine (hereinafter called "BCM"), a Texas nonprofit organization having its principal place of business at One Baylor Plaza, Houston, Texas 77030, and Stem Med, Limited Partnership, a corporation organized under the laws of Texas and having a principal place of business at 7000 Fannin St., Houston, Texas 77030, and its Affiliates (hereinafter, collectively referred to as "LICENSEE").

WITNESSETH:

WHEREAS, BCM and LICENSEE have executed an Exclusive Option Agreement dated [***] (the "Exclusive Option Agreement") pursuant to which LICENSEE has obtained from BCM and BCM has granted to LICENSEE an exclusive option to obtain an exclusive worldwide, royalty bearing license to the "Subject Technology" and "Patent Rights" as defined in the Exclusive Option Agreement;

WHEREAS, BCM's mission is to advance human health through the integration of education, research, patient care and community service; and

WHEREAS, BCM is the owner of the Subject Technology and Patent Rights as defined below; and

WHEREAS, BCM is willing to grant a royalty bearing, worldwide, exclusive license to the Subject Technology and Patent Rights to LICENSEE on the terms set forth herein; and

WHEREAS, LICENSEE has elected to exercise said option and desires to obtain said exclusive license under the Subject Technology and Patent Rights.

NOW, THEREFORE, for and in consideration of the promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto expressly agree as follows:

1. DEFINITIONS AS USED HEREIN

1.1 The term "Affiliates" shall mean any corporation, partnership, joint venture or other entity which LICENSEE, directly or indirectly, owns or controls by LICENSEE's ownership of at least fifty percent (50%) of the entity's common stock or other ownership.

1.2 The term "Confidential Information" shall mean any proprietary and secret ideas, proprietary technical information, know-how and proprietary commercial information or other similar proprietary information that are owned by BCM. The term "Confidential Information" is further defined in Section 17 below.

- 1.3 The term "Developers" shall mean [***].
- 1.4 The term "Field" shall mean all fields of use.

1.5 The term "Legal Costs" shall mean all legal fees and expenses, filing or maintenance fees, assessments and all other costs and expenses related to prosecuting, obtaining and maintaining patent protection on the Patent Rights in the United States and foreign countries.

1.6 The term "Licensed Product(s)" shall mean any product, process or service that incorporates, utilizes or is made with the use of the Subject Technology and/or Patent Rights.

1.7 The term "Net Sales" shall mean [***]:

(i) [***];

(ii) [***];

- (iii) [***]; and
- (iv) [***].

[***]

1.8 The term "Party" shall mean either LICENSEE or BCM, and "Parties" shall mean LICENSEE and BCM.

1.9 The term "Patent Rights" shall mean [***], the inventions described and claimed therein, and all other pending United States patent applications or parts thereof and any United States patent which issues from any such pending applications and any and all divisions, reissues, reexaminations, renewals, continuations, continuations-in-part to the extent the claims are directed to subject matter specifically described in the aforementioned patent application and are dominated by the claims of the existing Patent Rights, and extensions thereof, and all other counterpart, pending or issued patents in all other countries. Patent Rights shall specifically include the patents and/or patent applications identified in Appendix A.

1.10 The term "Subject Technology" shall mean the technology, cell lines, biological materials, compounds, methods, documents, materials, tests and all confidential information developed as of [***] and supplied by BCM (identified in Appendix B), together with any progeny, mutants or derivatives thereof supplied by BCM or created by LICENSEE.

1.11 The term "Sublicensing Revenue" shall mean all [***]

(a) [***];

- (b) [***];
- (c) [***]; and
- (d) [***].

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2. GRANT OF LICENSE

2.1 <u>License Grant</u>. Subject to the reservations of rights set forth herein, BCM hereby grants to LICENSEE an exclusive, worldwide, sublicensable license under the Patent Rights and Subject Technology, to make, have made, use, market, sell, offer to sell, lease and import Licensed Products in the Field.

- 2.2 <u>Restrictions on License</u>. The grant in Section 2.1 shall be further subject to, restricted by and non-exclusive with respect to:
- (i) the making or use of the Subject Technology and Patent Rights by BCM for non-commercial research, patient care, teaching and other educationally related purposes;
- (ii) the making or use of the Subject Technology and Patent Rights by the Developers for non-commercial research purposes at academic or research institutions;
- (iii) any non-exclusive license of the Subject Technology and/or Patent Rights that BCM grants to other academic or research institutions for noncommercial research purposes;
- (iv) the making or use of the Subject Technology and Patent Rights by academic and research institutions for non-commercial research purposes; and
- (v) any non exclusive license of the Subject Technology and/or Patent Rights that BCM is required by law or regulation to grant to the United States of America or to a foreign state pursuant to an existing or future treaty with the United States of America.

2.3 <u>Government Reservation</u>. Rights under this Agreement are subject to rights required to be granted to the Government of the United States of America pursuant to 35 USC Section 200-212, including a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject inventions throughout the world.

3. DILIGENCE

LICENSEE shall use reasonable efforts, as defined herein, to introduce Licensed Products into the commercial market as soon as practicable. Such efforts shall include, but not be limited to: Developmental events to be achieved by LICENSEE or its sublicensee:

- a. [***] of payment of [***];
 b. [***] or payment of [***];
 c. [***] of payment of [***];
- d. [***] or payment of [***]; and
 e. [***].

4. <u>PAYMENTS</u>

4.1 License Execution Fee. As partial consideration for the rights conveyed by BCM under this Agreement, LICENSEE shall pay BCM a nonrefundable license fee of Seventy Five Thousand Dollars (\$75,000), with [***] payable upon [***] and [***] payable on the [***]. Such payment shall be delivered to BCM in accordance with the invoice instructions provided below. 4.2 Annual Maintenance Fee: Thirty Thousand Dollars (\$30,000), beginning on the [***], and increasing to Fifty Thousand Dollars (\$50,000) on the [***] and thereafter until the introduction of a licensed product.

4.3 <u>Responsibility for Legal Costs</u>. In addition to the foregoing license execution fee, LICENSEE shall reimburse BCM for all Legal Costs incurred prior to execution of this Agreement. Such payment shall be due within [***] of receipt of invoice from BCM. As provided for in Paragraph 9.1 herein, LICENSEE will be responsible for all Legal Costs incurred after the Agreement Date.

4.4 <u>Royalty on Net Sales</u>. In addition to the foregoing, LICENSEE shall pay BCM a non-reducible royalty of [***] of Net Sales by LICENSEE, its Affiliates, or sublicensees. Collectively the royalty payments that are the subject of this Paragraph 4.3 are termed "Royalties" for purposes of this Agreement and shall be due and payable as provided in Section 5 and delivered to BCM in accordance with the invoice instructions provided below.

4.5 <u>Milestone Payments</u>. LICENSEE shall also pay BCM the following milestone payments set forth below:

- a. Investigational New Drug Filing
 - i. \$50,000 USD for first oncology indication.
 - ii. \$50,000 USD for first non-oncology indication.

b. Initiation of Phase II Clinical Trials

- i. \$125,000 USD for the first oncology indication.
- ii. \$125,000 USD for the first non-oncology indication.

c. [***]

- i. [***] for the first oncology indication.
- ii. [***] for the first non-oncology indication.

d. [***]

b.

- i. [***] for the first oncology indication.
- ii. [***] for the first non-oncology indication.

LICENSEE shall notify BCM in writing within [***] upon the achievement of each milestone, such notice to be accompanied by payment of the appropriate milestone payment. Milestones are to be paid regardless of whether LICENSEE or LICENSEE's sublicensee attains such milestone.

4.6 <u>Sublicense Revenue Payments</u>. LICENSEE shall have the right to sublicense the Patent Rights and Subject Technology. In the event LICENSEE sublicenses the Subject Technology and Patent Rights under this Agreement, LICENSEE agrees to pay to BCM the following percentages of all Sublicensing Revenue received by LICENSEE:

a. [***] of Sublicensing Revenue shall be payable to BCM if the sublicense agreement is [***] within [***] of the Agreement Date.

[***] of sublicense revenue shall be payable to BCM if the sublicense agreement is [***] after the [***] of the Agreement Date.

4.7 <u>Payment Addresses</u>. Payments sent by check are to be made payable to "Baylor College of Medicine" and shall be sent to the address below. If payments are sent by wire transfer, they shall be sent using wiring instructions provided in Appendix D. All payments shall reference **BLG number(s)** [***] listed on the front page of the Agreement.

[***] Baylor College of Medicine

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Licensing Group
[***]

Telephone No.	[***]
Facsimile No.	[***]
E-Mail	[***]

Payments shall be deemed received only upon confirmation that all funds have been received by the LICENSING GROUP as referenced above. LICENSEE hereby accepts responsibility for ensuring that payment is addressed correctly.

Licensee Payment Contact. For questions about payments, BCM can contact LICENSEE at the address below:

[***] [***] [***] Tel: [***] Fax: [***] Email: [***]

4.8 <u>Payment Conditions</u>. All payments due hereunder are payable in United States dollars. No transfer, exchange, collection or other charges, **including any wire transfer fees**, shall be deducted from such payments. For sales of Licensed Products in currencies other than the United States, LICENSEE shall use exchange rates [***] that such payment is due.

4.9 <u>Late Payments</u>. Late payments shall be subject to a charge of [***] per month, the interest being [***], or [***], whichever is greater. LICENSEE shall calculate the correct late payment charge, and shall add it to each such late payment. Said late payment charge and the payment and acceptance thereof shall not negate or waive the right of BCM to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment. LICENSEE shall indemnify BCM for all attorneys' fees and costs BCM incurs in obtaining a full payment of that which is owed to BCM.

4.10 <u>Invoice Procedures</u>. Any amounts payable to BCM hereunder shall be made in full within [***] after receipt by LICENSEE of an invoice covering such payment. The Parties understand and agree that one (1) invoice will be sent to LICENSEE by BCM for each fee due. The invoice shall be in the form in Appendix D. Any additional fees, such as taxes, wire or transfer fees, will not be included in the invoice, but payment of such fees shall remain the responsibility of LICENSEE and shall not be deducted from the payment due BCM. Subsequent invoices, if requested by LICENSEE, shall be subject to an administrative fee of [***], in addition to the original payment due to BCM plus any interest charges incurred due to delays in payment, if applicable. The calculation and payment of such interest payments shall not be invoiced and shall be the sole responsibility of the LICENSEE. Invoices shall be sent electronically or via facismile to the address listed above.

5. <u>REPORTING</u>

5.1 <u>Annual Progress Report</u>. No later than [***] after [***], LICENSEE shall provide to BCM a written annual progress report describing progress on all research and development and commercial activities, during the most recent twelve (12) month period ending [***] and plans for the forthcoming year ("Annual Progress Report"). If multiple technologies are covered by the license granted hereunder, the progress report shall provide the information set forth above for each technology. At BCM's request, LICENSEE shall also provide any reasonable additional data BCM requires to evaluate LICENSEE's or its sublicensee performance.

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5.2 <u>Notification of First Sale</u>. LICENSEE shall notify BCM the date on which LICENSEE and the sublicensees make a first sale of Licensed Products in each country in which it occurs within [***] of occurrence.

5.3 <u>Royalty reports</u>. LICENSEE shall submit to BCM within [***] after [***], a written report on a form provided by BCM (a current version of which is attached as <u>Appendix C</u>) setting forth for such [***] at least the following information:

(i) [***]

The royalty report shall be certified as correct by an officer of LICENSEE. After termination or expiration of this Agreement, LICENSEE will continue to submit royalty reports and payments to BCM until all Licensed Products made, used, marketed, leased or imported under the Agreement have been sold.

5.4 <u>Payment to Accompany Royalty Reports</u>. LICENSEE shall pay to BCM with each such royalty report the amount of Royalties and other payments due with respect to such [***]. If multiple technologies are covered by the license granted hereunder, LICENSEE shall specify which Subject Technology and Patent Rights are utilized for each Licensed Product included in the royalty report by citing the applicable **BLG number** listed on the front page of the Agreement.

5.5 Notification of Merger or Acquisition. In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, LICENSEE shall notify BCM in writing within [***] of such event.

5.6 <u>Entity Status</u>. If LICENSEE or sublicensee does not qualify as a "small entity" as provided by the United States Patent and Trademark Office, LICENSEE must notify BCM immediately.

6. TRANSFER OF SUBJECT TECHNOLOGY

6.1 <u>Transfer Schedule</u>. Upon receipt of the license fee described in Paragraph 4.1, BCM shall, within [***] thereof, provide LICENSEE with reasonable quantities of the Subject Technology. The Parties understand and agree that BCM will use reasonable efforts to provide the Subject Technology within [***] of receipt of the license fee, however the Parties acknowledge that unforeseen circumstances might delay delivery.

6.2 <u>Transfer Address and Payment</u>. Such Subject Technology shall be sent to the address below, via _____ overnight courier using LICENSEE's courier account number _____.

[***] [***] Tel: [***] Fax: [***] Email: [***]

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7. <u>RECORDS AND INSPECTION</u>

7.1 <u>Accounting Records</u>. LICENSEE shall maintain, and shall cause its sublicensees to maintain, complete and accurate records relating to the rights and obligations under this Agreement and any amounts payable to BCM in relation to this Agreement, which records shall contain sufficient information to permit BCM to confirm the accuracy of any reports delivered to BCM and compliance in other respects with this Agreement. The relevant party shall retain such records for at least [***] to which they pertain.

7.2 <u>Audit by BCM</u>. During the Term of this Agreement as defined below and for a period of [***] thereafter, BCM or its representatives shall have the right to inspect the books and records of LICENSEE in conjunction with the performance of LICENSEE's obligations under the terms and conditions of this Agreement upon reasonable written notice. The scope of such audit and inspection activities may include the review of records supporting activities performed by LICENSEE in conjunction with its obligations under this Agreement[***]. LICENSEE agrees to provide representatives of BCM reasonable access to books, records[***], and shall cooperate fully with BCM's representatives in support of their inspection and audit activities during LICENSEE's normal business hours.

7.3 <u>Payment Deficiency</u>. If a payment deficiency is determined, LICENSEE and its sublicensee(s), as applicable, shall pay the outstanding amounts within [***] of receiving written notice thereof, plus interest on such outstanding amounts as described in Section 5.

7.4 <u>Responsibility for Audit Costs</u>. BCM will pay for any audit done under Paragraph 7.2. However, in the event that the audit reveals an underpayment of Royalties or fees by more than [***] for the period being audited, the cost of the audit shall be paid by LICENSEE. If the underpayment is less than [***] but more than [***] for the period being audited, [***] cost of the audit. LICENSEE shall indemnify BCM for all attorneys' fees and costs BCM incurs in obtaining access to conduct the audit and collecting, when applicable, for the cost of the audit and any underpaid amounts and interest.

8. <u>SUBLICENSES</u>

All sublicenses granted by LICENSEE of its rights hereunder shall be subject to the terms of this Agreement. LICENSEE shall be responsible for its sublicensees and shall not grant any rights which are inconsistent with the rights granted to and obligations of LICENSEE hereunder. Any act or omission of a sublicensee which would be a breach of this Agreement if performed by LICENSEE shall be deemed to be a breach by LICENSEE of this Agreement. [***]

9. <u>PATENTS AND INFRINGEMENT</u>

9.1 <u>Patent Prosecution Responsibility</u>. For the Term of this Agreement as defined below, BCM shall be responsible for filing, prosecuting and maintaining all patent applications and patents included in the Patent Rights, and LICENSEE agrees to pay all Legal Costs. BCM shall select all outside counsel for prosecution of the Patent Rights and such counsel shall represent BCM in such prosecution BCM shall instruct its patent counsel to invoice LICENSEE directly for all such Legal Costs. LICENSEE agrees to pay all such invoices within [***] of receipt.

9.2 Notification of Intent Not to Pursue. In the event that LICENSEE decides not to pay for the costs associated with either: (i) the prosecution of the Patent Rights to issuance or (ii) maintenance of any United States or foreign issued patent on the Patent Rights, LICENSEE shall timely notify BCM in writing thereof. LICENSEE's right under this Agreement to practice the invention under this patent shall immediately terminate upon the giving of such notice. If LICENSEE fails to notify BCM in sufficient time for BCM to assume said costs prior to the abandonment or expiration of any Patent Rights, LICENSEE shall be considered in default of this Agreement.

9.3 <u>Notification of Patent Prosecution Action</u>. BCM agrees to keep LICENSEE fully informed, at LICENSEE's expense, of all prosecutions and other actions pursuant to this Section 9, including submitting to LICENSEE copies of all official actions and responses thereto.

9.4 <u>Cooperation</u>. BCM agrees to reasonably cooperate with LICENSEE to whatever extent is reasonably necessary to provide LICENSEE the full benefit of the license granted herein.

9.5 <u>Infringement Procedures</u>. During the Term of this Agreement as defined below, each Party shall promptly inform the other of any suspected infringement of any claims in the Patent Rights or the misuse, misappropriation, theft or breach of confidence of other proprietary rights in the Subject Technology and/or Patent Rights by a third party, and with respect to such activities as are suspected. Any action or proceeding against such third party shall be instituted as following:

- (i) BCM and LICENSEE may agree to jointly institute an action for infringement, misuse, misappropriation, theft or breach of confidence of the proprietary rights against such third party. Such joint action shall be brought in the names of both BCM and LICENSEE. If BCM or LICENSEE decides to jointly prosecute an action or proceeding after it has been instituted by one Party, the action shall be continued in the name or names they both agree is expedient for efficient prosecution of such action. LICENSEE and BCM shall agree to the manner in which they shall exercise control over any joint action or proceeding, providing however that if they cannot agree BCM shall have the right to unilaterally decide on control. In such joint action or proceeding, the out-of-pocket costs shall be borne [***], and any recovery or settlement shall be [***].
- (ii) If LICENSEE does not agree to participate in a joint action or proceeding then BCM shall have the right, but not the obligation, to institute an action for infringement, misuse, misappropriation, theft or breach of confidence of the proprietary rights against such third party. If BCM fails to bring such an action or proceeding within a period of [***] after receiving notice or otherwise having knowledge of such infringement, then LICENSEE shall have the right, but not the obligation, to prosecute the same at its own expense; BCM will reasonably cooperate with LICENSEE in such action. In addition, if BCM cooperates in such action, such cooperation shall be at LICENSEE's sole expense. Should either BCM or LICENSEE commence action under the provisions of this Paragraph 9.5 and thereafter elect to abandon the same, it shall give timely notice to the other Party who may, if it so desires, continue prosecution of such action or proceeding. All recoveries, whether by judgment, award, decree or settlement, from infringement or misuse of Subject Technology and/or Patent Rights shall be apportioned as follows: (a) the Party bringing the action or proceeding shall first recover an amount equal the costs and expenses incurred by such Party directly related to the prosecution of such action or proceeding shall then recover costs and expenses incurred by such Party, if any, directly related to its cooperation in the prosecution of such action or proceeding and (c) the remainder [***].

9.6 <u>Consent to Settle</u>. Neither BCM nor LICENSEE shall settle any action covered by Paragraph 9.5 without first obtaining the consent of the other Party, which consent will not be unreasonably withheld.

9.7 <u>Liability for Losses</u>. BCM shall not be liable for any losses incurred as the result of an action for infringement brought against LICENSEE as the result of LICENSEE's exercise of any right granted under this Agreement. The decision to defend or not defend shall be in LICENSEE's sole discretion.



10. <u>TERM</u>

Unless sooner terminated as otherwise provided in Section 11, the license to employ Patent Rights and Subject Technology granted herein as part of Section 2 shall expire on a country-by-country basis, on the later of (i) the date of expiration of the last of the Patent Rights to expire or (ii) in the event no patents included within the Patent Rights issue in such country, the first date following the tenth (10th) anniversary of the first commercial sale of Licensed Products by LICENSEE in such country ("Term"). After such expiration, but not termination, LICENSEE shall have a perpetual, paid-in-full (i.e., royalty free) license in such country.

11. TERMINATION

11.1 <u>Termination for Default</u>. In the event of default or failure by LICENSEE to perform any of the terms, covenants or provisions of this Agreement, including failure to make timely payment, LICENSEE shall have [***] after the giving of written notice of such default by BCM to correct such default. If such default is not corrected within the said [***] period, BCM shall have the right, at its option, to cancel and terminate this Agreement. The failure of BCM to exercise such right of termination, for non-payment of Royalties/fees or otherwise, shall not be deemed to be a waiver of any right BCM might have, nor shall such failure preclude BCM from exercising or enforcing said right upon any subsequent failure by LICENSEE.

11.2 <u>Termination for Insolvency</u>. BCM shall have the right, at its option, to cancel and terminate this Agreement in the event that LICENSEE shall (i) become involved in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of its business or (ii) make an assignment of all or substantially all of its assets for the benefit of creditors, or in the event that (iii) a receiver or trustee is appointed for LICENSEE and LICENSEE shall, after the expiration of [***] following any of the events enumerated above, have been unable to secure a dismissal, stay or other suspension of such proceedings.

11.3 <u>Termination by Licensee</u>. LICENSEE shall have the right in its sole discretion to terminate this Agreement upon [***] written notice to BCM.

11.4 <u>Effect of Termination</u>. In the event of termination of this Agreement, all rights to the Subject Technology and Patent Rights shall revert to BCM. At the date of any termination of this Agreement, LICENSEE shall immediately cease using any of the Subject Technology and Patent Rights and LICENSEE shall immediately destroy the Subject Technology and send to BCM a written affirmation of such destruction signed by an officer of LICENSEE; provided, however, that LICENSEE may sell any Licensed Products actually in the possession of LICENSEE on the date of termination, provided that LICENSEE continues to submit royalty reports to BCM and pays to BCM the Royalties on all such sales in accordance with Paragraph 5.3 with respect thereto and otherwise complying with the terms of this Agreement.

11.5 <u>Effect of Termination on Sublicensees</u>. LICENSEE shall provide, in all sublicenses granted by it under this Agreement, that LICENSEE's interest in such sublicenses shall, at BCM's option, terminate or be assigned to BCM upon termination of this Agreement.

11.6 <u>No Refund</u>. In the event this Agreement is terminated pursuant to this Section 11, or expires as provided for in Section 10, BCM is under no obligation to refund any payments made by LICENSEE to BCM prior to the effective date of such termination or expiration.

11.7 <u>Survival of Termination</u>. No termination of this Agreement shall constitute a termination or a waiver of any rights of either Party against the other Party accruing at or prior to the time of such termination. The obligations of Sections 4, 5, 7, 11, 13, 14, 15, 16, 17 and 18 shall survive termination of this Agreement.

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12. ASSIGNABILITY

Without the prior written approval of BCM, which will not be unreasonably withheld, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by LICENSEE to any person or entity whether voluntarily or involuntarily, by operation of law or otherwise. Notwithstanding the foregoing, LICENSEE may assign this Agreement and its rights and obligations hereunder without BCM's consent, (i) in connection with the transfer or sale of all or substantially all of its assets or the business of LICENSEE to which this Agreement relates or (ii) to any Affiliate; so long as LICENSEE gives BCM prompt notice of such action and the successor entity or Affiliate, as the case may be, acknowledges its consent and agreement to the terms of this Agreement in writing before such assignment; and so long as such action is not entered into solely to satisfy creditors of LICENSEE. This Agreement shall be binding upon and shall inure to the benefit of the respective successors, legal representatives and assignees of each of the Parties.

13. GOVERNMENTAL COMPLIANCE

13.1 <u>Compliance with Applicable Laws</u>. LICENSEE shall at all times during the Term of this Agreement and for so long as it shall use the Subject Technology and/or Patent Rights, or sell Licensed Products, comply and cause its sublicensees to comply with all laws that may control the import, export, manufacture, use, sale, marketing, distribution and other commercial exploitation of the Subject Technology, Patent Rights, Licensed Products or any other activity undertaken pursuant to this Agreement.

13.2 <u>Requirement for U.S. Manufacture</u>. LICENSEE agrees that Licensed Products leased or sold in the United States shall be manufactured substantially in the United States. However, LICENSEE may request an exception to this requirement and if it is able to secure an appropriate waiver or release from this requirement that Licensed Products leased or sold in the United States shall be manufactured substantially in the United States, LICENSEE will be released from this requirement. BCM shall reasonably cooperate with LICENSEE's efforts to obtain an appropriate waiver or release from any requirement that Licensed Products leased or sold in the United States shall be manufactured substantially in the United States.

13.3 Export Control Regulations. The Subject Technology is subject to, and LICENSEE agrees to comply in all respects with, U.S. law including but not limited to U.S. export controls under the Export Administration Regulations (15 C.F.R. Part 734 et seq.) and U.S. economic sanctions and embargoes codified in 31 C.F.R. Chapter V. LICENSEE agrees that LICENSEE bears sole responsibility for understanding and complying with current U.S. trade controls laws and regulations as applicable to its activities subject to this Agreement. Without limitation on the general agreement to comply set forth in the first sentence of this Paragraph 13.3, LICENSEE agrees not to sell any goods, services, or technologies subject to this Agreement, or to release or disclose or re-export the same: (i) to any destination prohibited by U.S. law, including any destination subject to U.S. economic embargo; (ii) to any end-user prohibited by U.S. law, including any person or entity listed on the U.S. government's Specially Designated Nationals list, Denied Parties List, Debarred Persons List, Unverified List, or Entities List; (iii) to any foreign national in the U.S. or abroad without prior license if required; or (iv) to any user, for any use, or to any destination without prior license if required.

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14. DISPUTE RESOLUTION

14.1 <u>Amicable Resolution</u>. The Parties shall attempt to settle any controversy between them amicably. To this end, a senior executive from each Party shall consult and negotiate to reach a solution. The Parties agree that the period of amicable resolution shall toll any otherwise applicable statute of limitations.

14.2 <u>Failure to Amicably Resolve</u>. If the senior executives from each Party fail to meet or if the matter remains unresolved for a period of [***], then the parties hereby irrevocably submit to mandatory mediation, then the jurisdiction of a court of competent jurisdiction in the State of Texas, and, by execution and delivery of this Agreement, each (a) accepts, generally and unconditionally, the jurisdiction of such court and any related appellate court and (b) irrevocably waives any objection it may now or hereafter have as to the venue of any such suit, action or proceeding brought in such court or that such court is an inconvenient forum.

14.3 <u>Construction and Jurisdiction</u>. This Agreement shall be deemed to be subject to, and have been made under, and shall be construed and interpreted in accordance with the laws of the State of Texas. No conflict-of-laws rule or law that might refer such construction and interpretation to the laws of another state, republic, or country shall be considered. This Agreement is performable in part in Harris County, Texas, and the Parties mutually agree that personal jurisdiction and venue shall be proper in the state and federal courts situated in Harris County, Texas, and agree that any litigated dispute will be conducted solely in such courts.

15. NOTICES

15.1 <u>Addresses for Notices</u>. All notices, reports or other communication pursuant to this Agreement shall be sent to such Party via (i) United States Postal Service postage prepaid, (ii) overnight courier, or (iii) facsimile transmission, addressed to it at its address set forth below or as it shall designate by written notice given to the other Party. Notice shall be sufficiently made, or given and received (a) on the date of mailing or (b) when a facsimile printer reflects transmission.

In the case of BCM: [***] Telephone No. [***] Facsimile No. [***] E-Mail [***]

In the case of LICENSEE:

[***] [***] Tel: [***] Fax: [***] Email: [***]

15.2 <u>Use of Reference Number</u>. Each such report, notice or other communication shall include **BLG number(s)** [***] listed on the front page of the Agreement.

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16. INDEMNITY, INSURANCE & WARRANTIES

16.1 <u>INDEMNITY</u>.

EACH PARTY SHALL NOTIFY THE OTHER OF ANY CLAIM, LAWSUIT OR OTHER PROCEEDING RELATED TO THE (i) SUBJECT TECHNOLOGY AND PATENT RIGHTS. LICENSEE AGREES THAT IT WILL DEFEND, INDEMNIFY AND HOLD HARMLESS BCM, ITS FACULTY MEMBERS, SCIENTISTS, RESEARCHERS, EMPLOYEES, STUDENTS, OFFICERS, TRUSTEES AND AGENTS AND EACH OF THEM (THE "INDEMNIFIED PARTIES"), FROM AND AGAINST ANY AND ALL CLAIMS, CAUSES OF ACTION, LAWSUITS OR OTHER PROCEEDINGS (THE "BCM CLAIMS") FILED OR OTHERWISE INSTITUTED AGAINST ANY OF THE INDEMNIFIED PARTIES RELATED DIRECTLY OR INDIRECTLY TO OR ARISING OUT OF THE DESIGN, PROCESS, MANUFACTURE OR USE BY ANY PERSON OR PARTY OF THE SUBJECT TECHNOLOGY, PATENT RIGHTS, LICENSED PRODUCTS OR ANY OTHER EMBODIMENT OF THE SUBJECT TECHNOLOGY AND PATENT RIGHTS EVEN THOUGH SUCH BCM CLAIMS AND THE COSTS (INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE) RELATED THERETO RESULT IN WHOLE OR IN PART FROM THE NEGLIGENCE OF ANY OF THE INDEMNIFIED PARTIES OR ARE BASED UPON DOCTRINES OF STRICT LIABILITY OR PRODUCT LIABILITY; PROVIDED, HOWEVER, THAT SUCH INDEMNITY SHALL NOT APPLY TO ANY BCM CLAIMS ARISING FROM THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF ANY INDEMNIFIED PARTY, LICENSEE WILL ALSO ASSUME RESPONSIBILITY FOR ALL COSTS AND EXPENSES RELATED TO SUCH BCM CLAIMS FOR WHICH IT IS OBLIGATED TO INDEMNIFY THE INDEMNIFIED PARTIES PURSUANT TO THIS PARAGRAPH 16.1, INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE.

(ii) LICENSEE FURTHER AGREES NOT TO SETTLE ANY CLAIM AGAINST AN INDEMNIFIED PARTY WITHOUT THE INDEMNIFIED PARTY'S WRITTEN CONSENT WHICH CONSENT SHALL NOT BE UNREASONABLY WITHHELD. LICENSEE FURTHER AGREES TO KEEP THE INDEMNIFIED PARTIES FULLY APPRISED OF THE BCM CLAIMS.

16.2 Insurance.

- (i) LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s), maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of [***].
- (ii) LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s) [***], maintain in full force and effect policies of

 (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence,
 (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of [***].
- (iii) LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s) [***], maintain in full force and effect policies of

 (a) worker's compensation insurance within, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of
 [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of
 [***].

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- (iv) Such coverage(s) shall be purchased from a carrier or carriers having an A. M. Best rating of at least [***] and shall name BCM as an additional insured. LICENSEE shall provide to BCM copies of certificates of insurance within [***] after execution of this Agreement. Upon request by BCM, LICENSEE shall provide to BCM copies of said policies of insurance. It is the intention of the Parties hereto that LICENSEE shall, throughout the Term of this Agreement, continuously and without interruption, maintain in force the required insurance coverages set forth in this Paragraph 16.2. Failure of LICENSEE to comply with this requirement shall constitute a default of LICENSEE allowing BCM, at its option, to immediately terminate this Agreement.
- (v) BCM reserves the right to reasonably request additional policies of insurance where appropriate and reasonable in light of LICENSEE's business operations and availability of coverage.

16.3 DISCLAIMER OF WARRANTY. BCM MAKES NO WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF FITNESS OR MERCHANTABILITY, REGARDING OR WITH RESPECT TO THE SUBJECT TECHNOLOGY, PATENT RIGHTS OR LICENSED PRODUCTS AND BCM MAKES NO WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, OF THE PATENTABILITY OF THE SUBJECT TECHNOLOGY, PATENT RIGHTS OR LICENSED PRODUCTS OR OF THE ENFORCEABILITY OF ANY PATENTS ISSUING THEREUPON, IF ANY, OR THAT THE SUBJECT TECHNOLOGY, PATENT RIGHTS OR LICENSED PRODUCTS ARE OR SHALL BE FREE FROM INFRINGEMENT OF ANY PATENT OR OTHER RIGHTS OF THIRD PARTIES. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS UNDER ANY PATENTS OF BCM OTHER THAN THE PATENT RIGHTS, REGARDLESS OF WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS.

17. <u>CONFIDENTIALITY</u>

17.1 <u>Scope</u>. LICENSEE shall not, directly or indirectly, divulge or reveal to any person or entity the Confidential Information of BCM without BCM's prior written consent or use such Confidential Information except as permitted hereunder. LICENSEE shall maintain the Subject Technology and Patent Rights in strictest confidence and use the same only in accordance with this Agreement. Employees, agents or subcontractors of LICENSEE shall be given access to the Confidential Information only on a legitimate "need to know" basis and after agreeing to be bound in writing to not divulge or reveal the Confidential Information. The public disclosure with the permission of BCM of any one component of that which was identified as or constituted the Confidential Information of BCM shall not prevent the other components from retaining their status as Confidential Information and the property of BCM. Confidential Information shall include any and all information that is produced or results from the disclosure of Confidential Information by BCM to LICENSEE and its sublicensees during the course of the relationship that is the subject of this Agreement.

17.2 <u>Exclusion</u>. Such obligation of confidentiality shall not apply to information which LICENSEE can demonstrate: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no fault of LICENSEE; (iii) was known to LICENSEE prior to disclosure thereof by BCM; (iv) was lawfully disclosed to LICENSEE by a third party which was not under an obligation of confidence to BCM with respect thereto; (v) LICENSEE was compelled to disclose by law or legal process; or (vi) was approved for public release by prior written permission of BCM.

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17.3 <u>Court Order</u>. LICENSEE may make disclosures of Confidential Information required by a Court Order, provided LICENSEE first gives a timely opportunity to BCM to participate in the proceeding to the extent that the proceeding permits such participation.

17.4 <u>Confidentiality of Agreement</u>. Unless otherwise provided for in this Agreement, the Parties agree that this Agreement and its terms are to be considered Confidential Information and shall be treated as such.

18. ADDITIONAL PROVISIONS

18.1 <u>Use of BCM Name</u>. LICENSEE agrees that it shall not use in any way the name of "Baylor College of Medicine" or any logotypes or symbols associated with BCM or the names of any of the scientists or other researchers at BCM without the prior written consent of BCM.

18.2 <u>Marking of Licensed Products</u>. To the extent commercially feasible and consistent with prevailing business practices, LICENSEE shall mark, and shall cause its sublicensees to mark, all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent under the Patent Rights that applies to such Licensed Product.

18.3 <u>BCM's Disclaimers</u>. Neither BCM, nor any of its faculty members, scientists, researchers, employees, students, officers, trustees or agents assume any responsibility for the manufacture, product specifications, sale or use of the Subject Technology, Patent Rights or Licensed Products which are manufactured by or sold by LICENSEE.

18.4 <u>Independent Contractors</u>. The Parties hereby acknowledge and agree that each is an independent contractor and that neither Party shall be considered to be the agent, representative, master or servant of the other Party for any purpose whatsoever, and that neither Party has any authority to enter into a contract, to assume any obligation or to give warranties or representations on behalf of the other Party. Nothing in this relationship shall be construed to create a relationship of joint venture, partnership, fiduciary or other similar relationship between the Parties.

18.5 <u>Non-Waiver</u>. The Parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

18.6 <u>Reformation</u>. The Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries, and that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the Parties hereto, in a final, unappealable order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto. In lieu of such inoperative words, sentences, paragraphs or clauses, or combination of clauses, there will be added automatically as part of this Agreement, a valid, enforceable and operative provision as close to the original language as may be possible which preserves the economic benefits to the Parties.

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18.7 <u>Force Majeure</u>. No liability hereunder shall result to a Party by reason of delay in performance caused by force majeure, that is circumstances beyond the reasonable control of the Party, including, without limitation, acts of God, fire, flood, war, terrorism, civil unrest, labor unrest, or shortage of or inability to obtain material or equipment.

18.8 <u>Section and Paragraph Headings</u>. The section and paragraph headings used in this Agreement are intended for purposes of reference and convenience only, and shall not factor into any interpretation of the Agreement.

18.9 <u>Entire Agreement</u>. The terms and conditions herein constitute the entire agreement between the Parties and shall supersede all previous agreements, whether electronic, oral or written, between the Parties hereto with respect to the subject matter hereof. No agreement of understanding bearing on this Agreement shall be binding upon either Party hereto unless it shall be in writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement. Electronic communication between the Parties shall not constitute an agreement of understanding, unless it is subsequently reduced to writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement.

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IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the Agreement Date.

LICENSE	E	BAYLOR	COLLEGE OF MEDICINE
Signature:	/s/ Jenny Chang	Signature:	/s/ Adam Kuspa
Name:	Jenny Chang	Name:	Adam Kuspa, Ph.D.
Title:	Partner, Stemmed, Limited Partnership	Title:	Vice President for Research
Date:	7/21/2012	Date:	7/15/12
02.07.2012 LICENSEE BLG #[***]			

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Appendix A [***] [***]

Appendix B

Appendix C [***] [***]

Appendix D

FIRST AMENDMENT TO LICENSE AGREEMENT

This First Amendment (hereinafter called "the First Amendment") to the License Agreement, as defined below, to be effective as of the <u>26th</u> day of <u>April</u>, 2015 (hereinafter called "First Amendment Date"), is by and between Baylor College of Medicine (hereinafter called "BCM"), a Texas nonprofit corporation having its principal place of business at One Baylor Plaza, Houston, Texas 77030, and Stem Med, Limited Partnership, a corporation organized under the laws of Texas and having a principal place of business at 7000 Fannin St., Houston, Texas 77030, and its Affiliates (hereinafter, collectively referred to as "LICENSEE").

WHEREAS, BCM and LICENSEE have entered into that certain agreement effective July 16th, 2012 ("License Agreement") under which LICENSEE has obtained from BCM and BCM has granted to LICENSEE a certain exclusive license to the Patent Rights and Subject Technology as defined in said License Agreement; and

WHEREAS, BCM and LICENSEE desire to amend said License Agreement as provided herein.

NOW, THEREFORE, in consideration of the mutual provisions and covenants contained herein, BCM and LICENSEE hereby agree as follows:

1. The terms in the License Agreement shall have the same meanings in this First Amendment.

2. In partial consideration of the execution of the First Amendment, LICENSEE shall pay BCM a non-refundable Amendment Fee of [***]. Such payment shall be due upon execution of the First Amendment and delivered to BCM within [***] in accordance with the invoice instructions provided in the License Agreement.

3. Paragraph 1.3 is hereby amended and shall read as follows:

1.3 The term "Developers" shall mean

4. [***]Paragraph 1.10 (i) is hereby incorporated into the License Agreement and shall read as follows:

1.10(i) BLG# [***] and BLG# [***]: the technology, cell lines, biological materials, compounds, methods, documents, materials, tests and all confidential information developed as of the First Amendment Date and supplied by BCM (identified in Appendix B), together with any progeny, mutants or derivatives thereof supplied by BCM or created by LICENSEE.

5. Paragraph 4.6 is hereby amended and shall read as follows:

4.6 <u>Payment Addresses</u>. Payments sent by check are to be made payable to "Baylor College of Medicine" and shall be sent to the address below. If payments are sent by wire transfer, they shall be sent using wiring instructions provided in Appendix D. All payments shall reference **BILG numbers** [***], [***], **and/or** [***] as appropriate.

[***] Baylor College of Medicine Licensing Group

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[***] Telephone No. [***] Facsimile No. [***] E-Mail [***]

Payments shall be deemed received only upon confirmation that all funds have been received by the **LICENSING GROUP** as referenced above. LICENSEE hereby accepts responsibility for ensuring that payment is addressed correctly.

Licensee Payment Contact. For questions about payments, BCM can contact LICENSEE at the address below:

[***] [***] Phone: [***] Email: [***] Website: [***]

6. Appendix A is hereby amended and shall read as follows:

Appendix A [***]

7. Except as amended hereby, the License Agreement shall be and remain in full force and effect.

8. The First Amendment shall be effective as of the First Amendment Date provided above.

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IN WITNESS WHEREOF, the Parties hereto have executed and delivered this First Amendment in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the First Amendment Date.

LICEN	SEE	BAYL	OR COLLEGE OF MEDICINE		
Name:	/s/ David Tweardy David A. Tweardy, M.D.	Name:	/s/ Adam Kuspa Adam Kuspa, Ph. D.		
Title:	President & CEO	Title:	Senior Vice President and Dean of Research		
Date:	4/26/15	Name:	1/28/15		
01/15/2	01/15/2015 StemMed BLG# [***], [***], and [***]				
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STEMMED, LTD. 7000 Fannin Street Suite 1960M Houston, TX 77030

January 24, 2018

Baylor College of Medicine Attn: Patrick Turley Associate General Counsel One Baylor Plaza, BC210-600D Houston, Texas 77030

Re: Notice of Assignment regarding Exclusive License Agreement, dated July 16, 2012, by and between Baylor College of Medicine and StemMed, Ltd., as amended

Dear Mr. Turley:

Reference is hereby made to that certain Exclusive License Agreement, dated July 16, 2012, by and between Baylor College of Medicine and StemMed, Ltd. ("StemMed"), as amended (the "License Agreement"). StemMed has assigned the License Agreement to, an affiliate, Tvardi Therapeutics, Inc. ("Tvardi") in connection with the transfer to Tvardi of all or substantially all of the assets and business to which the License Agreement relates. Accordingly, acting in accordance with Section 12 of the License Agreement, we hereby provide you notice of the assignment of the License Agreement from StemMed to Tvardi and we confirm that in connection with such transfer, Tvardi has acknowledged its consent and agreement to the terms of the License Agreement.

Please indicate your acknowledgment of receipt of this notice of assignment by executing the acknowledgment below, e-mailing a copy of the signed letter to the attention of Andrea Sorrentino@wilmerhale.com or returning an original copy of the signed letter via U.S. mail to our attention at StemMed, Ltd., 7000 Fannin Street, Suite 1960M, Houston, Texas 77030.

If you have any questions regarding the information in this letter, please do not hesitate to contact us. We would appreciate your response as soon as possible. Thank you for your assistance and cooperation.

Very truly yours,

STEMMED, LTD.

By: StemMed Holdings, LLC, as the General Partner of StemMed, Ltd.

/s/ David J. Tweardy By: David J. Tweardy, Manager

Acknowledged and accepted as of date first written above:

BAYLOR COLLEGE OF MEDICINE

By:	/s/ Michael B Dilling
Name:	Michael B Dilling
Title:	Director, Baylor Licensing Group

SECOND AMENDMENT TO LICENSE AGREEMENT

This Second Amendment (hereinafter called "the Second Amendment") to the License Agreement, as defined below, to be effective as of the 13th day of August, 2019 (hereinafter called "Second Amendment Agreement Date"), is by and between Baylor College of Medicine (hereinafter called "BCM"), a Texas nonprofit corporation having its principal place of business at One Baylor Plaza, Houston, Texas 77030, and Tvardi Therapeutics, a corporation organized under the laws of Texas and having a principal place of business at 2450 Holcombe Blvd, Suite X, Houston, TX, 77021, and its Affiliates (hereinafter, collectively referred to as "LICENSEE").

WHEREAS, BCM and LICENSEE have entered into that certain agreement effective July 16th, 2012 ("License Agreement") and first amended effective April 26, 2015 ("First Amendment") under which LICENSEE has obtained from BCM and BCM has granted to LICENSEE a certain exclusive license to the Patent Rights and Subject Technology as defined in said License Agreement; and

WHEREAS, a previous licensee, StemMed Limited Partnership, assigned the License Agreement to LICENSEE on January 24, 2018 and the Parties updated the LICENSEE contact information; and

WHEREAS, BCM and LICENSEE desire to amend said License Agreement as provided herein.

NOW, THEREFORE, in consideration of the mutual provisions and covenants contained herein, BCM and LICENSEE hereby agree as follows:

The terms in the License Agreement shall have the same meanings in this Second Amendment.

Paragraph 3 is hereby amended and shall read as follows:

3. DILIGENCE

LICENSEE shall use reasonable efforts, as defined herein, to introduce Licensed Products into the commercial market as soon as practicable. Such efforts shall include, but not be limited to: Developmental events to be achieved by LICENSEE or its sublicensee:

- a. [***] or payment of [***];
- b. [***] or payment of [***];
- c. [***] or payment of [***];
- d. [***] or payment of [***]; and
- e. [***].

Paragraph 4.6 is hereby amended and shall read as follows:

<u>4.6 Payment Addresses</u>. Payments sent by check are to be made payable to "Baylor College of Medicine" and shall be sent to the address below. If payments are sent by wire transfer, they shall be sent using wiring instructions provided in Appendix D. All payments shall reference **BLG number(s)** [***], [***], **and/or** [***] listed on the front page of the Agreement.

[***] [***] Baylor College of Medicine Licensing Group [***] [***]]

Telephone No.[***]Facsimile No.[***]E-Mail[***]

Payments shall be deemed received only upon confirmation that all funds have been received by the LICENSING GROUP as referenced above. LICENSEE hereby accepts responsibility for ensuring that payment is addressed correctly.

Licensee Payment Contact. For questions about payments, BCM can contact LICENSEE at the address below:

[***] [***] Tel: [***] Email: [***] with copy to [***]

Paragraph 6.2 is hereby amended and shall read as follows:

<u>6.2 Transfer Address and Payment</u>. If additional documents regarding the Subject Technology are requested by LICENSEE, BCM will endeavor to provide Subject Technology via electronic delivery (email) to the address below.

[***] [***] [***] Tel: [***] Email: [***]

Paragraph 15.1 is hereby amended and shall read as follows:

<u>15.1 Addresses for Notices</u>. All notices, reports or other communication pursuant to this Agreement shall be sent to such Party via (i) United States Postal Service postage prepaid, (ii) overnight courier, (iii) facsimile transmission, or (iv) electronic (email) transmission, addressed to it at its address set forth below or as it shall designate by written notice given to the other Party. Notice shall be sufficiently made, or given and received (a) on the date of mailing, (b) when a facsimile printer reflects transmission, or (c) the date of electronic (email) transmission.

```
In the case of BCM:

[***]

[***]

[***]

[***]

[***]

Telephone No. [***]

Facsimile No. [***]

E-Mail [***]

In the case of LICENSEE:

[***]

[***]

[***]

[***]

Tel: [***]

Email: [***]
```

Paragraph 16.2 is hereby amended and shall read as follows:

16.2 Insurance.

LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s), maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***].

LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s) [***], maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***].

LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s) [***], maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***].

Such coverage(s) shall be purchased from a carrier or carriers having an A. M. Best rating of at least [***] and shall name BCM as an additional insured. LICENSEE shall provide to BCM copies of certificates of insurance within [***] after execution of this Agreement. Upon request by BCM, LICENSEE shall provide to BCM copies of said policies of insurance. It is the intention of the Parties hereto that LICENSEE shall, throughout the Term of this Agreement, continuously and without interruption, maintain in force the required insurance coverages set forth in this Paragraph 16.2. Failure of LICENSEE to comply with this requirement shall constitute a default of LICENSEE allowing BCM, at its option, to immediately terminate this Agreement.

BCM reserves the right to reasonably request additional policies of insurance where appropriate and reasonable in light of LICENSEE's business operations and availability of coverage.

Appendix A is hereby amended and shall read as follows:

Appendix A [***]

Except as amended hereby, the License Agreement shall be and remain in full force and effect.

The Second Amendment shall be effective as of the Second Amendment Agreement Date provided above.

[Remainder of page intentionally left blank. Signature page follows.]

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Second Amendment in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the Second Amendment Agreement Date.

TVARDI TERAPEUTICS	BAYLOR COLLEGE OF MEDICINE			
Name: <i>/s/ Imran Alibhai, Ph.D</i> Imran Alibhai, Ph.D.	Name: <i>/s/Adam Kuspa, Ph.D.</i> Adam Kuspa, Ph.D.			
Title: CEO	Title: Senior Vice President and Dean of Research			
Date: <u>9/1/19</u>	Date: 8/28/2019			
	BLG #[***]			
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	-			

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE TVARDI THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO TVARDI THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

EXCLUSIVE LICENSE AGREEMENT

Re: BCM BLG # [***]; NIH# [***]

Entitled "Stat3 inhibition to treat disorders involving mast cell degranulation"

This Exclusive License Agreement (hereinafter called "Agreement"), to be effective as of the 19th day of June, 2015 (hereinafter called "Agreement Date"), is by and between Baylor College of Medicine (hereinafter called "BCM"), a Texas nonprofit organization having its principal place of business at One Baylor Plaza, Houston, Texas 77030, and StemMed Ltd., a corporation organized under the laws of Texas and having a principal place of business at 7000 Fannin St., Houston, Texas 77030, and its Affiliates (hereinafter, collectively referred to as "LICENSEE").

WITNESSETH:

WHEREAS, BCM's mission is to advance human health through the integration of education, research, patient care and community service; and

WHEREAS, BCM and the National Institutes of Health ("NIH") are the owners of the Patent Rights as defined below; and

WHEREAS, BCM and the NIH have jointly develop the invention described in U.S. Provisional Patent Application Serial No. [***], filed [***], entitled "Methods and Compositions for Prevention of Allergic Reaction", which was jointly invented by [***] (hereinafter, individually referred to as an "Inventor" and collectively referred to as "Inventors"); and

WHEREAS, BCM and the NIH have entered into an Interinstitutional Agreement dated [***] ("BCM-NIH IIA") under which NIH grant to BCM an exclusive license for commercialization of the Patent Rights; and

WHEREAS, BCM is willing to grant a royalty bearing, worldwide, exclusive license to the Patent Rights to LICENSEE on the terms set forth herein; and

WHEREAS, LICENSEE desires to obtain said exclusive license under the Patent Rights.

NOW, THEREFORE, for and in consideration of the promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto expressly agree as follows:

1. DEFINITIONS AS USED HEREIN

1.1 The term "Affiliates" shall mean any corporation, partnership, joint venture or other entity which LICENSEE, directly or indirectly, owns or controls by LICENSEE's ownership of at least fifty percent (50%) of the entity's common stock or other ownership.

1.2 The term "Confidential Information" shall mean any proprietary and secret ideas, proprietary technical information, know-how and proprietary commercial information or other similar proprietary information that are owned by BCM. The term "Confidential Information" is further defined in Section 17 below.

- 1.3 "Government" means the government of the United States of America.
- 1.4 The term "Field" shall mean all fields of use.

1.5 The term "Legal Costs" shall mean all legal fees and expenses, filing or maintenance fees, assessments and all other costs and expenses related to prosecuting, obtaining and maintaining patent protection on the Patent Rights in the United States and foreign countries.

1.6 The term "Licensed Product(s)" shall mean any product, process or service that incorporates, utilizes or is made with the use of the Patent Rights.

- 1.7 The term "Net Sales" shall mean [***]:
 - (i) [***];
 - (ii) [***];
 - (iii) [***]; and
 - (iv) [***].

[***]

- 1.8 The term "Party" shall mean either LICENSEE or BCM, and "Parties" shall mean LICENSEE and BCM.
- 1.9 The term "Patent Rights" shall mean:
 - (a) Patent applications (including provisional patent applications and PCT patent applications) or patents as follows: [***], and any patent application(s) claiming the benefit of priority thereof including all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all these patents to the extent that at least one Inventor from the BCM is an Inventor thereon;
 - (b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 1.9(a) and to the extent that [***]:
 - (i) continuations-in-part of 1.9(a);
 - (ii) all divisions and continuations of these continuations-in-part;
 - (iii) all patents issuing from these continuations-in-part, divisions, and continuations;
 - (iv) priority patent application(s) of 1.9(a); and

- (v) any reissues, reexaminations, and extensions of all these patents; and
- (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 1.9(a) and to the extent that [***]: all counterpart foreign and U.S. patent applications and patents to 1.9(a) and 1.9(b); and
- (d) Patent Rights shall not include 1.9(b) or 1.9(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 1.9(a).

1.10 The term "Research License" shall mean nontransferable, nonexclusive license to make and to use any tangible embodiment of the Patent Rights and to practice any process(es) included within the Patent Rights for purposes of internal research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

1.11 The term "Practical Application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or by regulations of the Government, available to the public on reasonable terms.

- 1.12 The term "Sublicensing Revenue" shall mean all [***]
 - (a) [***];
 - (b) [***];
 - (c) [***]; and
 - (d) [***].

2. <u>GRANT OF LICENSE</u>

2.1 License Grant. Subject to the reservations of rights set forth herein, BCM hereby grants to LICENSEE an exclusive, worldwide, sublicensable license under the Patent Rights, to make, have made, use, market, sell, offer to sell, lease and import Licensed Products in the Field.

- 2.2 <u>Restrictions on License</u>. The grant in Section 2.1 shall be further subject to, restricted by and non-exclusive with respect to:
 - (i) the making or use of the Patent Rights by BCM for non-commercial research, patient care, teaching and other educationally related purposes;
 - (ii) the making or use of the Patent Rights by the Inventors for non-commercial research purposes at academic or research institutions;
 - (iii) any non-exclusive license of the Patent Rights that BCM grants to other academic or research institutions for non-commercial research purposes;
 - (iv) the making or use of the Patent Rights by academic and research institutions for non-commercial research purposes; and

- (v) any non-exclusive license of the Patent Rights that BCM is required by law or regulation to grant to the United States of America or to a foreign state pursuant to an existing or future treaty with the United States of America; and
- (vi) any Research License of the Patent Rights that BCM is required by the NIH to grant to a third-party. The purpose of these Research Licenses is to encourage basic research, whether conducted at an academic or corporate facility.

2.3 <u>Government Reservation</u>. Rights under this Agreement are subject to rights required to be granted to the Government pursuant to 35 USC Section 200-212, including a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the Patent Rights throughout the world.

3. <u>DILIGENCE</u>

LICENSEE shall use reasonable efforts, as defined herein, to introduce Licensed Products into the commercial market as soon as practicable. Such efforts shall include, but not be limited to: Developmental events to be achieved by LICENSEE or its sublicensee:

- (a) [***] or payment of [***];
- (b) [***] or payment of [***];
- (c) [***] or payment of [***];
- (d) [***]

4. <u>PAYMENTS</u>

4.1 <u>License Execution Fee.</u> As partial consideration for the rights conveyed by BCM under this Agreement, LICENSEE shall pay BCM a non-refundable license fee of Five Thousand Dollars (\$5,000). Such payment shall be due upon [***] and delivered to BCM in accordance with the invoice instructions provided below.

4.2 <u>Annual Maintenance Fee:</u> Thirty Thousand Dollars (\$30,000), beginning on the [***] of the Agreement, and increasing to Fifty Thousand Dollars (\$50,000) on the [***] of the Agreement and thereafter until the introduction of a licensed product.

4.3 <u>Responsibility for Legal Costs.</u> In addition to the foregoing license execution fee, LICENSEE shall reimburse BCM for all Legal Costs incurred prior to execution of this Agreement. Such payment shall be due within [***] days of receipt of invoice from BCM. As provided for in Paragraph 9.1 herein, LICENSEE will be responsible for all Legal Costs incurred after the Agreement Date.

4.4 <u>Royalty on Net Sales.</u> In addition to the foregoing, LICENSEE shall pay BCM a non-reducible royalty of [***] of Net Sales by LICENSEE, its Affiliates, or sublicensees. Collectively the royalty payments that are the subject of this Paragraph 4.3 are termed "Royalties" for purposes of this Agreement and shall be due and payable as provided in Section 5 and delivered to BCM in accordance with the invoice instructions provided below.

4.5 <u>Milestone Payments.</u> LICENSEE shall also pay BCM the following milestone payments set forth below:

- (a) Investigational New Drug Filing of a first Licensed Product: \$50,000 USD
- (b) [***]: [***]
- (c) [***]: [***]
- (d) [***]: [***]

LICENSEE shall notify BCM in writing within [***] upon the achievement of each milestone, such notice to be accompanied by payment of the appropriate milestone payment. Milestones are to be paid regardless of whether LICENSEE or LICENSEE's sublicensee attains such milestone.

4.6 <u>Sublicense Revenue Payments.</u> LICENSEE shall have the right to sublicense the Patent Rights. In the event LICENSEE sublicenses the Patent Rights under this Agreement, LICENSEE agrees to pay to BCM the following percentages of all Sublicensing Revenue received by LICENSEE:

- (a) [***] of Sublicensing Revenue shall be payable to BCM if the sublicense agreement is [***] within [***] of the Agreement Date.
- (b) [***] of sublicense revenue shall be payable to BCM if the sublicense agreement is [***] after the [***] of the Agreement Date.

4.7 <u>Payment Addresses</u>. Payments sent by check are to be made payable to "Baylor College of Medicine" and shall be sent to the address below. If payments are sent by wire transfer, they shall be sent using wiring instructions provided in Appendix B. All payments shall reference BLG number(s) [***] listed on the front page of the Agreement.

[***] Baylor College of Medicine Licensing Group [***] Telephone No. [***] Facsimile No. [***] E-Mail [***]

Payments shall be deemed received only upon confirmation that all funds have been received by the **LICENSING GROUP** as referenced above. LICENSEE hereby accepts responsibility for ensuring that payment is addressed correctly.

Licensee Payment Contact. For questions about payments, BCM can contact LICENSEE at the address below:

[***] Phone: [***] Email: [***] Website: [***]

4.8 <u>Payment Conditions.</u> All payments due hereunder are payable in United States dollars. No transfer, exchange, collection or other charges, **including any wire transfer fees**, shall be deducted from such payments. For sales of Licensed Products in currencies other than the United States, LICENSEE shall use exchange rates [***] that such payment is due.

4.9 <u>Late Payments.</u> Late payments shall be subject to a charge of [***] per month, the interest being [***], or [***], whichever is greater. LICENSEE shall calculate the correct late payment charge, and shall add it to each such late payment. Said late payment charge and the payment and acceptance thereof shall not negate or waive the right of BCM to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment. LICENSEE shall indemnify BCM for all attorneys' fees and costs BCM incurs in obtaining a full payment of that which is owed to BCM.

4.10 <u>Invoice Procedures.</u> Any amounts payable to BCM hereunder shall be made in full within [***] after receipt by LICENSEE of an invoice covering such payment. The Parties understand and agree that one (1) invoice will be sent to LICENSEE by BCM for each fee due. The invoice shall be in the form in Appendix B. Any additional fees, such as taxes, wire or transfer fees, will not be included in the invoice, but payment of such fees shall remain the responsibility of LICENSEE and shall not be deducted from the payment due BCM. Subsequent invoices, if requested by LICENSEE, shall be subject to an administrative fee of [***], in addition to the original payment due to BCM plus any interest charges incurred due to delays in payment, if applicable. The calculation and payment of such interest payments shall not be invoiced and shall be the sole responsibility of the LICENSEE. Invoices shall be sent electronically or via facsimile to the address listed above.

5. <u>REPORTING</u>

5.1 <u>Annual Progress Report.</u> No later than [***] after [***], LICENSEE shall provide to BCM a written annual progress report describing progress on all research and development and commercial activities, during the most recent twelve (12) month period ending [***] and plans for the forthcoming year ("Annual Progress Report"). If multiple technologies are covered by the license granted hereunder, the progress report shall provide the information set forth above for each technology. At BCM's request, LICENSEE shall also provide any reasonable additional data BCM requires to evaluate LICENSEE'S or its sublicense performance.

5.2 <u>Notification of First Sale.</u> LICENSEE shall notify BCM the date on which LICENSEE and the sublicensees make a first sale of Licensed Products in each country in which it occurs within [***] of occurrence.

5.3 <u>Royalty reports.</u> LICENSEE shall submit to BCM within [***] after [***], a written report on a form provided by BCM (a current version of which is attached as <u>Appendix A</u>) setting forth for such [***] at least the following information:

(i) [***]

The royalty report shall be certified as correct by an officer of LICENSEE. After termination or expiration of this Agreement, LICENSEE will continue to submit royalty reports and payments to BCM until all Licensed Products made, used, marketed, leased or imported under the Agreement have been sold.

5.4 <u>Payment to Accompany Royalty Reports.</u> LICENSEE shall pay to BCM with each such royalty report the amount of Royalties and other payments due with respect to such [***]. If multiple technologies are covered by the license granted hereunder, LICENSEE shall specify which Patent Rights are utilized for each Licensed Product included in the royalty report by citing the applicable BLG number listed on the front page of the Agreement.

5.5 <u>Notification of Merger or Acquisition.</u> In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, LICENSEE shall notify BCM in writing within [***] of such event.

5.6 <u>Entity Status.</u> If LICENSEE or sublicensee does not qualify as a "small entity" as provided by the United States Patent and Trademark Office, LICENSEE must notify BCM immediately.

6. PROVISION OF LICENSED PRODUCTS TO THE NIH

At the NIH's request, LICENSEE shall reasonably supply, subject to availability, to the mailing address indicated below, the Office of Technology Transfer, NIH with inert samples of the licensed products or licensed processes, as covered by the Patent Rights, or their packaging for educational and display purposes only.

The NIH's mailing address:

[***]

7. <u>RECORDS AND INSPECTION</u>

7.1 <u>Accounting Records.</u> LICENSEE shall maintain, and shall cause its sublicensees to maintain, complete and accurate records relating to the rights and obligations under this Agreement and any amounts payable to BCM in relation to this Agreement, which records shall contain sufficient information to permit BCM to confirm the accuracy of any reports delivered to BCM and compliance in other respects with this Agreement. The relevant party shall retain such records for at least [***] to which they pertain.

7.2 <u>Audit by BCM.</u> During the Term of this Agreement as defined below and for a period of [***] thereafter, BCM or its representatives shall have the right to inspect the books and records of LICENSEE in conjunction with the performance of LICENSEE's obligations under the terms and conditions of this Agreement upon reasonable written notice. The scope of such audit and inspection activities may include the review of records supporting activities performed by LICENSEE in conjunction with its obligations under this Agreement[***]. LICENSEE agrees to provide representatives of BCM reasonable access to books, records[***], and shall cooperate fully with BCM's representatives in support of their inspection and audit activities during LICENSEE's normal business hours.

7.3 <u>Payment Deficiency</u>. If a payment deficiency is determined, LICENSEE and its sublicensee(s), as applicable, shall pay the outstanding amounts within [***] of receiving written notice thereof, plus interest on such outstanding amounts as described in Section 5.

7.4 <u>Responsibility for Audit Costs.</u> BCM will pay for any audit done under Paragraph 7.2. However, in the event that the audit reveals an underpayment of Royalties or fees by more than [***] for the period being audited, the cost of the audit shall be paid by LICENSEE. If the underpayment is less than [***] but more than [***] for the period being audited, [***] of the cost of the audit. LICENSEE shall indemnify BCM for all attorneys' fees and costs BCM incurs in obtaining access to conduct the audit and collecting, when applicable, for the cost of the audit and any underpaid amounts and interest.

8. <u>SUBLICENSES</u>

8.1 <u>Sublicense Provisions.</u> All sublicenses granted by LICENSEE of its rights hereunder shall be subject to the terms of this Agreement. LICENSEE shall be responsible for its sublicensees and shall not grant any rights which are inconsistent with the rights granted to and obligations of LICENSEE hereunder. Any act or omission of a sublicensee which would be a breach of this Agreement if performed by LICENSEE shall be deemed to be a breach by LICENSEE of this Agreement. [***]

8.2 <u>Required Sublicensing.</u> LICENSEE may be required by the NM to grant sublicenses to responsible applicants, on terms that are reasonable under the circumstances when necessary to fulfill health or safety needs or when necessary to meet requirements for public use specified by Federal regulations. LICENSEE will, at the NIH's request, negotiate in good faith a sublicense with any such sublicensee.

9. <u>PATENTS AND INFRINGEMENT</u>

9.1 <u>Patent Prosecution Responsibility.</u> For the Term of this Agreement as defined below, BCM shall be responsible for filing, prosecuting and maintaining all patent applications and patents included in the Patent Rights, and LICENSEE agrees to pay all Legal Costs. BCM shall select all outside counsel for prosecution of the Patent Rights and such counsel shall represent BCM in such prosecution BCM shall instruct its patent counsel to invoice LICENSEE directly for all such Legal Costs. LICENSEE agrees to pay all such invoices within [***] of receipt.

9.2 Notification of Intent Not to Pursue. In the event that LICENSEE decides not to pay for the costs associated with either: (i) the prosecution of the Patent Rights to issuance or (ii) maintenance of any United States or foreign issued patent on the Patent Rights, LICENSEE shall timely notify BCM in writing thereof LICENSEE's right under this Agreement to practice the invention under this patent shall immediately terminate upon the giving of such notice. If LICENSEE fails to notify BCM in sufficient time for BCM to assume said costs prior to the abandonment or expiration of any Patent Rights, LICENSEE shall be considered in default of this Agreement.

9.3 <u>Notification of Patent Prosecution Action.</u> BCM agrees to keep LICENSEE fully informed, at LICENSEE's expense, of all prosecutions and other actions pursuant to this Section 9, including submitting to LICENSEE copies of all official actions and responses thereto.

9.4 <u>Cooperation.</u> BCM agrees to reasonably cooperate with LICENSEE to whatever extent is reasonably necessary to provide LICENSEE the full benefit of the license granted herein.

- 9.5 Infringement Procedures.
 - (i) In the event the NIH, BCM, including its LICENSEE, shall learn of the substantial infringement of any patent subject to this Agreement, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The BCM and LICENSEE, in cooperation with the NIH, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within [***] after the infringer has been formally notified of the infringement by the BCM, the BCM shall have the right, after consulting with the NIH, to commence suit on its own account. The NIH may join the BCM's suit or commence its own suit.
 - (ii) The BCM may permit LICENSEE to bring suit on their own account, but only if the NIH and the BCM elect not to commence separately or join each other in any suit, other than as nominal party plaintiff, either by formal notice or by failure to act within the [***] period set forth in Paragraph 9.5(i). The NIH shall retain the right to join any LICENSEE's suit.
 - (iii) Neither LICENSEE nor the BCM shall take action to compel the NIH either to initiate or to join in any suit for patent infringement. Should the Government be made a party to any suit by motion or any other action of LICENSEE or the BCM, [***].

- (iv) Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 9.5(i) shall be [***]. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages [***].
- (v) Each party agrees to cooperate with the other in litigation proceedings. The NIH may be represented, at its expense, by counsel of its choice in any suit.

10. <u>TERM</u>

Unless sooner terminated as otherwise provided in Section 11, the license to employ Patent Rights granted herein as part of Section 2 shall expire on a country-by-country basis, on the later of (i) the date of expiration of the last of the Patent Rights to expire or (ii) in the event no patents included within the Patent Rights issue in such country, the first date following the tenth (10th) anniversary of the first commercial sale of Licensed Products by LICENSEE in such country ("Term"). After such expiration, but not termination, LICENSEE shall have a perpetual, paid-in-full (i.e., royalty free) license in such country.

11. TERMINATION

11.1 <u>Termination for Default.</u> In the event of default or failure by LICENSEE to perform any of the terms, covenants or provisions of this Agreement, including failure to make timely payment, LICENSEE shall have [***] after the giving of written notice of such default by BCM to correct such default. If such default is not corrected within the said [***] period, BCM shall have the right, at its option, to cancel and terminate this Agreement. The failure of BCM to exercise such right of termination, for non-payment of Royalties/ fees or otherwise, shall not be deemed to be a waiver of any right BCM might have, nor shall such failure preclude BCM from exercising or enforcing said right upon any subsequent failure by LICENSEE.

11.2 <u>Termination for Insolvency</u>. BCM shall have the right, at its option, to cancel and terminate this Agreement in the event that LICENSEE shall (i) become involved in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of its business or (ii) make an assignment of all or substantially all of its assets for the benefit of creditors, or in the event that (iii) a receiver or trustee is appointed for LICENSEE and LICENSEE shall, after the expiration of [***] following any of the events enumerated above, have been unable to secure a dismissal, stay or other suspension of such proceedings.

11.3 <u>Termination by Licensee.</u> LICENSEE shall have the right in its sole discretion to terminate this Agreement upon [***] written notice to BCM.

11.4 <u>Effect of Termination</u>. In the event of termination of this Agreement, all rights to the Patent Rights shall revert to BCM. At the date of any termination of this Agreement, LICENSEE shall immediately cease using any of the Patent Rights; provided, however, that LICENSEE may sell any Licensed Products actually in the possession of LICENSEE on the date of termination, provided that LICENSEE continues to submit royalty reports to BCM and pays to BCM the Royalties on all such sales in accordance with Paragraph 5.3 with respect thereto and otherwise complying with the terms of this Agreement.

11.5 <u>Effect of Termination on Sublicensees</u>. LICENSEE shall provide, in all sublicenses granted by it under this Agreement, that LICENSEE'S interest in such sublicenses shall, at BCM's option, terminate or be assigned to BCM upon termination of this Agreement.

11.6 <u>No Refund.</u> In the event this Agreement is terminated pursuant to this Section 11, or expires as provided for in Section 10, BCM is under no obligation to refund any payments made by LICENSEE to BCM prior to the effective date of such termination or expiration.

11.7 <u>Survival of Termination</u>. No termination of this Agreement shall constitute a termination or a waiver of any rights of either Party against the other Party accruing at or prior to the time of such termination. The obligations of Sections 4, 5, 7, 11, 13, 14, 15, 16, 17 and 18 shall survive termination of this Agreement.

11.8 <u>Termination by the NIH.</u> Notwithstand the foregoing, LICENSEE hereby acknowledges and agrees that the NIH may terminate the BCM-NIH IIA when:

- (a) it is determined by the NIH's Office of Technology Transfer that:
 - (i) LICENSEE has not taken and is not expected to take effective steps to achieve Practical Application of the Patent Rights;
 - (ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by LICENSEE;
 - (iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by LICENSEE; or
 - (iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the Patent Rights in the United States is in breach of its agreement obtained pursuant to 35 U.S.C. §204;
- (b) LICENSEE has been notified of this determination and has been given at least [***] to provide a response to this determination, and
- (c) LICENSEE's response to the determination of 11.8(a)(i)-(iv) is determined to be unsatisfactory by the NIH's Office of Technology Transfer.

Following termination by the NIH, the NIH shall have no further rights or obligations under the BCM-NIH IIA, and if such termination occurs, Patent Rights under the Agreement shall be limited to BCM's own rights.

12. <u>ASSIGNABILITY</u>

Without the prior written approval of BCM, which will not be unreasonably withheld, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by LICENSEE to any person or entity whether voluntarily or involuntarily, by operation of law or otherwise. Notwithstanding the foregoing, LICENSEE may assign this Agreement and its rights and obligations hereunder without BCM's consent, (i) in connection with the transfer or sale of all or substantially all of its assets or the business of LICENSEE to which this Agreement relates or (ii) to any Affiliate; so long as LICENSEE gives BCM prompt notice of such action and the successor entity or Affiliate, as the case may be, acknowledges its consent and agreement to the terms of this Agreement in writing before such assignment; and so long as such action is not entered into solely to satisfy creditors of LICENSEE. This Agreement shall be binding upon and shall inure to the benefit of the respective successors, legal representatives and assignees of each of the Parties.

13. GOVERNMENTAL COMPLIANCE

13.1 <u>Compliance with Applicable Laws.</u> LICENSEE shall at all times during the Term of this Agreement and for so long as it shall use the Patent Rights, or sell Licensed Products, comply and cause its sublicensees to comply with all laws that may control the import, export, manufacture, use, sale, marketing, distribution and other commercial exploitation of the Patent Rights, Licensed Products or any other activity undertaken pursuant to this Agreement.

13.2 <u>Requirement for U.S. Manufacture</u>. LICENSEE agrees that Licensed Products leased or sold in the United States shall be manufactured substantially in the United States. However, LICENSEE may request an exception to this requirement and if it is able to secure an appropriate waiver or release from this requirement that Licensed Products leased or sold in the United States shall be manufactured substantially in the United States, LICENSEE will be released from this requirement. BCM shall reasonably cooperate with LICENSEE's efforts to obtain an appropriate waiver or release from any requirement that Licensed Products leased or sold in the United States shall be manufactured substantially in the United States.

13.3 <u>Export Control Regulations.</u> The Patent Rights and Licensed Products are subject to, and LICENSEE agrees to comply in all respects with, U.S. law including but not limited to U.S. export controls under the Export Administration Regulations (15 C.F.R. Part 734 et seq.) and U.S. economic sanctions and embargoes codified in 31 C.F.R. Chapter V. LICENSEE agrees that LICENSEE bears sole responsibility for understanding and complying with current U.S. trade controls laws and regulations as applicable to its activities subject to this Agreement. Without limitation on the general agreement to comply set forth in the first sentence of this Paragraph 13.3, LICENSEE agrees not to sell any goods, services, or technologies subject to this Agreement, or to release or disclose or re-export the same: (i) to any destination prohibited by U.S. law, including any destination subject to U.S. economic embargo; (ii) to any end-user prohibited by U.S. law, including any person or entity listed on the U.S. government's Specially Designated Nationals list, Denied Parties List, Debarred Persons List, Unverified List, or Entities List; (iii) to any foreign national in the U.S. or abroad without prior license if required; or (iv) to any user, for any use, or to any destination without prior license if required. Furthermore, LICENSEE agrees that any transfer of Patent Rights from BCM to LICENSEE under this Agreement is subject to U.S. export license authorization as may be required under U.S. law.

14. DISPUTE RESOLUTION

14.1 <u>Amicable Resolution</u>. The Parties shall attempt to settle any controversy between them amicably. To this end, a senior executive from each Party shall consult and negotiate to reach a solution. The Parties agree that the period of amicable resolution shall toll any otherwise applicable statute of limitations.

14.2 <u>Failure to Amicably Resolve.</u> If the senior executives from each Party fail to meet or if the matter remains unresolved for a period of [***], then the parties hereby irrevocably submit to mandatory mediation, then the jurisdiction of a court of competent jurisdiction in the State of Texas, and, by execution and delivery of this Agreement, each (a) accepts, generally and unconditionally, the jurisdiction of such court and any related appellate court and (b) irrevocably waives any objection it may now or hereafter have as to the venue of any such suit, action or proceeding brought in such court or that such court is an inconvenient forum.

14.3 <u>Construction and Jurisdiction</u>. This Agreement shall be deemed to be subject to, and have been made under, and shall be construed and interpreted in accordance with the laws of the State of Texas. No conflict-of-laws rule or law that might refer such construction and interpretation to the laws of another state, republic, or country shall be considered. This Agreement is performable in part in Harris County, Texas, and the Parties mutually agree that personal jurisdiction and venue shall be proper in the state and federal courts situated in Harris County, Texas, and agree that any litigated dispute will be conducted solely in such courts.

15. NOTICES

15.1 <u>Addresses for Notices.</u> All notices, reports or other communication pursuant to this Agreement shall be sent to such Party via (i) United States Postal Service postage prepaid, (ii) overnight courier, or (iii) facsimile transmission, addressed to it at its address set forth below or as it shall designate by written notice given to the other Party. Notice shall be sufficiently made, or given and received (a) on the date of mailing or (b) when a facsimile printer reflects transmission.

In the case of BCM: [***] Telephone No. [***] Facsimile No. [***] E-Mail [***]

In the case of LICENSEE:

[***] Phone: [***] Email: [***] Website: <u>[***</u>]

15.2 <u>Use of Reference Number</u>. Each such report, notice or other communication shall include BLG number(s) [***] listed on the front page of the Agreement.

16. INDEMNITY. INSURANCE & WARRANTIES

- 16.1 INDEMNITY.
 - EACH PARTY SHALL NOTIFY THE OTHER OF ANY CLAIM, LAWSUIT OR OTHER PROCEEDING RELATED (i) TO THE PATENT RIGHTS. LICENSEE AGREES THAT IT WILL DEFEND, INDEMNIFY AND HOLD HARMLESS BCM AND THE NIH, ITS FACULTY MEMBERS, SCIENTISTS, RESEARCHERS, EMPLOYEES, STUDENTS, OFFICERS, TRUSTEES AND AGENTS AND EACH OF THEM (THE "INDEMNIFIED PARTIES"), FROM AND AGAINST ANY AND ALL CLAIMS, CAUSES OF ACTION, LAWSUITS OR OTHER PROCEEDINGS (THE "BCM CLAIMS") FILED OR OTHERWISE INSTITUTED AGAINST ANY OF THE INDEMNIFIED PARTIES RELATED DIRECTLY OR INDIRECTLY TO OR ARISING OUT OF THE DESIGN, PROCESS, MANUFACTURE OR USE BY ANY PERSON OR PARTY OF THE PATENT RIGHTS, LICENSED PRODUCTS OR ANY OTHER EMBODIMENT OF THE PATENT RIGHTS EVEN THOUGH SUCH BCM CLAIMS AND THE COSTS (INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE) RELATED THERETO RESULT IN WHOLE OR IN PART FROM THE NEGLIGENCE OF ANY OF THE INDEMNIFIED PARTIES OR ARE BASED UPON DOCTRINES OF STRICT LIABILITY OR PRODUCT LIABILITY; PROVIDED, HOWEVER, THAT SUCH INDEMNITY SHALL NOT APPLY TO ANY BCM CLAIMS ARISING FROM THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF ANY INDEMNIFIED PARTY. LICENSEE WILL ALSO ASSUME RESPONSIBILITY FOR ALL COSTS AND EXPENSES RELATED TO SUCH BCM CLAIMS FOR WHICH IT IS OBLIGATED TO INDEMNIFY THE INDEMNIFIED PARTIES PURSUANT TO THIS PARAGRAPH 16.1, INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE.



(ii) LICENSEE FURTHER AGREES NOT TO SETTLE ANY CLAIM AGAINST AN INDEMNIFIED PARTY WITHOUT THE INDEMNIFIED PARTY'S WRITTEN CONSENT WHICH CONSENT SHALL NOT BE UNREASONABLY WITHHELD. LICENSEE FURTHER AGREES TO KEEP THE INDEMNIFIED PARTIES FULLY APPRISED OF THE BCM CLAIMS.

16.2 Insurance.

- LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s), maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of [***].
- (ii) LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s) [***], maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of [***].
- (iii) LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s) [***], maintain in full force and effect policies of (a) worker's compensation insurance within, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of [***].

- (iv) Such coverage(s) shall be purchased from a carrier or carriers having an A. M. Best rating of at least [***] and shall name BCM as an additional insured. LICENSEE shall provide to BCM copies of certificates of insurance within [***] after execution of this Agreement. Upon request by BCM, LICENSEE shall provide to BCM copies of said policies of insurance. It is the intention of the Parties hereto that LICENSEE shall, throughout the Term of this Agreement, continuously and without interruption, maintain in force the required insurance coverages set forth in this Paragraph 16.2. Failure of LICENSEE to comply with this requirement shall constitute a default of LICENSEE allowing BCM, at its option, to immediately terminate this Agreement.
- (v) BCM reserves the right to reasonably request additional policies of insurance where appropriate and reasonable in light of LICENSEE'S business operations and availability of coverage.

16.3 DISCLAIMER OF WARRANTY. BCM AND THE NIH MAKES NO WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF FITNESS OR MERCHANTABILITY, REGARDING OR WITH RESPECT TO THE PATENT RIGHTS OR LICENSED PRODUCTS AND BCM AND THE NIH MAKES NO WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, OF THE PATENTABILITY OF THE PATENT RIGHTS OR LICENSED PRODUCTS OR OF THE ENFORCEABILITY OF ANY PATENTS ISSUING THEREUPON, IF ANY, OR THAT THE PATENT RIGHTS OR LICENSED PRODUCTS ARE OR SHALL BE FREE FROM INFRINGEMENT OF ANY PATENT OR OTHER RIGHTS OF THIRD PARTIES. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS UNDER ANY PATENTS OF BCM OTHER THAN THE PATENT RIGHTS, REGARDLESS OF WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS.

17. CONFIDENTIALITY

17.1 <u>Scope.</u> LICENSEE shall not, directly or indirectly, divulge or reveal to any person or entity the Confidential Information of BCM without BCM's prior written consent or use such Confidential Information except as permitted hereunder. LICENSEE shall maintain the Patent Rights in strictest confidence and use the same only in accordance with this Agreement. Employees, agents or subcontractors of LICENSEE shall be given access to the Confidential Information only on a legitimate "need to know" basis and after agreeing to be bound in writing to not divulge or reveal the Confidential Information. The public disclosure with the permission of BCM of any one component of that which was identified as or constituted the Confidential Information of BCM shall not prevent the other components from retaining their status as Confidential Information and the property of BCM. Confidential Information shall include any and all information that is produced or results from the disclosure of Confidential Information by BCM to LICENSEE and its sublicensees during the course of the relationship that is the subject of this Agreement.

17.2 <u>Exclusion</u>. Such obligation of confidentiality shall not apply to information which LICENSEE can demonstrate: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no fault of LICENSEE; (iii) was known to LICENSEE prior to disclosure thereof by BCM; (iv) was lawfully disclosed to LICENSEE by a third party which was not under an obligation of confidence to BCM with respect thereto; (v) LICENSEE was compelled to disclose by law or legal process; or (vi) was approved for public release by prior written permission of BCM.

17.3 <u>Court Order</u>. LICENSEE may make disclosures of Confidential Information required by a Court Order, provided LICENSEE first gives a timely opportunity to BCM to participate in the proceeding to the extent that the proceeding permits such participation.

17.4 <u>Confidentiality of Agreement</u>. Unless otherwise provided for in this Agreement, the Parties agree that this Agreement and its terms are to be considered Confidential Information and shall be treated as such. Notwithstanding the foregoing, BCM may disclose this Agreement and its terms to the NIH.

18. ADDITIONAL PROVISIONS

18.1 <u>Use of BCM and the NIH Name.</u> LICENSEE agrees that it shall not use in any way the name of "Baylor College of Medicine", "National Institutes of Health" or any logotypes or symbols associated with BCM or the NIH, respectively, or the names of any of the scientists or other researchers at BCM and/or the NIH without the prior written consent of BCM and/or the NIH.

18.2 <u>Marking of Licensed Products.</u> To the extent commercially feasible and consistent with prevailing business practices, LICENSEE shall mark, and shall cause its sublicensees to mark, all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent under the Patent Rights that applies to such Licensed Product.

18.3 <u>BCM and the NIH's Disclaimers.</u> Neither BCM, or the NIH, nor any of their faculty members, scientists, researchers, employees, students, officers, trustees or agents assume any responsibility for the manufacture, product specifications, sale or use of the Patent Rights or Licensed Products which are manufactured by or sold by LICENSEE.

18.4 <u>Independent Contractors.</u> The Parties hereby acknowledge and agree that each is an independent contractor and that neither Party shall be considered to be the agent, representative, master or servant of the other Party for any purpose whatsoever, and that neither Party has any authority to enter into a contract, to assume any obligation or to give warranties or representations on behalf of the other Party. Nothing in this relationship shall be construed to create a relationship of joint venture, partnership, fiduciary or other similar relationship between the Parties.

18.5 <u>Non-Waiver</u>. The Parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

18.6 <u>Reformation</u>. The Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries, and that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the Parties hereto, in a final, unappealable order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto. In lieu of such inoperative words, sentences, paragraphs or clauses, or combination of clauses, there will be added automatically as part of this Agreement, a valid, enforceable and operative provision as close to the original language as may be possible which preserves the economic benefits to the Parties.

18.7 <u>Force Majeure</u>. No liability hereunder shall result to a Party by reason of delay in performance caused by force majeure, that is circumstances beyond the reasonable control of the Party, including, without limitation, acts of God, fire, flood, war, terrorism, civil unrest, labor unrest, or shortage of or inability to obtain material or equipment.

18.8 <u>Section and Paragraph Headings</u>. The section and paragraph headings used in this Agreement are intended for purposes of reference and convenience only, and shall not factor into any interpretation of the Agreement.

18.9 <u>Entire Agreement.</u> The terms and conditions herein constitute the entire agreement between the Parties and shall supersede all previous agreements, whether electronic, oral or written, between the Parties hereto with respect to the subject matter hereof. No agreement of understanding bearing on this Agreement shall be binding upon either Party hereto unless it shall be in writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement. Electronic communication between the Parties shall not constitute an agreement of understanding, unless it is subsequently reduced to writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement.

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the Agreement Date.

LICENSEE		BAYLOR COLLEGE OF MEDICINE			
Signature: /s/ David Tweardy		Signature: /s/ Adam Kuspa, Ph.D.			
Name:	David Tweardy	Name:	Adam Kuspa, Ph.D.		
Title:	President & CEO	Title:	Senior Vice President and Dean of Research		
Date:	6/19/15	Date:	6/11/15		
	1	7			

Appendix A Royalty Report [***]

STEMMED, LTD. 7000 Fannin Street Suite 1960M Houston, TX 77030

February 22, 2018

Baylor College of Medicine Attn: Patrick Turley Associate General Counsel One Baylor Plaza, BC210-600D Houston, Texas 77030

Re: <u>Notice of Assignment regarding Exclusive License Agreement, dated</u> June 19, 2015, by and between Baylor College of Medicine and StemMed, Ltd. (BLG # 14-014; NIH # A-346-2014)

Dear Mr. Turley:

Reference is hereby made to that certain Exclusive License Agreement, dated June 19, 2015, by and between Baylor College of Medicine and StemMed, Ltd. ("StemMed") (the "License Agreement"). StemMed has assigned the License Agreement to Tvardi Therapeutics, Inc. ("Tvardi") in connection with the transfer to Tvardi of all or substantially all of the assets and business to which the License Agreement relates. Accordingly, acting in accordance with Section 12 of the License Agreement, we hereby provide you notice of the assignment of the License Agreement from StemMed to Tvardi and we confirm that in connection with such transfer, Tvardi has acknowledged its consent and agreement to the terms of the License Agreement.

Please indicate your acknowledgment of receipt of this notice of assignment by executing the acknowledgment below, e-mailing a copy of the signed letter to the attention of Andrea Sorrentino at Andrea.Sorrentino@wilmerhale.com or returning an original copy of the signed letter via U.S. mail to our attention at StemMed, Ltd., 7000 Fannin Street, Suite 1960M, Houston, Texas 77030.

If you have any questions regarding the information in this letter, please do not hesitate to contact us. We would appreciate your response as soon as possible. Thank you for your assistance and cooperation.

Very truly yours,

STEMMED, LTD.

By: StemMed Holdings, LLC, as the General Partner of StemMed, Ltd.

/s/ David J. Tweardy By: David J. Tweardy, Manager

Acknowledged and accepted as of date first written above:

BAYLOR COLLEGE OF MEDICINE

By: /s/ Michael B Dilling

Name:Michael B DillingTitle:Director, Baylor Licensing Group

FIRST AMENDMENT TO LICENSE AGREEMENT

This First Amendment (hereinafter called "the First Amendment") to the License Agreement, as defined below, to be effective as of the 18th day of June, 2019 (hereinafter called "First Amendment Agreement Date"), is by and between Baylor College of Medicine (hereinafter called "BCM"), a Texas nonprofit corporation having its principal place of business at One Baylor Plaza, Houston, Texas 77030, and Tvardi Therapeutics, a corporation organized under the laws of Texas and having a principal place of business at 2450 Holcombe Blvd, Suite X, Houston, TX, 77021, and its Affiliates (hereinafter, collectively referred to as "LICENSEE").

WHEREAS, BCM and LICENSEE have entered into that certain agreement effective June 19, 2015 ("License Agreement") under which LICENSEE has obtained from BCM and BCM has granted to LICENSEE a certain exclusive license to the Patent Rights and Subject Technology as defined in said License Agreement; and

WHEREAS, a previous licensee, StemMed Limited Partnership, assigned the License Agreement to LICENSEE on February 22, 2018 and the Parties updated the LICENSEE contact information; and

WHEREAS, BCM and LICENSEE desire to amend said License Agreement as provided herein.

NOW, THEREFORE, in consideration of the mutual provisions and covenants contained herein, BCM and LICENSEE hereby agree as follows:

The terms in the License Agreement shall have the same meanings in this First Amendment.

Paragraph 3 is hereby amended and shall read as follows:

3. DILIGENCE

LICENSEE shall use reasonable efforts, as defined herein, to introduce Licensed Products into the commercial market as soon as practicable. Such efforts shall include, but not be limited to: Developmental events to be achieved by LICENSEE or its sublicensee:

[***] of payment of [***]; [***] or payment of [***]; [***] or payment of [***];

[***].

For clarity, the Parties agree that [***].

Paragraph 4.7 is hereby amended and shall read as follows:

<u>4.7 Payment Addresses</u>. Payments sent by check are to be made payable to "Baylor College of Medicine" and shall be sent to the address below. If payments are sent by wire transfer, they shall be sent using wiring instructions provided in Appendix D. All payments shall reference **BLG number(s)** [***] listed on the front page of the Agreement.

[***] Baylor College of Medicine Licensing Group [***] Telephone No. [***]

Facsimile No. [***] E-Mail [***]

Payments shall be deemed received only upon confirmation that all funds have been received by the LICENSING GROUP as referenced above. LICENSEE hereby accepts responsibility for ensuring that payment is addressed correctly.

Licensee Payment Contact. For questions about payments, BCM can contact LICENSEE at the address below:

[***] Tel: [***] Email: [***]

Paragraph 15.1 is hereby amended and shall read as follows:

<u>15.1 Addresses for Notices</u>. All notices, reports or other communication pursuant to this Agreement shall be sent to such Party via (i) United States Postal Service postage prepaid, (ii) overnight courier, (iii) facsimile transmission, or (iv) electronic (email) transmission, addressed to it at its address set forth below or as it shall designate by written notice given to the other Party. Notice shall be sufficiently made, or given and received (a) on the date of mailing, (b) when a facsimile printer reflects transmission, or (c) the date of electronic (email) transmission.

In the case of BCM:

[***]

```
Telephone No. [***]
Facsimile No. [***]
Email: [***]
```

In the case of LICENSEE:

[***] Tel: [***] Email: [***]

Paragraph 16.2 is hereby amended and shall read as follows:

16.2 Insurance.

(i) LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s), maintain in full force and effect policies of
(a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence,
(c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of [***].

(ii) LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s) [***], maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of [***].

(iii) LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s) [***], maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than [***] per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than [***] per occurrence with an annual aggregate of [***] and (d) products liability insurance, with limits of not less than [***] per occurrence with an annual aggregate of [***].

(iv) Such coverage(s) shall be purchased from a carrier or carriers having an A. M. Best rating of at least [***] and shall name BCM as an additional insured. LICENSEE shall provide to BCM copies of certificates of insurance within [***] after execution of this Agreement. Upon request by BCM, LICENSEE shall provide to BCM copies of said policies of insurance. It is the intention of the Parties hereto that LICENSEE shall, throughout the Term of this Agreement, continuously and without interruption, maintain in force the required insurance coverages set forth in this Paragraph 16.2. Failure of LICENSEE to comply with this requirement shall constitute a default of LICENSEE allowing BCM, at its option, to immediately terminate this Agreement.

(v) BCM reserves the right to reasonably request additional policies of insurance where appropriate and reasonable in light of LICENSEE's business operations and availability of coverage.

Except as amended hereby, the License Agreement shall be and remain in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this First Amendment in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the First Amendment Agreement Date.

TVARDI THERAPEUTICS	BAYLOR COLLEGE OF MEDICINE			
Name: /s/ Imran Alibhai Imran Alibhai	Name: /s/ Michael B. Dilling Michael B. Dilling, Ph.D., CLP			
Title: CEO	Title: Executive Director, Baylor Licensing Group			
Date: <u>10/28/19</u>	Date: <u>10-25-2019</u>			
BLG [***]	APPROVED AS TO FORM Office of the General Counsel Baylor College of Medicine By: <u>OV</u>			

SECOND AMENDMENT TO LICENSE AGREEMENT

This Second Amendment (hereinafter called "the Second Amendment") to the License Agreement, as defined below, to be effective as of the 6th day of April, 2023 (hereinafter called "Second Amendment Agreement Date"), is by and between Baylor College of Medicine (hereinafter called "BCM"), a Texas nonprofit corporation having its principal place of business at One Baylor Plaza, Houston, Texas 77030, and Tvardi Therapeutics, Inc. (hereinafter referred to as "LICENSEE"), a corporation organized under the laws of Texas and having a principal place of business at 3 Sugar Creek Center Blvd, Sugar Land, Texas 77478.

WHEREAS, BCM and StemMed Limited Partnership ("StemMed"), a previous licensee, entered into that certain agreement effective June 19, 2015 ("License Agreement") under which StemMed obtained from BCM and BCM granted to StemMed a certain exclusive license to the Patent Rights and Subject Technology as defined as said License Agreement; and

WHEREAS, StemMed assigned the License Agreement to LICENSEE on February 22, 2018 and the Parties updated the LICENSEE contact information; and

WHEREAS, the License Agreement was amended by BCM and LICENSEE pursuant to the First Amendment to License Agreement effective as of the 18th day of June, 2019; and

WHEREAS, BCM and LICENSEE desire to amend further said License Agreement as provided herein.

NOW, THEREFORE, in consideration of the mutual provisions and covenants contained herein, BCM and LICENSEE hereby agree as follows:

The terms in the License Agreement shall have the same meanings in this Second Amendment.

Paragraph 3 is hereby amended and shall read as follows:

3. DILIGENCE

LICENSEE shall use reasonable efforts, as defined herein, to introduce Licensed Products into the commercial market as soon as practicable. Such efforts shall include, but not be limited to: Development events to be achieved by LICENSEE or its sublicensee:

[***], or payment of [***]; [***] or payment of [***]; [***] or payment of [***]; [***].

Paragraph 4.2 is hereby amended and shall read as follows:

<u>Annual Maintenance Fee</u>: Fifty Thousand Dollars (\$50,000), beginning on the first (1st) anniversary of receipt of notice from the United States Patent Office that Tvardi has been granted a patent in respect of TTI-101 for use in the treatment of anaphylaxis and annually thereafter until the introduction of a licensed product.

[***].

Licensee Payment Contact. For questions about payments, BCM can contact LICENSEE at the address below:

[***] Tel: [***] Email: [***]

Paragraph 15.1 is hereby amended and shall read as follows:

<u>15.1 Addresses for Notices</u>. All notices, reports or other communication pursuant to this Agreement shall be sent to such Party via (i) United States Postal Service postage prepaid, (ii) overnight courier, or (iii) electronic (email) transmission, addressed to it at its address set forth below. Notice shall be sufficiently made, given and received (a) on the date of mailing, or (b) on the date of electronic (email) transmission.

In the case of BCM:

[***] Telephone No. [***] Email: [***]

In the case of LICENSEE:

[***] Email: [***]

And to:

[***] Tel: [***] Email: [***]

Except as amended hereby, the License Agreement shall be and remain in full force and effect.

The Second Amendment shall be effective as of the Second Amendment Agreement Date provided above.

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Second Amendment in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the Second Amendment Date.

TVARDI THERAPEUTICS	BAYLOR COLLEGE OF MEDICINE			
Name: /s/ Dan Conn Dan Conn	Name: /s/ Michael B. Dilling			
Dan Conn	Michael B. Dilling, Ph.D., CLP			
Title: CFO	Title: Executive Director, Baylor Licensing Group			
Date: June 14, 2023	Date: 5/25/2023 12:12 PM CDT			
	APPROVED AS TO FORM			
	Office of the General Counsel			
	Baylor College of Medicine			
BLG [***]	By: /s/ Patrick Turley, J.D., Ph.D. 5/25/2023 12:12 PM CDT			
	3			

In connection with the filing by Cara Therapeutics, Inc. of the Registration Statement on Form S-4 (the "Registration Statement") with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act"), I hereby consent, pursuant to Rule 438 of the Securities Act, to being named as a nominee to the board of directors of Cara Therapeutics, Inc. following the consummation of the merger in the Registration Statement and any and all amendments and supplements thereto. I also consent to the filing of this consent as an exhibit to such Registration Statement and any amendments thereto.

Date: December 18, 2024

/s/ Sujal Shah Sujal Shah

In connection with the filing by Cara Therapeutics, Inc. of the Registration Statement on Form S-4 (the "Registration Statement") with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act"), I hereby consent, pursuant to Rule 438 of the Securities Act, to being named as a nominee to the board of directors of Cara Therapeutics, Inc. following the consummation of the merger in the Registration Statement and any and all amendments and supplements thereto. I also consent to the filing of this consent as an exhibit to such Registration Statement and any amendments thereto.

Date: December 18, 2024

/s/ Wallace Hall Wallace Hall

In connection with the filing by Cara Therapeutics, Inc. of the Registration Statement on Form S-4 (the "Registration Statement") with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act"), I hereby consent, pursuant to Rule 438 of the Securities Act, to being named as a nominee to the board of directors of Cara Therapeutics, Inc. following the consummation of the merger in the Registration Statement and any and all amendments and supplements thereto. I also consent to the filing of this consent as an exhibit to such Registration Statement and any amendments thereto.

Date: December 18, 2024

/s/ Imran Alibhai, Ph.D. Imran Alibhai, Ph.D.

In connection with the filing by Cara Therapeutics, Inc. of the Registration Statement on Form S-4 (the "Registration Statement") with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act"), I hereby consent, pursuant to Rule 438 of the Securities Act, to being named as a nominee to the board of directors of Cara Therapeutics, Inc. following the consummation of the merger in the Registration Statement and any and all amendments and supplements thereto. I also consent to the filing of this consent as an exhibit to such Registration Statement and any amendments thereto.

Date: December 18, 2024

/s/ Shaheen Wirk, M.D. Shaheen Wirk, M.D.

In connection with the filing by Cara Therapeutics, Inc. of the Registration Statement on Form S-4 (the "Registration Statement") with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act"), I hereby consent, pursuant to Rule 438 of the Securities Act, to being named as a nominee to the board of directors of Cara Therapeutics, Inc. following the consummation of the merger in the Registration Statement and any and all amendments and supplements thereto. I also consent to the filing of this consent as an exhibit to such Registration Statement and any amendments thereto.

Date: December 18, 2024

/s/ Michael Wyzga Michael Wyzga

Subsidiaries of Cara Therapeutics, Inc.

Name of Subsidiary Cara Royalty Sub, LLC CT Convergence Merger Sub, Inc.

Jurisdiction of Incorporation Delaware Delaware

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in the Registration Statement on Form S-4 and related proxy statement/prospectus of Cara Therapeutics, Inc. and to the incorporation by reference therein of our reports dated March 6, 2024, with respect to the consolidated financial statements of Cara Therapeutics, Inc., and the effectiveness of internal control over financial reporting of Cara Therapeutics, Inc., included in its Annual Report (Form 10-K) for the year ended December 31, 2023, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Stamford, Connecticut December 18, 2024

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement on Form S-4 of our report dated December 18, 2024, relating to the financial statements of Tvardi Therapeutics, Inc. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Deloitte & Touche LLP

Houston, Texas December 18, 2024

CALCULATION OF FILING FEE TABLE

FORM S-4

(Form Type)

CARA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Table I: Newly Registered and Carry Forward Securities

Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered (1)	Proposed Maximum Offering Price Per Unit	Maximum Offering Price	Fee Rate	Amount of Registration Fee
Equity	Common Stock, par value \$0.001 per share	457(c), 457(f)(1)	311,701,096 (2)	\$0.25945	\$80,870,849.40 (3)	0.0001531	\$12,381.33
Total Offering Amounts					\$80,870,849.40		\$12,381.33
Total Fees Previously Paid							
Total Fee Offsets							
Net Fee Due						\$12,381.33	

(1) Pursuant to Rule 416(a) of the Securities Act of 1933, as amended (Securities Act), Cara Therapeutics, Inc. (Cara) is also registering an indeterminate number of additional shares of common stock, par value \$0.001 per share (Cara Common Stock), that may become issuable as a result of any stock split, stock dividend, recapitalization or other similar transaction.

(2) Based on the maximum number of shares of Cara Common Stock estimated to be issued in connection with the merger described herein between Cara, CT Convergence Merger Sub Inc., and Tvardi Therapeutics, Inc.

(3) Pursuant to Rules 457(c) and 457(f)(1) promulgated under the Securities Act and solely for the purpose of calculating the registration fee, the proposed maximum aggregate offering price is calculated as the product of (i) 311,701,096 shares of Cara Common Stock and (ii) \$0.25945, the average of the high and low trading prices of the Cara Common Stock on The Nasdaq Capital Market on December 13, 2024 (a date within five business days prior to the date of this registration statement).