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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2023**

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**COMMISSION FILE NUMBER 001-36279  
CARA THERAPEUTICS, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**75-3175693**  
(I.R.S. Employer  
Identification No.)

**4 Stamford Plaza  
107 Elm Street, 9<sup>th</sup> Floor  
Stamford, Connecticut**  
(Address of registrant's principal executive offices)

**06902**  
(Zip Code)

**Registrant's telephone number, including area code: (203) 406-3700**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	CARA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No.

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  Yes  No.

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No.

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of May 11, 2023 was: 53,983,227.

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CARA THERAPEUTICS, INC.

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FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2023

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**PART I  
FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**CARA THERAPEUTICS, INC.**

**CONDENSED BALANCE SHEETS  
(amounts in thousands, excluding share and per share data)  
(unaudited)**

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 47,391	\$ 63,741
Marketable securities	66,892	81,658
Accounts receivable, net - related party	6,066	3,260
Inventory, net	3,515	2,383
Income tax receivable	697	697
Other receivables	495	496
Prepaid expenses	17,195	16,267
Restricted cash	408	408
Total current assets	<u>142,659</u>	<u>168,910</u>
Operating lease right-of-use assets	1,175	1,551
Marketable securities, non-current	9,074	11,350
Property and equipment, net	368	426
Total assets	<u>\$ 153,276</u>	<u>\$ 182,237</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,222	\$ 21,540
Operating lease liabilities, current	1,456	1,918
Total current liabilities	<u>16,678</u>	<u>23,458</u>
Commitments and contingencies (Note 16)	—	—
Stockholders' equity:		
Preferred stock; \$0.001 par value; 5,000,000 shares authorized at March 31, 2023 and December 31, 2022, zero shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock; \$0.001 par value; 100,000,000 shares authorized at March 31, 2023 and December 31, 2022, 53,974,352 shares and 53,797,341 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	54	53
Additional paid-in capital	730,542	726,630
Accumulated deficit	(592,897)	(566,232)
Accumulated other comprehensive loss	(1,101)	(1,672)
Total stockholders' equity	<u>136,598</u>	<u>158,779</u>
Total liabilities and stockholders' equity	<u>\$ 153,276</u>	<u>\$ 182,237</u>

See Notes to Condensed Financial Statements.

## CARA THERAPEUTICS, INC.

**CONDENSED STATEMENTS OF COMPREHENSIVE LOSS**  
**(amounts in thousands, excluding share and per share data)**  
**(unaudited)**

	<b>Three Months Ended</b>	
	<b>March 31, 2023</b>	<b>March 31, 2022</b>
Revenue:		
Collaborative revenue	\$ 2,750	\$ —
Commercial supply revenue	3,191	4,790
Royalty revenue	125	—
Clinical compound revenue	99	—
Total revenue	<u>6,165</u>	<u>4,790</u>
Operating expenses:		
Cost of goods sold	2,590	2,081
Research and development	24,334	21,273
General and administrative	6,891	9,347
Total operating expenses	<u>33,815</u>	<u>32,701</u>
Operating loss	(27,650)	(27,911)
Other income, net	985	162
Net loss	<u>\$ (26,665)</u>	<u>\$ (27,749)</u>
Net loss per share:		
Basic and Diluted	<u>\$ (0.49)</u>	<u>\$ (0.52)</u>
Weighted average shares:		
Basic and Diluted	<u>53,872,038</u>	<u>53,507,060</u>
Other comprehensive income (loss), net of tax of \$0:		
Change in unrealized gains (losses) on available-for-sale marketable securities	571	(1,365)
Total comprehensive loss	<u>\$ (26,094)</u>	<u>\$ (29,114)</u>

See Notes to Condensed Financial Statements.

**CARA THERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**(amounts in thousands except share and per share data)**  
**(unaudited)**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
	Balance at December 31, 2022	53,797,341				
Stock-based compensation expense	—	—	2,972	—	—	2,972
Shares issued upon exercise of stock options	93,218	1	559	—	—	560
Shares issued upon vesting of restricted stock units	83,793	—	381	—	—	381
Net loss	—	—	—	(26,665)	—	(26,665)
Other comprehensive income	—	—	—	—	571	571
Balance at March 31, 2023	<u>53,974,352</u>	<u>\$ 54</u>	<u>\$ 730,542</u>	<u>\$ (592,897)</u>	<u>\$ (1,101)</u>	<u>\$ 136,598</u>

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
	Balance at December 31, 2021	53,480,812				
Stock-based compensation expense	—	—	4,266	—	—	4,266
Shares issued upon exercise of stock options	470	—	3	—	—	3
Shares issued upon vesting of restricted stock units	109,943	—	1,438	—	—	1,438
Net loss	—	—	—	(27,749)	—	(27,749)
Other comprehensive loss	—	—	—	—	(1,365)	(1,365)
Balance at March 31, 2022	<u>53,591,225</u>	<u>\$ 53</u>	<u>\$ 714,292</u>	<u>\$ (508,507)</u>	<u>\$ (1,723)</u>	<u>\$ 204,115</u>

See Notes to Condensed Financial Statements.

## CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS  
(amounts in thousands)  
(unaudited)

	Three Months Ended	
	March 31, 2023	March 31, 2022
<b>Operating activities</b>		
Net loss	\$ (26,665)	\$ (27,749)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,353	5,704
Depreciation and amortization	58	63
Amortization expense component of lease expense	375	344
(Accretion)/amortization of available-for-sale marketable securities, net	(94)	292
Changes in operating assets and liabilities:		
Accounts receivable, net - related party	(2,806)	(2,496)
Inventory, net	(1,132)	677
Other receivables	1	17
Prepaid expenses	(928)	(2,594)
Accounts payable and accrued expenses	(6,318)	640
Operating lease liabilities	(462)	(423)
Net cash used in operating activities	<u>(34,618)</u>	<u>(25,525)</u>
<b>Investing activities</b>		
Proceeds from maturities of available-for-sale marketable securities	29,500	44,000
Proceeds from redemptions of available-for-sale marketable securities, at par	4,000	—
Purchases of available-for-sale marketable securities	(15,792)	(10,526)
Purchases of property and equipment	—	(43)
Net cash provided by investing activities	<u>17,708</u>	<u>33,431</u>
<b>Financing activities</b>		
Proceeds from the exercise of stock options	560	3
Net cash provided by financing activities	<u>560</u>	<u>3</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(16,350)	7,909
Cash, cash equivalents and restricted cash at beginning of period	64,149	13,861
Cash, cash equivalents and restricted cash at end of period	<u>\$ 47,799</u>	<u>\$ 21,770</u>

See Notes to Condensed Financial Statements.

CARA THERAPEUTICS, INC.

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**  
**(unaudited)**

**1. Business**

Cara Therapeutics, Inc., or the Company, is a commercial-stage biopharmaceutical corporation formed on July 2, 2004. The Company is leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company's primary activities to date have been organizing and staffing the Company, developing its lead product and product candidates, including conducting preclinical studies and clinical trials of difelikefalin-based product candidates, and raising capital.

In August 2021, the Company received U.S. Food and Drug Administration, or FDA, approval for KORSUVA® (difelikefalin) injection, or KORSUVA injection, for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. Commercial launch of KORSUVA injection began in the United States in April 2022 and the Company began recording the associated profit-sharing revenues in the second quarter of 2022.

In April 2022, the European Commission granted marketing authorization to difelikefalin injection under the brand name Kapruvia® (difelikefalin), or Kapruvia, for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult hemodialysis patients. The marketing authorization approved Kapruvia for use in all member states of the European Union, or EU, as well as Iceland, Liechtenstein, and Norway. Kapruvia was also approved in the United Kingdom in April 2022. Commercial launches in Austria, Germany, Sweden, France, the Netherlands, and Finland have commenced. In August 2022, as part of the Access Consortium, difelikefalin injection was approved in Switzerland under the brand name Kapruvia, as well as Singapore and Canada under the brand name KORSUVA. Commercial launch in Switzerland has also commenced. In November 2022, difelikefalin injection was approved in the last Access Consortium country, Australia, under the brand name KORSUVA. The Company expects additional commercial launches to commence over the next 12-18 months.

In 2018, the Company entered into a license and collaboration agreement with a joint venture between Vifor Pharma Group and Fresenius Medical Care Renal Pharmaceutical Ltd., or Vifor Fresenius Medical Care Renal Pharma Ltd., that provides full commercialization rights of Kapruvia, and where applicable KORSUVA, to Vifor Fresenius Medical Care Renal Pharma Ltd. worldwide (excluding the United States, Japan and South Korea). In markets outside of the United States, the Company is eligible to receive tiered double-digit royalty payments based on annual net sales, as defined in the agreement with Vifor Fresenius Medical Care Renal Pharma Ltd., of difelikefalin injection in the licensed territories. In the U.S. market, the agreement with Vifor Fresenius Medical Care Renal Pharma Ltd. provides that Vifor Fresenius Medical Care Renal Pharma Ltd. will promote difelikefalin injection in the dialysis clinics of Fresenius Medical Care North America, or FMCNA, under a profit-sharing arrangement, whereby the Company is generally entitled to 50% of the annual net profits (as defined in the agreement with Vifor Fresenius Medical Care Renal Pharma Ltd.) based on net FMCNA clinic sales (as defined in the agreement with Vifor Fresenius Medical Care Renal Pharma Ltd.) and Vifor Fresenius Medical Care Renal Pharma Ltd. is entitled to 50% of such net profits, subject to potential adjustments in a calendar year based on certain conditions (see Note 11, *Collaboration and Licensing Agreements*).

In 2020, the Company entered into a second licensing and collaboration agreement, along with stock purchase agreements, with Vifor (International) Ltd., or Vifor International, that provides full commercialization rights of KORSUVA injection to Vifor International in dialysis clinics in the United States under a profit-sharing arrangement, whereby total net sales of KORSUVA injection in the United States, as recorded by Vifor International, are reduced by Vifor International's cost of goods sold, or COGS, as well as a marketing and distribution fee owed by the Company based on the level of annual net sales, and the resulting amount is shared according to a 60% (Company)/40% (Vifor International) profit split (excluding sales to Fresenius Medical Center dialysis clinics, compensation for which is governed by the agreement with Vifor Fresenius Medical Care Renal Pharma Ltd.), subject to potential temporary adjustment in future years based on certain conditions (see Note 11, *Collaboration and Licensing Agreements*).

**CARA THERAPEUTICS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**  
**(unaudited)**

In May 2022, Vifor International assigned its rights and obligations under the license agreement and a supply agreement, as permitted under the agreements, to Vifor Fresenius Medical Care Renal Pharma Ltd. The Company's rights and obligations under these agreements were unaffected by this assignment and the assignment did not affect the Company's economic rights under the agreements with Vifor International.

In August 2022, Vifor Pharma Group (which includes Vifor International) was acquired by CSL Limited and subsequently renamed CSL Vifor as part of the acquisition. The acquisition of Vifor Pharma Group did not affect any of the Company's rights and obligations pursuant to these agreements.

The Company also has a license agreement with Maruishi Pharmaceutical Co. Ltd., or Maruishi, under which the Company granted Maruishi an exclusive license to develop, manufacture, and commercialize drug products containing difelikefalin for acute pain and/or uremic pruritus in Japan. In September 2022, Maruishi submitted a New Drug Application in Japan for approval of difelikefalin injection for the treatment of pruritus in hemodialysis patients (see Note 11, *Collaboration and Licensing Agreements*).

As of March 31, 2023, the Company had raised aggregate net proceeds of approximately \$519,600 from several rounds of equity financing, including its initial public offering, or IPO, which closed in February 2014 and four follow-on public offerings of common stock, which closed in July 2019, July 2018, April 2017 and August 2015, respectively, and the issuance of convertible preferred stock and debt prior to the IPO. Including profit share revenue and royalties, the Company has also earned approximately \$273,000 under its license and supply agreements for difelikefalin, primarily with CSL Vifor, Maruishi, and Chong Kun Dang Pharmaceutical Corp., or CKDP, and an earlier product candidate for which development efforts ceased in 2007. The Company has also received aggregate net proceeds of approximately \$98,000 from the issuance and sale of the Company's common stock to Vifor International in connection with the Company's licensing agreement with CSL Vifor (see Note 11, *Collaboration and Licensing Agreements*).

As of March 31, 2023, the Company had unrestricted cash and cash equivalents and marketable securities of \$123,357 and an accumulated deficit of \$592,897. The Company has incurred substantial net losses and negative cash flows from operating activities in nearly every fiscal period since inception and expects this trend to continue for the foreseeable future. The Company recognized net losses of \$26,665 and \$27,749 for the three months ended March 31, 2023 and 2022, respectively, and had net cash used in operating activities of \$34,618 and \$25,525 for the three months ended March 31, 2023 and 2022, respectively.

The Company is subject to risks common to other life science companies including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing, and compliance with FDA and other government regulations. If the Company does not successfully commercialize KORSUVA injection, Kapruvia or any of its other product candidates, it will be unable to generate additional recurring product revenue or achieve profitability.

## **2. Basis of Presentation**

The unaudited interim condensed financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations and cash flows in conformity with generally accepted accounting principles in the United States of America, or GAAP. In the opinion of management, these unaudited interim financial statements reflect all adjustments, consisting primarily of normal recurring accruals, necessary for a fair presentation of results for the periods presented. The results of operations for



CARA THERAPEUTICS, INC.

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**  
**(unaudited)**

interim periods are not necessarily indicative of the results for the full year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by SEC rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. The condensed balance sheet data as of December 31, 2022 were derived from audited financial statements, but do not include all disclosures required by GAAP. These unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

*Use of Estimates*

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, as of the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. The more significant estimates include the fair value of marketable securities that are classified as level 2 of the fair value hierarchy, the amount and periods over which certain revenues will be recognized, including licensing and collaborative revenue recognized from non-refundable up-front and milestone payments, related party accounts receivable reserve, as applicable, inventory valuation and related reserves, research and development, or R&D, clinical costs and accrued research projects included in prepaid expenses and accounts payable and accrued expenses, the amount of non-cash compensation costs related to share-based payments to employees and non-employees, the incremental borrowing rate used in lease calculations and the likelihood of realization of deferred tax assets.

The impact from global economic conditions and potential and continuing disruptions to and volatility in the credit and equity markets in the United States and worldwide are highly uncertain and cannot be predicted, including impacts from the COVID-19 pandemic or future public health crises, geopolitical tensions, such as the ongoing military conflict between Russia and Ukraine and related sanctions against Russia, decades-high inflation, rising interest rates, uncertainty and liquidity concerns in the broader financial services industry, such as those caused by certain recent banking failures, and a potential recession in the United States. Estimates and assumptions about future events and their effects cannot be determined with certainty and therefore require the exercise of judgment. As of the date of issuance of these condensed financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, assumptions and judgments or revise the reported amounts of assets and liabilities or the disclosure of contingent assets and liabilities. These estimates, however, may change as new events occur and additional information is obtained, and are recognized in the condensed financial statements as soon as they become known.

Actual results could differ materially from the Company's estimates and assumptions.

*Significant Accounting Policies*

There have been no material changes to the significant accounting policies previously disclosed in Note 2 to the Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

**3. Available-for-Sale Marketable Securities**

As of March 31, 2023 and December 31, 2022, the Company's available-for-sale marketable securities consisted of debt securities issued by U.S. government-sponsored entities and investment grade institutions as well as municipal bonds.

CARA THERAPEUTICS, INC.

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**  
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The following tables summarize the Company's available-for-sale marketable securities by major type of security as of March 31, 2023 and December 31, 2022:

**As of March 31, 2023**

Type of Security	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
U.S. government agency obligations	\$ 9,500	\$ —	\$ (483)	\$ 9,017
Corporate bonds	35,704	—	(403)	35,301
Commercial paper	15,943	1	(1)	15,943
Municipal bonds	15,920	—	(215)	15,705
Total available-for-sale marketable securities	\$ 77,067	\$ 1	\$ (1,102)	\$ 75,966

**As of December 31, 2022**

Type of Security	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
U.S. government agency obligations	\$ 9,500	\$ —	\$ (623)	\$ 8,877
Corporate bonds	35,828	—	(643)	35,185
Commercial paper	26,879	2	(6)	26,875
Municipal bonds	22,473	—	(402)	22,071
Total available-for-sale marketable securities	\$ 94,680	\$ 2	\$ (1,674)	\$ 93,008

The following tables summarize the fair value and gross unrealized losses of the Company's available-for-sale marketable securities by investment category and disaggregated by the length of time that individual debt securities have been in a continuous unrealized loss position as of March 31, 2023 and December 31, 2022:

**As of March 31, 2023**

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government agency obligations	\$ —	\$ —	\$ 9,017	\$ (483)	\$ 9,017	\$ (483)
Corporate bonds	4,000	(4)	31,301	(399)	35,301	(403)
Commercial paper	4,975	(1)	—	—	4,975	(1)
Municipal bonds	—	—	15,705	(215)	15,705	(215)
Total	\$ 8,975	\$ (5)	\$ 56,023	\$ (1,097)	\$ 64,998	\$ (1,102)

## CARA THERAPEUTICS, INC.

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**  
**(unaudited)**

As of December 31, 2022

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government agency obligations	\$ —	\$ —	\$ 8,877	\$ (623)	\$ 8,877	\$ (623)
Corporate bonds	1,470	(26)	33,715	(617)	35,185	(643)
Commercial paper	15,906	(6)	—	—	15,906	(6)
Municipal bonds	982	(16)	19,589	(386)	20,571	(402)
<b>Total</b>	<b>\$ 18,358</b>	<b>\$ (48)</b>	<b>\$ 62,181</b>	<b>\$ (1,626)</b>	<b>\$ 80,539</b>	<b>\$ (1,674)</b>

As of March 31, 2023 and December 31, 2022, no allowance for credit losses were recognized on the Company's available-for-sale debt securities as no portion of the unrealized losses associated with those securities were due to credit losses. The information that the Company considered in reaching the conclusion that an allowance for credit losses was not necessary is as follows:

As of March 31, 2023 and December 31, 2022, the Company held a total of 30 out of 35 positions and 35 out of 39 positions, respectively, that were in an unrealized loss position, 27 of which had been in an unrealized loss position for 12 months or greater as of March 31, 2023. Unrealized losses individually and in aggregate, including any in an unrealized loss position for 12 months or greater, were not considered to be material for each respective period. Based on the Company's review of these securities, the Company believes that the cost basis of its available-for-sale marketable securities is recoverable.

**U.S. government agency obligations.** The unrealized losses on the Company's investments in direct obligations of government agencies were due to changes in interest rates and non-credit related factors. The credit ratings of these investments in the Company's portfolio have not been downgraded below investment grade status. The contractual terms of these investments do not permit the issuer to repay principal at a price less than the amortized cost bases of the investments, which is equivalent to the par value on the maturity date. The Company expects to recover the entire amortized cost bases of these securities on the maturity date. The Company does not intend to sell these investments, and it is not "more likely than not" that the Company will be required to sell these investments before recovery of their amortized cost bases. The Company held 3 out of 3 positions for its U.S. government agency obligations, that were in unrealized loss positions as of March 31, 2023.

**Corporate bonds, commercial paper, and municipal bonds.** The unrealized losses on the Company's investments in corporate bonds, commercial paper and municipal bonds were due to changes in interest rates and non-credit related factors. The credit ratings of these investments in the Company's portfolio have not been downgraded below investment grade status. The contractual terms of these investments do not permit the issuer to repay principal at a price less than the amortized cost bases of the investments, which is equivalent to the par value on the maturity date. The Company expects to recover the entire amortized cost bases of these securities on the maturity date. The Company does not intend to sell these investments, and it is not "more likely than not" that the Company will be required to sell these investments before recovery of their amortized cost bases. The Company held 13 out of 13 positions for its corporate bonds, 2 out of 7 positions for its commercial paper, and 12 out of 12 positions for its municipal bonds, that were in unrealized loss positions as of March 31, 2023.

CARA THERAPEUTICS, INC.

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(amounts in thousands, except share and per share data)**  
**(unaudited)**

The Company classifies its marketable debt securities based on their contractual maturity dates. As of March 31, 2023, the Company's marketable debt securities mature at various dates through November 2024. The amortized cost and fair values of marketable debt securities by contractual maturity were as follows:

Contractual maturity	As of March 31, 2023		As of December 31, 2022	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	\$ 67,565	\$ 66,892	\$ 82,678	\$ 81,658
One year to two years	9,502	9,074	12,002	11,350
Total	\$ 77,067	\$ 75,966	\$ 94,680	\$ 93,008

All available-for-sale marketable securities are classified as marketable securities, current or marketable securities, non-current depending on the contractual maturity date of the individual available-for-sale security. Other income, net includes interest and dividends, accretion/amortization of discounts/premiums, realized gains and losses on sales of securities and credit loss expense due to declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method.

There were no sales of available-for-sale marketable securities during the three months ended March 31, 2023 and 2022.

As of March 31, 2023 and December 31, 2022, accrued interest receivables on the Company's available-for-sale debt securities were \$495 and \$489, respectively, and were included within other receivables.

**4. Accumulated Other Comprehensive Loss**

The following table summarizes the changes in accumulated other comprehensive loss, net of tax, from unrealized gains (losses) on available-for-sale marketable securities, the Company's only component of accumulated other comprehensive loss, for the three months ended March 31, 2023 and 2022, respectively.

	Total Accumulated Other Comprehensive Loss
Balance, December 31, 2022	\$ (1,672)
Other comprehensive income before reclassifications	571
Amount reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive income	571
Balance, March 31, 2023	\$ (1,101)
Balance, December 31, 2021	\$ (358)
Other comprehensive loss before reclassifications	(1,365)
Amount reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive loss	(1,365)
Balance, March 31, 2022	\$ (1,723)

Amounts reclassified out of accumulated other comprehensive loss into net loss are determined by specific identification. There were no reclassifications out of accumulated other comprehensive loss and into net loss for the three months ended March 31, 2023 and 2022.

CARA THERAPEUTICS, INC.

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**5. Fair Value Measurements**

As of March 31, 2023 and December 31, 2022, the Company's financial instruments consisted of cash, cash equivalents, available-for-sale marketable securities, accounts receivable, net – related party, prepaid expenses, restricted cash, accounts payable and accrued liabilities. The fair values of cash, cash equivalents, accounts receivable, net – related party, prepaid expenses, restricted cash, accounts payable and accrued liabilities approximate their carrying values due to the short-term nature of these financial instruments. Available-for-sale marketable securities are reported at their fair values, based upon pricing of securities with the same or similar investment characteristics as provided by third-party pricing services.

The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods, obtaining market values from other pricing sources, and comparing them to the share prices presented by the third-party pricing services. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by its third-party pricing services as of March 31, 2023 or December 31, 2022.

The following tables summarize the Company's financial assets measured at fair value on a recurring basis as of March 31, 2023 and December 31, 2022.

**Fair value measurement as of March 31, 2023:**

Financial assets	Type of Instrument	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Cash and cash equivalents:</b>					
	Money market funds and checking accounts	\$ 47,391	\$ 47,391	\$ —	\$ —
<b>Available-for-sale marketable securities:</b>					
	U.S. government agency obligations	9,017	—	9,017	—
	Corporate bonds	35,301	—	35,301	—
	Commercial paper	15,943	—	15,943	—
	Municipal bonds	15,705	—	15,705	—
<b>Restricted cash:</b>					
	Commercial money market account	408	408	—	—
	Total financial assets	<u>\$ 123,765</u>	<u>\$ 47,799</u>	<u>\$ 75,966</u>	<u>\$ —</u>

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Fair value measurement as of December 31, 2022:

Financial assets	Type of Instrument	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Cash and cash equivalents:</b>					
	Money market funds and checking accounts	\$ 63,741	\$ 63,741	\$ —	\$ —
<b>Available-for-sale marketable securities:</b>					
	U.S. government agency obligations	8,877	—	8,877	—
	Corporate bonds	35,185	—	35,185	—
	Commercial paper	26,875	—	26,875	—
	Municipal bonds	22,071	—	22,071	—
<b>Restricted cash:</b>					
	Commercial money market account	408	408	—	—
	Total financial assets	<u>\$ 157,157</u>	<u>\$ 64,149</u>	<u>\$ 93,008</u>	<u>\$ —</u>

There were no purchases, sales or maturities of Level 3 financial assets and no unrealized gains or losses related to Level 3 available-for-sale marketable securities during the three months ended March 31, 2023 and 2022, respectively. There were no transfers of financial assets into or out of Level 3 classification during the three months ended March 31, 2023 and 2022, respectively.

**6. Restricted Cash**

The Company is required to maintain a stand-by letter of credit as a security deposit under its leases for its office space in Stamford, Connecticut (refer to Note 16, *Commitments and Contingencies: Leases*). The fair value of the letter of credit approximates its contract value. The Company's bank requires the Company to maintain a restricted cash balance to serve as collateral for the letter of credit issued to the landlord by the bank. As of March 31, 2023, the restricted cash balance for the Stamford Lease was invested in a commercial money market account.

As of March 31, 2023 and December 31, 2022, the Company had \$408 of restricted cash related to the Stamford Lease in current assets.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Condensed Balance Sheets that sum to the total of the same such amounts shown in the Condensed Statements of Cash Flows.

	March 31, 2023	December 31, 2022
Cash and cash equivalents	\$ 47,391	\$ 63,741
Restricted cash, current assets	408	408
Total cash, cash equivalents, and restricted cash shown in the Condensed Statements of Cash Flows	<u>\$ 47,799</u>	<u>\$ 64,149</u>

## CARA THERAPEUTICS, INC.

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Inventory, net consists of the following:

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Raw materials	\$ 2,504	\$ 1,918
Work-in-process	1,009	499
Finished goods	2	—
	<u>3,515</u>	<u>2,417</u>
Less Inventory Reserve for Obsolescence	—	(34)
Total	<u>\$ 3,515</u>	<u>\$ 2,383</u>

As of March 31, 2023 and December 31, 2022, inventory balances include inventory costs subsequent to regulatory approval of KORSUVA injection on August 23, 2021. There were no write-downs of commercial supply inventory during the three months ended March 31, 2023.

**8. Prepaid expenses**

As of March 31, 2023, prepaid expenses were \$17,195, consisting of \$14,407 of prepaid R&D clinical costs, \$1,887 of prepaid insurance and \$901 of other prepaid costs. As of December 31, 2022, prepaid expenses were \$16,267, consisting of \$15,188 of prepaid R&D clinical costs, \$543 of prepaid insurance, and \$536 of other prepaid costs.

**9. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses consist of the following:

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Accounts payable	\$ 4,424	\$ 9,604
Accrued research projects	5,824	5,200
Accrued compensation and benefits	2,947	5,219
Accrued professional fees and other	2,027	1,517
Total	<u>\$ 15,222</u>	<u>\$ 21,540</u>

**10. Stockholders' Equity**

In March 2023, as a result of the completion of the second year of the three-year vesting period for restricted stock units granted in March 2021, an aggregate of 15,999 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In February 2023, as a result of the completion of the first year of the three-year vesting period for restricted stock units granted in February 2022, an aggregate of 42,920 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

Also in February 2023, as a result of the completion of the third year of the three-year vesting period for restricted stock units granted in February 2020, an aggregate of 15,999 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

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In January 2023, as a result of satisfaction of the quarterly vesting period for restricted stock units granted in October 2021, an aggregate 8,875 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In March 2022, as a result of the achievement of certain performance targets, an aggregate of 37,999 performance-based restricted stock units of certain employees vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In March 2022, as a result of the completion of the first year of the three-year vesting period for restricted stock units granted in March 2021 and the full vesting of the second tranche of restricted stock units granted to the new Chief Executive Officer in October 2021, an aggregate of 39,278 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In March 2022, the Company filed a universal shelf registration statement, or the Shelf Registration Statement, which provides for aggregate offerings of up to \$300,000 of common stock, preferred stock, debt securities, warrants or any combination thereof. The Shelf Registration Statement was declared effective on May 11, 2022. The securities registered under the Shelf Registration Statement include \$154,525 of unsold securities that had been registered under the Company's previous Registration Statement on Form S-3 (File No. 333-230333) that was declared effective on April 4, 2019.

Also in March 2022, the Company entered into an open market sales agreement, or the Sales Agreement, with Jefferies LLC, as sales agent, pursuant to which it may, from time to time, issue and sell common stock with an aggregate value of up to \$80,000 in an at-the-market offering. Jefferies is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. The common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. No shares were sold under the Sales Agreement as of March 31, 2023.

The Company may offer additional securities under its Shelf Registration Statement from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interests of its stockholders.

In February 2022, as a result of the completion of the second year of the three-year vesting period for restricted stock units granted in February 2020, an aggregate of 32,666 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

#### **11. Collaboration and Licensing Agreements**

##### *Vifor (International) Ltd. (Vifor International)*

In October 2020, the Company entered into a license agreement with Vifor International, or Vifor Agreement No. 1, under which the Company granted Vifor International an exclusive license solely in the United States to use, distribute, offer for sale, promote, sell and otherwise commercialize difelikefalin injection for all therapeutic uses relating to the inhibition, prevention or treatment of itch associated with pruritus in hemodialysis and peritoneal dialysis patients in the United States. Under Vifor Agreement No. 1, the Company retains all rights with respect to the clinical development of, and activities to gain regulatory approvals of, difelikefalin injection in the United States.

After the assignment of rights of Vifor Agreement No. 1 from Vifor International to Vifor Fresenius Medical Care Renal Pharma Ltd. in May 2022, Vifor Agreement No. 1 provides full commercialization rights in dialysis clinics to



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CSL Vifor in the United States under a profit-sharing arrangement. Pursuant to the profit-sharing arrangement, the Company is generally entitled to 60% of the net profits (as defined in Vifor Agreement No. 1) from sales of difelikefalin injection in the United States and CSL Vifor is entitled to 40% of such net profits (excluding sales to Fresenius Medical Center dialysis clinics, compensation for which is governed by Vifor Agreement No. 2, as defined below), subject to potential temporary adjustment in future years based on certain conditions. Under Vifor Agreement No. 1, in consideration of CSL Vifor's conduct of the marketing, promotion, selling and distribution of difelikefalin injection in the United States, the Company pays a marketing and distribution fee to CSL Vifor based on the level of annual net sales. This fee as well as CSL Vifor's COGS are deducted from net sales in calculating the net profits that are subject to the profit-sharing arrangement under Vifor Agreement No. 1.

In addition, pursuant to Vifor Agreement No. 1, the Company is eligible to receive payments of up to \$240,000 upon the achievement of certain sales-based milestones.

The Company retains the rights to make and have made difelikefalin injection, or the Licensed Product, on a non-exclusive basis, in the United States for commercial sale of the Licensed Product for use in all therapeutic areas to prevent, inhibit or treat itch associated with pruritus in hemodialysis and peritoneal-dialysis patients, or the Field, anywhere in the world and for supply of Licensed Product to CSL Vifor under the terms of a supply agreement, or the Vifor International Supply Agreement, which was executed in September 2021. The supply price is the Company's COGS, as calculated under GAAP, plus an agreed upon margin. The Vifor International Supply Agreement will co-terminate with Vifor Agreement No. 1. The Company also retains the rights to import, distribute, promote, sell and otherwise commercialize the Licensed Product on an exclusive basis outside of the Field either in or outside of the United States.

The Vifor International Supply Agreement is accounted for as a customer option that is not a material right because the selling price of the Licensed Product under the Vifor International Supply Agreement is the Company's COGS plus an agreed upon margin, which is commensurate with the "COGS plus" model that the Company would charge other parties under similar agreements (the standalone selling price) and not at a discount. Therefore, the sale of commercial supply to CSL Vifor is not a performance obligation under Vifor Agreement No. 1 but rather the Vifor International Supply Agreement is a separate agreement from Vifor Agreement No. 1. The only performance obligation under the Vifor International Supply Agreement is the delivery of the Licensed Product to CSL Vifor for commercialization.

*Vifor Fresenius Medical Care Renal Pharma Ltd.*

In May 2018, the Company entered into a license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd., or Vifor Agreement No. 2, under which the Company granted Vifor Fresenius Medical Care Renal Pharma Ltd. an exclusive, royalty-bearing license, or the Vifor License, to seek regulatory approval to commercialize, import, export, use, distribute, offer for sale, promote, sell and otherwise commercialize the Licensed Product in the Field worldwide (excluding the United States, Japan and South Korea), or the Territory.

The Company is eligible to receive from Vifor Fresenius Medical Care Renal Pharma Ltd. additional commercial milestone payments in the aggregate of up to \$440,000, all of which are sales related. The Company is also eligible to receive tiered double-digit royalty payments based on annual net sales, as defined in Vifor Agreement No. 2, of difelikefalin injection in the licensed territories. The Company retained full commercialization rights for difelikefalin injection for the treatment of chronic kidney disease associated pruritus in the United States except in the dialysis clinics of FMCNA, where Vifor Fresenius Medical Care Renal Pharma Ltd. will promote difelikefalin injection under a profit-sharing arrangement (as defined in Vifor Agreement No. 2), based on net FMCNA clinic sales (as defined in Vifor Agreement No. 2) and the Company and Vifor Fresenius Medical Care Renal Pharma Ltd. are each entitled to 50% of such net profits, subject to potential adjustments in a calendar year based on certain conditions.

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The Company retains the rights to make and have made the Licensed Product in the Territory for commercial sale by Vifor Fresenius Medical Care Renal Pharma Ltd. in the Field in or outside the Territory and for supply of Licensed Product to Vifor Fresenius Medical Care Renal Pharma Ltd. under the terms of a supply agreement, or the Vifor Supply Agreement, which was executed in May 2020. The supply price is the Company's COGS, as calculated under GAAP, plus an agreed upon margin. The Vifor Supply Agreement will co-terminate with Vifor Agreement No. 2.

The Vifor Supply Agreement is accounted for as a customer option that is not a material right because the selling price of the Licensed Product under the Vifor Supply Agreement is the Company's COGS plus an agreed upon margin, which is commensurate with the "COGS plus" model that the Company would charge other parties under similar agreements (the standalone selling price) and not at a discount. Therefore, the sale of compound to Vifor Fresenius Medical Care Renal Pharma Ltd. is not a performance obligation under Vifor Agreement No. 2 but rather the Vifor Supply Agreement is a separate agreement from Vifor Agreement No. 2. The only performance obligation under the Vifor Supply Agreement is the delivery of the Licensed Product to Vifor Fresenius Medical Care Renal Pharma Ltd. for commercialization.

*Maruishi Pharmaceutical Co., Ltd. (Maruishi)*

In April 2013, the Company entered into a license agreement with Maruishi, or the Maruishi Agreement, under which the Company granted Maruishi an exclusive license to develop, manufacture, and commercialize drug products containing difelikefalin for acute pain and/or uremic pruritus in Japan. Maruishi has the right to grant sub-licenses in Japan, which entitles the Company to receive sub-license fees, net of prior payments made by Maruishi to the Company. Under the Maruishi Agreement, the Company and Maruishi are required to use commercially reasonable efforts, at their own expense, to develop, obtain regulatory approval for and commercialize difelikefalin in the United States and Japan, respectively. In addition, the Company provided Maruishi specific clinical development services for difelikefalin used in Maruishi's field of use.

Under the terms of the Maruishi Agreement, the Company is eligible to receive milestone payments upon the achievement of defined clinical and regulatory events as well as tiered, low double-digit royalties with respect to any sales of the licensed product sold in Japan by Maruishi, if any, and share in any sub-license fees.

In September 2022, Maruishi submitted a New Drug Application in Japan for approval of difelikefalin injection for the treatment of pruritus in hemodialysis patients.

*Chong Kun Dang Pharmaceutical Corporation (CKDP)*

In April 2012, the Company entered into a license agreement with CKDP, or the CKDP Agreement, in South Korea, under which the Company granted CKDP an exclusive license to develop, manufacture and commercialize drug products containing difelikefalin in South Korea. The Company and CKDP are each required to use commercially reasonable efforts, at their respective expense, to develop, obtain regulatory approval for and commercialize difelikefalin in the United States and South Korea, respectively.

Under the terms of the CKDP Agreement, the Company is eligible to receive milestone payments upon the achievement of defined clinical and regulatory events as well as tiered royalties, with percentages ranging from the high single digits to the high teens, based on net sales of products containing difelikefalin in South Korea, if any, and share in any sub-license fees.

## CARA THERAPEUTICS, INC.

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The Company primarily recognizes revenue under its license and collaboration agreements from (1) collaborative revenue from its share of the profit generated by KORSUVA injection sales in the United States; (2) commercial supply revenue from the Company's sales of commercial product to CSL Vifor, which is subsequently sold to wholesalers; (3) royalty revenue from net sales of Kaprivia in Europe; (4) sales-based or regulatory milestone payments, which could be earned in the future in accordance with certain licensing agreements. As of March 31, 2023, the Company has not earned any sales-based milestones under its collaboration agreements.

As of March 31, 2023, the Company had license and collaboration agreements with CSL Vifor, Maruishi and CKDP. The following table provides amounts included in the Company's Condensed Statements of Comprehensive Loss as revenue for the three months ended March 31, 2023 and 2022, respectively:

	Three Months Ended March 31,	
	2023	2022
<b>Collaborative revenue</b>		
CSL Vifor (KORSUVA injection profit sharing)	\$ 2,750	\$ —
Total collaborative revenue	<u>\$ 2,750</u>	<u>\$ —</u>
<b>Commercial supply revenue</b>		
CSL Vifor* (KORSUVA injection)	\$ 3,191	\$ 4,790
Total commercial supply revenue	<u>\$ 3,191</u>	<u>\$ 4,790</u>
<b>Royalty revenue</b>		
CSL Vifor (Kaprivia ex U.S.)	\$ 125	\$ —
Total royalty revenue	<u>\$ 125</u>	<u>\$ —</u>
<b>Clinical compound revenue</b>		
Maruishi	\$ 99	\$ —
Total clinical compound revenue	<u>\$ 99</u>	<u>\$ —</u>

\* Includes amounts earned from Vifor International prior to Vifor International's assignment of its rights and obligations to Vifor Fresenius Medical Care Renal Pharma Ltd. in May 2022.

*Collaborative revenue*

Beginning in April 2022, the Company began recording its share of the profit generated by KORSUVA injection sales by CSL Vifor to third parties in the United States. Under the license agreements with CSL Vifor, KORSUVA injection net sales are calculated by CSL Vifor which are net of discounts, rebates, and allowances. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. The Company records its share of the net profits from the sales of KORSUVA injection in the United States on a net basis (since the Company is not the primary obligor and does not retain inventory risk) and presents the revenue earned each period as collaborative revenue. During the three months ended March 31, 2023, the Company recorded \$2,750 as collaborative revenue for its profit-share from the sales of KORSUVA injection in the United States. There was no profit share revenue recorded during the three months ended March 31, 2022.

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*Commercial supply revenue*

Under the Vifor International Supply Agreement, the Company's only performance obligation is the delivery of KORSUVA injection to CSL Vifor in accordance with the receipt of purchase orders. Revenue from the sale of commercial supply product to CSL Vifor is recognized as delivery of the product occurs. The Company had commercial supply revenue of \$3,191 for the three months ended March 31, 2023 with associated COGS of \$2,590. The Company had commercial supply revenue of \$4,790 for the three months ended March 31, 2022, of which \$2,295 was recognized in January 2022 with no associated COGS since these inventory costs were incurred prior to regulatory approval on August 23, 2021, and \$2,495 was recognized with associated COGS of \$2,081 since these inventory costs were capitalized as inventory subsequent to regulatory approval.

*Royalty revenue*

Royalty revenue includes amounts related to the Company's royalties earned from CSL Vifor on the net sales of Kaprivia in Europe, based on the amount of net sales in a licensed territory during a calendar year. Sales-based royalty payments related to a license of IP are recognized as revenue when the respective sales occur, and the net sales tier is achieved. During the three months ended March 31, 2023, the Company recorded \$125 as royalty revenue based on net sales of Kaprivia. There was no royalty revenue during the three months ended March 31, 2022.

*Clinical compound revenue*

The Company's only performance obligation under the supply agreement with Maruishi is to deliver clinical compound to Maruishi in accordance with the receipt of purchase orders. During the three months ended March 31, 2023, the Company recognized clinical compound revenue of \$99 from the sale of clinical compound to Maruishi. There were no sales of clinical compound to Maruishi during the three months ended March 31, 2022.

*Contract balances*

As of March 31, 2023 and December 31, 2022, respectively, the Company recorded accounts receivable, net – related party of \$6,066 and \$3,260 which primarily related to its profit-sharing revenue from sales of KORSUVA injection in the United States by CSL Vifor and its commercial supply of KORSUVA injection to CSL Vifor. There were no other contract assets or contract liabilities related to the CSL Vifor, Maruishi and CKDP agreements as of March 31, 2023 and December 31, 2022.

The Company routinely assesses the creditworthiness of its license and collaboration partners. The Company has not experienced any losses related to receivables from its license and collaboration partners as of March 31, 2023 and December 31, 2022.

**13. Net Loss Per Share**

The Company computes basic net income (loss) per share by dividing net income (loss) by the weighted-average number of shares of common stock outstanding. Diluted net income (loss) per share includes the potential dilutive effect of common stock equivalents as if such securities were exercised during the period, when the effect is dilutive. Common stock equivalents may include outstanding stock options or restricted stock units, which are included using the treasury stock method when dilutive. For the three months ended March 31, 2023 and 2022, the Company excluded the effects of potentially dilutive shares that were outstanding during those respective periods from the denominator as their inclusion would be anti-dilutive due to the Company's net losses during those periods.

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The denominators used in the net loss per share computations are as follows:

	Three Months Ended March 31,	
	2023	2022
<b>Basic:</b>		
Weighted average common shares outstanding	53,872,038	53,507,060
<b>Diluted:</b>		
Weighted average common shares outstanding - Basic	53,872,038	53,507,060
Common stock equivalents*	—	—
Denominator for diluted net loss per share	53,872,038	53,507,060

\* No amounts were considered as their effects would be anti-dilutive.

Basic and diluted net loss per share are computed as follows:

	Three Months Ended March 31,	
	2023	2022
Net loss - basic and diluted	\$ (26,665)	\$ (27,749)
Weighted-average common shares outstanding:		
Basic and diluted	53,872,038	53,507,060
Net loss per share, basic and diluted:	\$ (0.49)	\$ (0.52)

As of March 31, 2023, 8,992,759 stock options and 695,720 restricted stock units were outstanding, which could potentially dilute basic earnings per share in the future, but were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive as a result of the net loss for the period.

As of March 31, 2022, 7,430,629 stock options and 736,272 restricted stock units were outstanding, which could potentially dilute basic earnings per share in the future, but were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive as a result of the net loss for the period.

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**14. Stock-Based Compensation**

*2019 Inducement Plan*

In October 2019, the Company's Board of Directors adopted the 2019 Inducement Plan, or the 2019 Plan, which is a non-stockholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq Listing Rule 5635(c)(4), or Rule 5635, for the purpose of awarding (i) non-statutory stock options, (ii) restricted stock awards, (iii) restricted stock unit awards, (iv) other stock awards (collectively, the Inducement Awards) to new employees of the Company, as inducement material to such new employees entering into employment with the Company. In November 2019, the Company filed a Registration Statement on Form S-8 with the SEC covering the offering of up to 300,000 shares of its common stock, par value \$0.001, pursuant to the Company's 2019 Plan. Initial grants of Inducement Awards made to employees vest as to 25% on the first anniversary of the date of grant and the balance ratably over the next 36 months and subsequent grants vest monthly over a period of four years from the grant date.

*2014 Equity Incentive Plan*

The Company's 2014 Equity Incentive Plan, or the 2014 Plan, is administered by the Company's Board of Directors or a duly authorized committee thereof, referred to as the Plan administrator. The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of equity compensation, collectively referred to as Stock Awards. Additionally, the 2014 Plan provides for the grant of performance cash awards. Incentive stock options may be granted only to employees. All other awards may be granted to employees, including officers, non-employee directors, and consultants. No incentive stock options may be granted under the 2014 Plan after the tenth anniversary of the effective date of the 2014 Plan. Stock Awards granted under the 2014 Plan vest at the rate specified by the Plan administrator. Initial grants of Stock Awards made to employees and non-employee consultants generally vest as to 25% on the first anniversary of the date of grant and the balance ratably over the next 36 months and subsequent grants vest monthly over a period of four years from the grant date. Stock options initially granted to members of the Company's Board of Directors generally vest over a period of three years in equal quarterly installments from the date of the grant, subject to the option holder's continued service as a director through such date. Subsequent grants to directors that are made automatically at Annual Meetings of Stockholders vest fully on the earlier of the first anniversary of the date of grant and the next Annual Meeting of Stockholders. The Plan administrator determines the term of Stock Awards granted under the 2014 Plan up to a maximum of ten years.

The aggregate number of shares of the Company's common stock reserved for issuance under the 2014 Plan has automatically increased on January 1 of each year, beginning on January 1, 2015 and will continue to increase on January 1 of each year through and including January 1, 2024, by 3% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's Board of Directors. On January 1, 2023, the aggregate number of shares of common stock that may be issued pursuant to Stock Awards under the 2014 Plan automatically increased from 10,589,103 to 12,203,023. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2014 Plan is 30,000,000 shares.

*Restricted Stock Units*

On March 1, 2023, the Compensation Committee of the Company's Board of Directors, or the Compensation Committee, approved and granted a total of 407,000 restricted stock units to certain employees under the 2014 Plan with a grant date fair value of \$10.06 per share. Vesting of the restricted stock units is contingent on the achievement of certain performance targets, subject to the recipient's continuous service through each performance target. Recognition

**CARA THERAPEUTICS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
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of compensation expense associated with these awards begins when, and to the extent, the performance criteria are probable of achievement and the employee has met the service conditions. For the three months ended March 31, 2023, no stock compensation expense relating to these restricted stock units was recognized. As of March 31, 2023, 407,000 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.

On October 12, 2022, the Compensation Committee of the Company's Board of Directors, or the Compensation Committee, approved and granted a total of 7,267 time-based restricted stock units under the 2014 Plan, with a grant date fair value of \$9.42 per share, to an executive officer of the Company. The restricted stock unit grant fully vests on August 31, 2023, subject to the recipient's continued service through such date. For the three months ended March 31, 2023, the Company recognized \$19 of stock compensation expense associated with these awards, all of which was recorded within G&A expense. As of March 31, 2023, 7,267 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.

Pursuant to the Company's non-employee director compensation policy, an aggregate of 59,380 restricted stock units were granted to non-employee directors on June 2, 2022, the date of the Company's 2022 Annual Meeting of Stockholders, under the 2014 Plan with a grant date fair value of \$8.42 per share. The restricted stock units will vest on the earlier of (i) June 2, 2023 and (ii) immediately prior to the Company's next Annual Meeting of Stockholders following the grant date, subject to the recipient's continued service through such date. As a result, the Company recognizes compensation expense associated with these restricted stock units ratably over the one-year vesting period following the grant date. For the three months ended March 31, 2023, stock compensation expense associated with these awards of \$123 was recognized in G&A expense. As of March 31, 2023, 59,380 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.

On February 25, 2022, the Compensation Committee also approved and granted a total of 145,170 time-based restricted stock units to certain employees under the 2014 Plan with a grant date fair value of \$10.46 per share. The restricted stock units vest in three equal installments annually from the date of the grant. As a result, the Company recognizes compensation expense associated with these restricted stock units ratably over the three-year vesting period following the grant date. In February 2023, 42,920 of these restricted stock units vested and were settled in shares of the Company's common stock in satisfaction of the first year of vesting. For the three months ended March 31, 2023 and 2022, the Company recognized \$114 and \$50, respectively, of stock compensation expense associated with these awards, with \$47 recorded in R&D expense and \$67 recorded in G&A expense for the three months ended March 31, 2023, and \$18 recorded in R&D expense and \$32 recorded in G&A expense for the three months ended March 31, 2022. As of March 31, 2023, 82,250 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.

On December 17, 2021, the Compensation Committee approved and granted a total of 63,573 time-based restricted stock units to certain employees under the 2014 Plan with a grant date fair value of \$12.45 per share. The restricted stock units vest in two equal installments on December 15, 2022 and June 15, 2023. As a result, the Company recognizes compensation expense associated with these restricted stock units ratably over the 18-month vesting period following the grant date. For the three months ended March 31, 2023 and 2022, the Company recognized \$108 and \$131, respectively, of stock compensation expense associated with these awards, with \$52 recorded in R&D expense and \$56 recorded in G&A expense for the three months ended March 31, 2023, and \$52 recorded in R&D expense and \$79 recorded in G&A expense for the three months ended March 31, 2022. As of March 31, 2023, 26,199 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.

On October 29, 2021, the Compensation Committee also approved and granted 147,942 time-based restricted stock units in connection with the appointment of the Company's new CEO under the 2014 Plan with a grant date fair value of \$16.83 per share. The first tranche of 142,000 restricted stock units vests 25% on the first anniversary of the date of



**CARA THERAPEUTICS, INC.**

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grant and the balance quarterly over the next 36 months. The second tranche of 5,942 restricted stock units fully vested on March 31, 2022. As a result, the Company recognizes compensation expense associated with these two restricted stock unit tranches ratably over their respective vesting periods following the grant date. In January 2023, 8,875 of these restricted stock units vested and were settled in shares of the Company's common stock in satisfaction of the quarterly period of vesting. For the three months ended March 31, 2023 and 2022, stock compensation expense associated with these awards of \$147 and \$206, respectively, was recognized in G&A expense. As of March 31, 2023, 97,625 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.

Pursuant to the Company's non-employee director compensation policy, an aggregate of 43,200 restricted stock units were granted to non-employee directors on June 3, 2021, the date of the Company's 2021 Annual Meeting of Stockholders, under the 2014 Plan with a grant date fair value of \$13.06 per share. The restricted stock units vested on June 3, 2022. As a result, the Company recognized compensation expense associated with these restricted stock units ratably over the one-year vesting period following the grant date. For the three months ended March 31, 2023, there was no stock compensation expense recognized as these restricted stock units were fully vested in June 2022. For the three months ended March 31, 2022, stock compensation expense of \$139 was recognized in G&A expense for these restricted stock units. As of March 31, 2023, there were no outstanding restricted stock units available to vest or settle in shares of the Company's common stock.

On March 30, 2021, the Compensation Committee approved and granted a total of 176,000 restricted stock units to certain employees under the 2014 Plan with a grant date fair value of \$20.59 per share. Vesting of the restricted stock units was contingent on the achievement of certain performance targets related to clinical and regulatory milestones, subject to the recipient's continuous service through each performance target. Recognition of compensation expense associated with these awards begins when, and to the extent, the performance criteria is probable of achievement and the employee has met the service conditions. In February 2022, performance targets relating to 37,999 restricted stock units had been achieved and thus restricted stock units vested and the awards were settled in shares of common stock. For the three months ended March 31, 2023, there was no stock compensation expense recognized as all of these restricted stock units either vested or were forfeited prior to the current period. For the three months ended March 31, 2022, the Company recognized \$729 of stock compensation expense associated with these awards in G&A expense. G&A amounts recorded for the three months ended March 31, 2022 included \$303 of stock compensation expense relating to the modification of certain of these restricted stock units on November 1, 2021 (see *Stock Award Modifications* below). As of March 31, 2023, there were no outstanding restricted stock units available to vest or settle in shares of the Company's common stock.

Additionally on March 30, 2021, the Compensation Committee also approved and granted a total of 100,000 time-based restricted stock units to certain employees under the 2014 Plan with a grant date fair value of \$20.59 per share. The restricted stock units vest in three equal installments annually from the date of the grant. As a result, the Company recognizes compensation expense associated with these restricted stock units ratably over the three-year vesting period following the grant date. In March 2023, 15,999 of these restricted stock units vested and were settled in shares of the Company's common stock in satisfaction of the second year of vesting. In March 2022, 33,336 of these restricted stock units vested and were settled in shares of the Company's common stock in satisfaction of the first year of vesting. For the three months ended March 31, 2023 and 2022, the Company recognized \$81 and \$284, respectively, of stock compensation expense associated with these awards, with \$54 recorded in R&D expense and \$27 in G&A expense for the three months ended March 31, 2023, and \$54 recorded in R&D expense and \$230 in G&A expense for the three months ended March 31, 2022. G&A amounts recorded for the three months ended March 31, 2022 included \$203 of stock compensation expense relating to the modification of certain of these restricted stock units on November 1, 2021 (see *Stock Award Modifications* below). As of March 31, 2023, 15,999 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.



CARA THERAPEUTICS, INC.

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In February 2020, the Compensation Committee also approved and granted a total of 98,000 time-based restricted stock units to certain employees under the 2014 Plan with a grant date fair value of \$16.36 per share. The restricted stock units vest in three equal installments annually from the date of the grant. As a result, the Company recognizes compensation expense associated with these restricted stock units ratably over the three-year vesting period following the grant date. In February 2023, 15,999 of these restricted stock units vested and were settled in shares of the Company's common stock in satisfaction of the third year of vesting. In February 2022, 32,666 of these restricted stock units vested and were settled in shares of the Company's common stock in satisfaction of the second year of vesting. For the three months ended March 31, 2023 and 2022, the Company recognized \$39 and \$219, respectively, of stock compensation expense associated with these awards, with \$26 recorded in R&D expense and \$13 in G&A expense for the three months ended March 31, 2023, and \$43 recorded in R&D expense and \$176 in G&A expense for the three months ended March 31, 2022. G&A amounts recorded for the three months ended March 31, 2022 included \$155 of stock compensation expense relating to the modification of certain of these restricted stock units on November 1, 2021 (see *Stock Award Modifications* below). As of March 31, 2023, there were no outstanding restricted stock units available to vest or settle in shares of the Company's common stock.

A summary of restricted stock unit activity related to employees and non-employee members of the Company's Board of Directors as of and for the three months ended March 31, 2023 is presented below:

	Number of Units	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2022	372,513	\$ 13.20
Awarded	407,000	10.06
Vested and released	(83,793)	14.20
Outstanding, March 31, 2023	<u>695,720</u>	<u>\$ 11.24</u>
Restricted stock units exercisable (vested and deferred), March 31, 2023	<u>—</u>	

*Stock Options*

Under the 2014 Plan, the Company granted 1,449,154 and 977,438 stock options during the three months ended March 31, 2023 and 2022, respectively. No stock options were granted under the 2019 Inducement Plan during the three months ended March 31, 2023 and 2022. The fair values of stock options granted during the three months ended March 31, 2023 and 2022 were estimated as of the dates of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended March 31,	
	2023	2022
Risk-free interest rate	3.62% - 4.22%	1.70% - 2.35%
Expected volatility	76.3% - 81.3%	81.4% - 81.9%
Expected dividend yield	0%	0%
Expected life of employee and Board options (in years)	6.25	6.25

The weighted-average grant date fair value per share of options granted to employees and non-employee members of the Company's Board of Directors for their Board service during the three months ended March 31, 2023 and 2022 was \$7.08 and \$7.55. No options were granted to non-employee consultants during the three months ended March 31, 2023 and 2022.

## CARA THERAPEUTICS, INC.

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During the three months ended March 31, 2023 and 2022, the Company recognized compensation expense relating to stock options as follows:

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 1,480	\$ 1,917
General and administrative	1,241	2,030
Total stock option expense	<u>\$ 2,721</u>	<u>\$ 3,947</u>

The following were excluded from the table above as they are not related to stock options: compensation expense for (i) the vesting of certain employees' restricted stock units for \$179 in R&D expense and \$330 in G&A expense for the three months ended March 31, 2023; (ii) the vesting of certain employees' restricted stock units for \$167 in R&D expense and \$1,452 in G&A expense for the three months ended March 31, 2022; (iii) compensation expense relating to the Board of Directors' restricted stock units for \$123 in G&A expense for the three months ended March 31, 2023; and (iv) compensation expense relating to the Board of Directors' restricted stock units for \$139 in G&A expense for the three months ended March 31, 2022.

A summary of stock option award activity related to employees, non-employee members of the Company's Board of Directors and non-employee consultants as of and for the three months ended March 31, 2023 is presented below:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2022	7,689,449	\$ 14.35
Granted	1,449,154	10.06
Exercised	(93,218)	6.00
Forfeited	(52,626)	11.41
Outstanding, March 31, 2023	<u>8,992,759</u>	\$ 13.76
Options exercisable, March 31, 2023	<u>5,128,904</u>	

The Company does not expect to realize any tax benefits from its stock option activity or the recognition of stock-based compensation expense because the Company currently has net operating losses and has a full valuation allowance against its deferred tax assets. Accordingly, no amounts related to excess tax benefits have been reported in cash flows from operations for the three months ended March 31, 2023 and 2022.

#### *Stock Award Modifications*

In November 2021, the Company and the former President and CEO mutually agreed to a transition from CEO to a consulting role through June 30, 2022, if not terminated earlier per the terms of the consulting agreement. As a result, the Company modified the terms of its former CEO's outstanding Stock Awards to (1) automatically vest any unvested stock options or time-based restricted stock units that would have vested in the twelve month period following the end of the consulting period if continuous service is achieved with the Company during such twelve-month period; (2) extend the period during which the vested stock options may be exercised through the earlier of (i) eighteen months following the separation date (November 8, 2021); or (ii) the original expiration date applicable to each of the stock options, unless terminated earlier in accordance with the 2014 Plan, if continuous service is achieved with the Company; and (3) extend the period in which performance-based vesting milestones for restricted stock units may be achieved through March 31, 2022, if continuous service is achieved with the Company. The consulting agreement ended on June 30, 2022.

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The Company determined that vested Stock Awards which had modifications due to the extension of the exercise period were Type 1 modifications pursuant to Financial Accounting Standards Board Accounting Standards Codification 718, or ASC 718, because those Stock Awards would have vested before and after the modification. Acceleration of vesting for the Stock Awards that would have vested in the twelve-month period following the consulting term was determined to be a Type 3 modification requiring stock compensation expense pursuant to ASC 718 because absent the modification terms, those Stock Awards would have been forfeited as of the last day that the former CEO provided continuous service as a consultant. In addition, Type 4 performance-based restricted stock units were not considered probable of achieving performance targets on the modification date, but the vesting targets were achieved with respect to 17,333 performance-based restricted stock units in February 2022, which resulted in additional stock compensation expense being recorded during the three months ended March 31, 2022.

During the three months ended March 31, 2022, total incremental stock compensation expense relating to modifications of stock options, time-based and performance-based restricted stock units of the former CEO was \$1,564, which is included in G&A expense for the three months ended March 31, 2022. Of this total amount, \$903 is included in G&A expense in the stock option compensation expense table above for the three months ended March 31, 2022.

**15. Income Taxes**

The Company has recognized a full tax valuation allowance against its deferred tax assets as of March 31, 2023 and December 31, 2022. The tax benefit related to the exercise of stock options is recognized as a deferred tax asset that is offset by a corresponding valuation allowance. As such, the Company's effective tax rate is zero for the three months ended March 31, 2023 and 2022.

Historically, the Company's benefit from income taxes related to state R&D tax credits exchanged for cash pursuant to the Connecticut R&D Tax Credit Exchange Program, which permits qualified small businesses engaged in R&D activities within Connecticut to exchange their unused R&D tax credits for a cash amount equal to 65% of the value of the exchanged credits. It was not eligible to exchange its R&D tax credit for cash during the three months ended March 31, 2023 and 2022, therefore there was no benefit from income taxes for the three months ended March 31, 2023 and 2022. As of March 31, 2023, the Company recorded \$697 within income tax receivable which related to the 2020 R&D credit.

The Inflation Reduction Act of 2022 included tax legislation that became effective during the three months ended March 31, 2023. Significant legislation for corporate taxpayers includes a corporate alternative minimum tax of 15.0% for companies with \$1,000,000 or more in average net financial statement profits over the three previous years, as well as a 1.0% indirect excise tax on the repurchase of shares by a publicly traded company. The Company does not expect this legislation to have an effect on its tax provision as of March 31, 2023; however, the Company will continue to evaluate the effect on the tax provision each reporting period.

**16. Commitments and Contingencies**

*License Agreement with Enteris Biopharma, Inc.*

In August 2019, the Company entered into a non-exclusive license agreement, or the Enteris License Agreement, with Enteris Biopharma, Inc., or Enteris, pursuant to which Enteris granted to the Company a non-exclusive, royalty-bearing license, including the right to grant sublicenses, under certain proprietary technology and patent rights related to or covering formulations for oral delivery of peptide active pharmaceutical ingredients with functional excipients to

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enhance permeability and/or solubility, known as Enteris's Peptelligence<sup>®</sup> technology, to develop, manufacture and commercialize products using such technology worldwide, excluding Japan and South Korea.

The Company is also obligated, pursuant to the Enteris License Agreement, to pay Enteris (1) milestone payments upon the achievement of certain development, regulatory and commercial milestones and (2) low-single digit royalty percentages on net sales of licensed products, subject to reductions in specified circumstances. During the three months ended March 31, 2023 and 2022, no milestone payments or royalties were paid to Enteris by the Company in relation to the Enteris License Agreement.

*Manufacturing Agreements*

In July 2021, the Company entered into an API Commercial Supply Agreement with Polypeptide Laboratories S.A., or PPL, that defines each party's responsibilities with respect to PPL's manufacture and supply of the active pharmaceutical ingredient difelikefalin, or API, for the difelikefalin injection product candidate. Under the API Commercial Supply Agreement, PPL shall manufacture API at its facility for sale and supply to the Company, in the amounts as set forth in purchase orders to be provided by the Company. The Company will be required to purchase its requirements of API for each year of the term of the agreement, based on internal forecasts.

The API Commercial Supply Agreement will continue until the fifth anniversary of the approval by the FDA of the new drug application for KORSUVA injection, unless the API Commercial Supply Agreement is earlier terminated, and will automatically be extended for successive five-year periods unless either party gives notice to the other party of its intention to terminate.

In July 2019, the Company entered into a Master Manufacturing Services Agreement, or MSA, with Patheon UK Limited, or Patheon. The MSA governs the general terms under which Patheon, or one of its affiliates, will provide non-exclusive manufacturing services to the Company for the drug products specified by the Company from time to time. Pursuant to the MSA, the Company has agreed to order from Patheon at least a certain percentage of its commercial requirements for a product under a related Product Agreement. Each Product Agreement that the Company may enter into from time to time will be governed by the terms of the MSA, unless expressly modified in such Product Agreement.

In July 2019, the Company entered into two related Product Agreements under the MSA, one with each of Patheon and Patheon Manufacturing Services LLC, or Patheon Greenville, to govern the terms and conditions of the manufacture of commercial supplies of difelikefalin injection, the Company's lead product candidate. Pursuant to the Product Agreements, Patheon and Patheon Greenville will manufacture commercial supplies of difelikefalin injection at the Monza, Italy and Greenville, North Carolina manufacturing sites, respectively, from active pharmaceutical ingredient supplied by the Company. Patheon and Patheon Greenville will be responsible for supplying the other required raw materials and packaging components, and will also provide supportive manufacturing services such as quality control testing for raw materials, packaging components and finished product.

*Leases*

Lease expense is recognized on a straight-line basis over the lease term of the Company's lease agreements for its original headquarters, and additional office space, in Stamford, Connecticut. As a result, \$407 and \$406 of operating lease cost, or lease expense, was recognized for the three months ended March 31, 2023 and 2022, respectively, consisting of \$284 relating to R&D lease expense and \$123 relating to G&A lease expense for the 2023 period, and \$284 relating to R&D lease expense and \$122 relating to G&A lease expense for the 2022 period.

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Other information related to the leases was as follows:

	Three Months Ended March 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows relating to operating leases	\$ 494	\$ 485
ROU assets obtained in exchange for new operating lease liabilities	\$ —	\$ —
Remaining lease term - operating leases (years)	0.8	1.8
Discount rate - operating leases	7.0 %	7.0 %

Future minimum lease payments under non-cancellable operating leases, as well as a reconciliation of these undiscounted cash flows to the operating lease liabilities as of March 31, 2023, were as follows:

Year Ending December 31,	
2023 (Excluding the three months ended March 31, 2023)	\$ 1,498
Total future minimum lease payments, undiscounted	1,498
Less imputed interest	(42)
Total	<u>\$ 1,456</u>
Operating lease liabilities reported as of March 31, 2023:	
Operating lease liabilities - current	\$ 1,456
Operating lease liabilities - non-current	—
Total	<u>\$ 1,456</u>

**17. Related Party Transactions**

As of March 31, 2023, Vifor International owned 7,396,770, or 13.7%, of the Company's common stock. CSL Vifor and its affiliates are considered related parties as of March 31, 2023 and December 31, 2022 (see Note 11, *Collaboration and Licensing Agreements*).

As of March 31, 2023 and December 31, 2022, amounts due from CSL Vifor of \$6,066 and \$3,260 primarily relating to the Company's share of the profit generated by sales of KORSUVA injection in the United States by CSL Vifor and its commercial supply of KORSUVA injection to CSL Vifor were included within accounts receivable, net – related party.

The Company's collaborative revenue of \$2,750 from its share of the profit generated by sales of KORSUVA injection in the United States by CSL Vifor was included within collaborative revenue for the three months ended March 31, 2023.

Sales of KORSUVA injection to CSL Vifor of \$3,191 and \$4,790 were included within commercial supply revenue for the three months ended March 31, 2023 and 2022, respectively. The associated COGS for the Company's commercial supply revenue from CSL Vifor was \$2,590 and \$2,081 for the three months ended March 31, 2023 and 2022, respectively.

The Company recorded \$125 as royalty revenue based on net sales of Kapruvia during the three months ended March 31, 2023.

**Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

*In this Quarterly Report on Form 10-Q, the terms “we,” “us” and “our” refer to Cara Therapeutics, Inc. Also, in this Quarterly Report, unless the context otherwise requires, we use the term “CSL Vifor” to refer to CSL Vifor and its affiliated entities, including where applicable, the joint venture between CSL Vifor and Fresenius Medical Care with which we are a party to two collaborations for the commercialization of KORSUVA (difelikefalin) injection.*

**Cautionary Note Regarding Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words “aim,” “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “predict,” “project,” “potential,” “seek,” “should,” “will,” or “would,” and or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our ability to successfully commercialize KORSUVA® (difelikefalin) injection, or KORSUVA injection, our difelikefalin injection product which was granted marketing authorization in the United States, Canada, Australia, and Singapore, or Kaprivia® (difelikefalin), which was granted marketing authorization in the European Union, or the EU, the United Kingdom, or the UK, and Switzerland, or to execute on our marketing plans for any other drugs or indications that may be approved in the future;
- our ability to pursue regulatory submissions or obtain regulatory approvals for difelikefalin injection in any additional territories including receiving a positive outcome on the ongoing regulatory review in Japan;
- our ability to obtain and maintain coverage and adequate reimbursement for KORSUVA injection or Kaprivia in markets around the world;
- the potential approval of the U.S. Centers for Medicare & Medicaid Services, or CMS’s, end-stage renal disease, or ESRD, Prospective Payment System, or PPS, proposed rule to update Medicare payment policies and rates for renal dialysis services;
- the performance of our current and future collaborators and licensees, including CSL Vifor, a business formed as a result of CSL Limited’s acquisition of Vifor Pharma AG in August 2022, Vifor Fresenius Medical Care Renal Pharma Ltd. (CSL Vifor’s joint venture with Fresenius Medical Care), Maruishi Pharmaceuticals Co. Ltd., or Maruishi, and Chong Kun Dang Pharmaceutical Corp., or CKDP, as well as sub-licensees, including Winhealth Pharma and Kissei Pharmaceutical Co. Ltd., or Kissei, and our ability to maintain such collaborations;
- risks that KORSUVA injection and Kaprivia revenues, expenses and costs may not be as expected;
- the performance of third-party manufacturers, clinical research organizations, or CROs, and other vendors;
- risks relating to KORSUVA injection’s and Kaprivia’s market acceptance, competition, reimbursement and regulatory actions;

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- the size and growth of the potential markets for pruritus management, including chronic kidney disease associated pruritus, or CKD-aP, in hemodialysis and non-dialysis markets, pruritus associated with atopic dermatitis, or AD-aP, and pruritus associated with notalgia paresthetica, or NP, markets;
- the success and timing of our clinical trials and reporting of our results from these trials, including our clinical trial programs for oral difelikefalin in non-dialysis dependent advanced chronic kidney disease, or NDD-CKD, AD-aP, or NP;
- our plans to develop and commercialize oral difelikefalin and any future indication or product candidates;
- the potential results of ongoing and planned preclinical studies and clinical trials and future regulatory and development milestones for our product candidates;
- the rate and degree of market acceptance of any other future approved indications or products;
- our ability to obtain and maintain additional regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- the anticipated use of Enteris Biopharma, Inc.'s, or Enteris's, Peptelligence® technology to develop, manufacture and commercialize oral difelikefalin;
- our ability to establish additional collaborations for our product candidates;
- the continued service of our key scientific or management personnel;
- our ability to establish commercialization and marketing capabilities for any other future approved indications or products;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain coverage and adequate reimbursement from third-party payers for any other future approved indications or products;
- our planned use of our cash and cash equivalents and marketable securities and the clinical milestones we expect to fund with such proceeds;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- our ability to obtain funding for our operations;
- our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- our ability to maintain proper and effective internal controls, especially due to our high dependence on CSL Vifor for timely and accurate information;
- the success of competing drugs that are or may become available; and
- the potential effects of the COVID-19 pandemic or future global health crises, geopolitical tensions and macroeconomic conditions on our business, operations and clinical development and regulatory timelines and plans as well as commercial and clinical drug supply chain continuity and the commercial launch of KORSUVA injection and Kapruvia.

You should refer to the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2022 and in this Quarterly Report on Form 10-Q for a discussion of material factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate.

Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

The following *Management’s Discussion and Analysis of Financial Condition and Results of Operations* should be read in conjunction with: (i) the Condensed Financial Statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (ii) our Annual Report on Form 10-K for the year ended December 31, 2022.

## Overview

We are a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. Our KORSUVA injection is the first and only U.S. Food and Drug Administration, or FDA, approved treatment for moderate-to-severe pruritus associated with chronic kidney disease, or CKD, in adults undergoing hemodialysis. We are developing an oral formulation of difelikefalin and have initiated Phase 3 programs for the treatment of pruritus in patients with NDD-CKD and atopic dermatitis, or AD. We have also initiated a Phase 2/3 program of oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with NP.

On August 23, 2021, our lead product, KORSUVA injection, was approved by the FDA for the treatment of moderate-to-severe pruritus associated with CKD in adults undergoing hemodialysis in the United States. In December 2021, CMS granted Transition Drug Add-on Payment Adjustment, or TDAPA, to KORSUVA injection in the anti-pruritic functional category. TDAPA went into effect on April 1, 2022, for a minimum of two years. The commercial launch of KORSUVA injection commenced in April 2022 and we began recording the associated profit-sharing revenues in the second quarter of 2022. We are partnering with CSL Vifor to commercialize KORSUVA injection in dialysis patients with CKD-aP worldwide, excluding Japan (Maruishi/sub-licensee Kissei), and South Korea (CKDP).

In April 2022, the European Commission granted marketing authorization to difelikefalin injection under the brand name Kapruvia for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult hemodialysis patients. The marketing authorization approves Kapruvia for use in all member states of the EU, as well as Iceland, Liechtenstein, and Norway. Kapruvia was also approved in the UK in April 2022. Commercial launches in Austria, Germany, Sweden, France, the Netherlands, and Finland have commenced. In August 2022, as part of the Access Consortium, difelikefalin injection was approved in Switzerland under the brand name Kapruvia, as well as Singapore and Canada under the brand name KORSUVA. Commercial launch in Switzerland has also commenced. In November 2022, difelikefalin injection was approved in the last Access Consortium country, Australia, under the brand name KORSUVA. We expect additional commercial launches to commence over the next 12-18 months.

In 2018, we entered into a licensing and collaboration agreement with Vifor Fresenius Medical Care Renal Pharma Ltd. In 2020, we entered into a second licensing and collaboration agreement, along with stock purchase agreements, with Vifor International. In May 2022, Vifor International assigned its rights and obligations under the license agreement and a supply agreement, as permitted under the agreements, to Vifor Fresenius Medical Care Renal Pharma Ltd. Our rights and obligations under these agreements were unaffected by this assignment, and the assignment did not affect our economic rights under the agreements with Vifor International.



In August 2022, Vifor Pharma Group (which includes Vifor International) was acquired by CSL Limited and subsequently renamed CSL Vifor as part of the acquisition. The acquisition of Vifor Pharma Group did not affect any of the Company's rights and obligations pursuant to these agreements.

We are partnering with CSL Vifor to commercialize KORSUVA injection in dialysis patients with CKD-aP worldwide, excluding Japan (Maruishi/sub-licensee Kissei), and South Korea (CKDP). CSL Vifor is a leading nephrology organization with a significant presence in nephrology offices and dialysis centers. In the United States, we launched KORSUVA injection into a highly concentrated market. The dialysis market is dominated by two large dialysis organizations, or LDOs, Fresenius Medical Care, or FMC, and DaVita, which combined control about 75% of the market. In addition, reimbursement is dominated by Medicare which covers about 80% of the CKD hemodialysis patients. Outside of the United States, the dialysis market is not dominated by any corporate dialysis companies and is much more fragmented than in the United States. Furthermore, each country has its own unique reimbursement system for hemodialysis patients.

We have built a pipeline around an oral formulation of difelikefalin, the active compound in KORSUVA injection and Kaprivia. Our strategy is focused on maximizing the potential and utility of oral difelikefalin across our two core franchises: nephrology and medical dermatology. We have an active late-stage pipeline of oral difelikefalin that addresses broad, underserved, significant markets in nephrology and dermatology. We have three potentially pivotal programs underway for chronic pruritus in: a) NDD-CKD; b) AD; and c) NP.

Based on our completed Phase 2 trials and successful End of Phase 2 meetings with the FDA, we initiated two Phase 3 clinical programs of oral difelikefalin for the treatment of chronic pruritus, one in NDD-CKD and the other in AD, in the first quarter of 2022, as well as a Phase 2/3 program of oral difelikefalin for the treatment of moderate-to-severe pruritus in NP in the first quarter of 2023.

We were incorporated and commenced operations in 2004, and our primary activities to date have been organizing and staffing our company, developing our lead product and product candidates, including conducting preclinical studies and clinical trials of difelikefalin-based product candidates and raising capital. To date, we have financed our operations primarily through sales of our equity and debt securities and payments from license agreements.

## Overview of our Product Candidates

Our current product and product candidate pipeline is summarized in the table below:

Program	Product Candidate	Primary Indication	Status	Commercialization Rights
Pruritus	KORSUVA (difelikefalin) injection	Pruritus CKD - Hemodialysis	<ul style="list-style-type: none"> <li>• FDA approved in August 2021</li> <li>• TDAPA designation granted in December 2021 by CMS, effective April 2022</li> <li>• EMA MAA approved in April 2022 (Kaprivia)</li> <li>• UK MAA approved in April 2022 (Kaprivia)</li> <li>• Switzerland (Kaprivia), Canada (KORSUVA) and Singapore (KORSUVA) MAAs approved in August 2022</li> <li>• Australia (KORSUVA) approved in November 2022</li> <li>• Japan New Drug Application filed in September 2022</li> <li>• U.S. commercial launch commenced in April 2022</li> <li>• EU commercial launch commenced in third quarter of 2022</li> </ul>	CSL Vifor (Worldwide, other than Japan and South Korea); Maruishi (Japan); CKDP (South Korea)
	Oral difelikefalin	Pruritus AD-aP	<ul style="list-style-type: none"> <li>• Phase 3 program initiated in first quarter of 2022</li> </ul>	Cara (Worldwide, other than South Korea); CKDP (South Korea)
	Oral difelikefalin	Pruritus NDD-CKD	<ul style="list-style-type: none"> <li>• Phase 3 program initiated in first quarter of 2022</li> </ul>	Cara (Worldwide, other than Japan and South Korea); Maruishi (Japan); CKDP (South Korea)
	Oral difelikefalin	Pruritus NP	<ul style="list-style-type: none"> <li>• Phase 2 trial reported in second quarter of 2022</li> <li>• Phase 2/3 program initiated in first quarter of 2023</li> </ul>	Cara (Worldwide, other than South Korea); CKDP (South Korea)

## Our Nephrology Franchise

### *KORSUVA (difelikefalin) injection – Our Commercial Product*

#### *Overview*

On August 23, 2021, our lead product, KORSUVA injection, was approved by the FDA for the treatment of moderate-to-severe pruritus associated with CKD in adults undergoing hemodialysis. In December 2021, CMS granted TDAPA to KORSUVA injection in the anti-pruritic functional category. TDAPA went into effect on April 1, 2022, for a minimum of two years. The commercial launch of KORSUVA injection commenced in April 2022 and we began recording the associated profit-sharing revenues in the second quarter of 2022. We are partnering with CSL Vifor to commercialize KORSUVA injection in dialysis patients with CKD-aP worldwide, excluding Japan (Maruishi/sub-licensee Kissei), and South Korea (CKDP). For the three months ended March 31, 2023, CSL Vifor recorded net sales of

KORSUVA injection in the United States of approximately \$5.7 million and we recorded associated collaborative revenue of \$2.8 million which represented our share of the profit from these sales.

In April 2022, the European Commission granted marketing authorization to difelikefalin injection under the brand name Kapruvia for the treatment of moderate-to-severe pruritus associated with CKD in adult hemodialysis patients. The marketing authorization approves Kapruvia for use in all member states of the EU, as well as Iceland, Liechtenstein, and Norway. Kapruvia was also approved in the UK in April 2022. Commercial launches in Austria, Germany, Sweden, France, the Netherlands, and Finland have commenced. In August 2022, as part of the Access Consortium, difelikefalin injection was approved in Switzerland under the brand name Kapruvia, as well as Singapore and Canada under the brand name KORSUVA. Commercial launch in Switzerland has also commenced. In November 2022, difelikefalin injection was approved in the last Access Consortium country, Australia, under the brand name KORSUVA. For the three months ended March 31, 2023, we recorded royalty revenue of approximately \$125,000 which represented our royalties on net sales of Kapruvia in Europe. We expect additional commercial launches to commence over the next 12-18 months.

In addition, our partner in Japan, Maruishi, announced positive Phase 3 top-line data in January 2022. Maruishi and its sublicensee Kissei confirmed the primary endpoint was achieved in a Japanese Phase 3 clinical study (double-blind, placebo-controlled period) of difelikefalin injection for the treatment of pruritus in hemodialysis patients. In the Phase 3 study, 178 patients were administered difelikefalin or placebo for 6 weeks followed by an open-label extension period of difelikefalin administration for 52 weeks. The primary endpoint, change in itch numerical rating scale, or NRS, and the secondary endpoint, change in itch scores of Shiratori severity criteria, were significantly improved from baseline compared to the placebo group. Difelikefalin was well-tolerated.

In September 2022, Maruishi submitted a New Drug Application in Japan for the approval of difelikefalin injection for the treatment of pruritus in hemodialysis patients. A final decision on the application is expected in the second half of 2023.

In January 2023, Vifor Fresenius Medical Care Renal Pharma Ltd. and Winhealth Pharma signed a long-term exclusive licensing agreement for the co-development and commercialization of KORSUVA injection for the treatment of moderate-to-severe pruritus in adult patients undergoing hemodialysis in China.

*Summary of the Clinical Results for KORSUVA injection/Kapruvia:*

KORSUVA injection was approved by the FDA on August 23, 2021 and is the first and only product approved for the treatment of moderate-to-severe pruritus associated with CKD in adult patients undergoing hemodialysis in the United States.

It was approved based on the NDA filing that was supported by positive data from two pivotal Phase 3 trials – KALM™-1, conducted in the United States, and KALM-2 conducted globally, as well as supportive data from an additional 32 clinical studies. KORSUVA injection was found to be generally well tolerated in the pivotal studies highlighted below.

In April 2020, we announced positive top-line results from the double blinded KALM-2 pivotal Phase 3 trial of KORSUVA injection in hemodialysis patients with moderate-to-severe CKD-aP. The study met the primary efficacy endpoint with 54% of the patients receiving 0.5 mcg/kg of KORSUVA injection vs. 42% of patients receiving placebo achieving at least a three-point improvement from baseline with respect to the weekly mean of the daily 24-hour worst itch intensity NRS at week 12 ( $p=0.02$ ). The study also met the key secondary endpoint with 41% of patients receiving KORSUVA injection achieving a four-point or greater improvement from baseline in the weekly mean of the daily 24-hour worst itch NRS score at week 12 vs. 28% for patients receiving placebo ( $p=0.01$ ). In this trial, KORSUVA injection was generally well-tolerated with a safety profile consistent with that seen in KALM-1 and the KORSUVA clinical program in patients with CKD-aP.

Overall, the incidence of adverse effects, or AEs, and serious AEs were similar across both KORSUVA injection and placebo groups. The most common treatment emergent AEs reported in greater than 5% of patients were diarrhea

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(8.1% KORSUVA vs. 5.5% placebo), falls (6.8% KORSUVA vs. 5.1% placebo), vomiting (6.4% KORSUVA vs. 5.9% placebo), nausea (6.4% KORSUVA vs. 4.2% placebo) and dizziness (5.5% KORSUVA vs. 5.1% placebo).

In May 2019, we announced positive results from the double blinded phase of our KALM-1 pivotal Phase 3 trial of KORSUVA injection in hemodialysis patients with moderate-to-severe CKD-aP. The study met the primary efficacy endpoint with 51% of the patients receiving 0.5 mcg/kg of KORSUVA injection vs. 28% of patients receiving placebo achieving at least a three-point improvement from baseline with respect to the weekly mean of the daily 24-hour worst itch intensity NRS score at week 12 (p= 0.00019). The study also met all secondary endpoints, including assessment of itch-related quality of life changes measured using self-assessment Skindex-10 (patients receiving KORSUVA experienced 43% improvement vs. patients receiving placebo, p= 0.0004) and 5-D Itch scales (patients receiving KORSUVA experienced 35% improvement vs. patients receiving placebo, p= 0.0009). In addition, 39% of patients receiving KORSUVA injection achieved a four-point or greater improvement from baseline in the weekly mean of the daily 24-hour worst itch NRS score at week 12 vs. 18% of patients receiving placebo (p= 0.00032), another key secondary endpoint. In this trial, KORSUVA injection was generally well-tolerated with a safety profile consistent with that seen in earlier trials.

Overall, the incidence of AEs and serious AEs were similar across both KORSUVA injection and placebo groups. The most common treatment emergent AEs reported in greater than 5% of patients were diarrhea (9.5% KORSUVA vs. 3.7% placebo), dizziness (6.9% KORSUVA vs. 1.1% placebo), vomiting (5.3% KORSUVA vs. 3.2% placebo) and nasopharyngitis (3.2% KORSUVA vs. 5.3% placebo).

### *KORSUVA Injection U.S. Launch Progress*

In April 2022, our partner CSL Vifor initiated the commercialization of KORSUVA injection in the United States. The launch was initially driven by independent and mid-size dialysis organizations coupled with product stocking at the wholesaler level. In the third quarter of 2022, LDOs came on-line driving a significant quarter-to-quarter increase in order volume from the wholesaler. Specifically, Fresenius placed large orders to drive the trial and adoption of KORSUVA injection across its entire network of clinics. In the third quarter of 2022, CSL Vifor also contracted the sales force of Fresenius Renal Pharmaceuticals, a division of Fresenius Medical Care North America, to complement CSL Vifor's sales force in selling into Fresenius clinics in the United States. After the initial inventory building at both the wholesaler and certain clinics (primarily, Fresenius), we have started to see shipments to dialysis organizations reflect true end-user demand versus the stocking activity seen in prior quarters. In the first quarter of 2023, KORSUVA injection generated net sales of \$5.7 million and we recorded collaborative revenue of \$2.8 million, which represented our share of the profit from sales of KORSUVA injection. Wholesalers shipped 45,720 vials to dialysis centers, the majority of which were Fresenius clinics, during the first quarter of 2023. Vial orders more than doubled quarter to quarter, signifying an acceleration in patient demand.

### *KORSUVA Injection and Kapruvia Revenue and Other Metrics*

We generate revenue from our lead products KORSUVA injection and Kapruvia primarily through our collaboration agreements with CSL Vifor:

- Collaborative revenue from our share of the profit generated by KORSUVA injection sales in the United States. For the three months ended March 31, 2023, we recorded collaborative revenue of approximately \$2.8 million related to our share of the profit.
- Commercial supply revenue from our sales of commercial product to CSL Vifor, which is subsequently sold to wholesalers. For the three months ended March 31, 2023, we recorded commercial supply revenue of approximately \$3.2 million.
- Royalty revenue in conjunction with the launch of Kapruvia in Europe. For the three months ended March 31, 2023, we recorded royalty revenue of approximately \$125,000.

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- Sales-based or regulatory milestone payments, which could be earned in the future in accordance with certain licensing agreements. For the three months ended March 31, 2023, we did not record any sales-based milestone revenue.

In addition to the information above, there are metrics that we have reported in the past and intend to continue to report in the future, including:

- Net sales of KORSUVA injection in the United States. This amount is the net sales amount recorded by CSL Vifor to reflect shipments of KORSUVA injection vials from CSL Vifor to wholesalers. For the three months ended March 31, 2023, CSL Vifor recorded net sales of KORSUVA injection in the United States of approximately \$5.7 million.
- Our share of profit from KORSUVA injection that we record as collaborative revenue. For the three months ended March 31, 2023, we recorded collaborative revenue of approximately \$2.8 million related to our share of the profit.
- Shipments of KORSUVA injection vials from wholesalers to the dialysis clinics. For the three months ended March 31, 2023, 45,720 KORSUVA injection vials were shipped from wholesalers to the dialysis clinics.

### ***Oral Difelikefalin for Treatment of Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD) Associated Pruritus***

In December 2019, we announced top-line data from our Phase 2 trial of oral difelikefalin for the treatment of pruritus in NDD-CKD patients diagnosed with Stage III – V CKD. The Phase 2, multicenter, randomized, double-blind, placebo-controlled 12-week trial was designed to evaluate the safety and efficacy of three dosage strengths (0.25 mg, 0.5 mg and 1 mg, once daily administration) of oral difelikefalin vs. placebo in approximately 240 stage III - V (moderate-to-severe) CKD patients with moderate-to-severe pruritus. The primary efficacy endpoint was the change from baseline in the weekly mean of the daily 24-hour worst itch NRS score at week 12 of the treatment period. Secondary endpoints included change from baseline in itch-related quality of life scores at the end of week 12, as assessed by the total Skindex-10 and 5-D itch scores, as well as the proportion of patients achieving an improvement from baseline  $\geq 3$  points with respect to the weekly mean of the daily 24-hour worst itch NRS score at week 12.

Patients treated with the 1 mg dosage strength of oral difelikefalin achieved the primary endpoint of statistically significant reduction in weekly mean of the daily worst itch NRS scores vs. placebo after the 12-week treatment period (-4.4 difelikefalin vs. -3.3 placebo,  $p=0.018$ ). The treatment was statistically significant after two weeks of treatment with sustained benefit through the 12-week treatment period. Regarding secondary endpoints, the proportion of patients on 1 mg tablet strength achieving a 3 point or greater improvement from baseline in the weekly mean of the daily worst itch NRS score at week 12 was 72% vs. 58% for placebo but did not achieve statistical significance. Furthermore, patients on 1 mg dosage strength showed positive improvements vs. placebo in itch quality of life endpoints as measured by the self-assessment Skindex-10 and 5-D Itch scales but this did not achieve statistical significance.

Oral difelikefalin was generally well-tolerated with a safety profile consistent with that seen in earlier KORSUVA clinical trials. Overall, the incidence of treatment AEs were similar across difelikefalin and placebo groups. The most common AEs reported in  $>5\%$  of patients in the 1 mg difelikefalin group vs. placebo were dizziness (7.5% difelikefalin vs. 0% placebo), fall (6% difelikefalin vs. 0% placebo), diarrhea (6% difelikefalin vs. 1.5% placebo) and constipation (6% difelikefalin vs. 3% placebo).

In April 2021, we held an End of Phase 2 Meeting with the FDA to discuss the results of the Phase 2 trial of oral difelikefalin in NDD-CKD and the potential Phase 3 program. The FDA indicated the acceptability of Stage V pre-dialysis CKD patients as a viable patient population for a program. In November 2021, the FDA provided written guidance indicating the patient population can be expanded to include the group of Stage IV pre-dialysis patients with advanced CKD in a registration program consisting of two pivotal Phase 3 clinical trials.

In the first quarter of 2022, we initiated the Phase 3 NDD-CKD program. The Phase 3 program consists of two identically designed trials (U.S. and global), KICK 1 and KICK 2. Each trial is expected to enroll approximately 400 patients, who will be randomized 1:1 to either oral difelikefalin 1 mg once daily or matching placebo. The study population will include adult patients suffering from moderate-to-severe pruritus with advanced CKD in Stages IV or V, not on dialysis. The primary endpoint will be the proportion of patients with a  $\geq 4$ -point improvement at Week 12 from baseline in the worst-itch NRS after which patients will be re-randomized to either oral difelikefalin or placebo for 52-weeks. We expect to report top-line results from this program in the second half of 2024.

## **Our Dermatology Franchise**

### ***Oral Difelikefalin for Treatment of Moderate-to-Severe Pruritus Associated with Atopic Dermatitis (AD)***

In April 2021, we announced top-line data from our Phase 2 KARE clinical trial. The KARE Phase 2 trial was a randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of oral difelikefalin for moderate-to-severe pruritus in 401 adult subjects with AD-aP. KARE enrolled 64% of patients characterized as mild-to-moderate AD (Body Surface Area, or BSA,  $<10\%$ ) and 36% as moderate-to-severe AD (BSA  $>10\%$ ). Subjects were randomized to three dosage strengths of oral difelikefalin: 0.25 mg, 0.5 mg and 1 mg taken twice daily (BID) vs. matching placebo for 12 weeks followed by 4 weeks of an open-label active extension phase. A prespecified interim conditional power assessment was conducted after approximately 50% of the originally targeted patient number completed the 12-week treatment period. Based on the Independent Data Monitoring Committee's recommendation, the sample size for each of the 0.5 mg dose and placebo groups were increased, taking the total trial size up by 28%.

KARE's primary efficacy endpoint was change from baseline in the weekly mean of the daily 24-hour Itch NRS score at week 12 of the treatment period for the intent to treat, or ITT, population. Although no dose group met this endpoint, a statistically significant improvement from baseline was evident as early as week 1 for the 1 mg dose group, which was sustained through 75% of the treatment period.

In a prespecified analysis, a statistically significant change in the primary efficacy endpoint was observed in the mild-to-moderate (BSA  $<10\%$ ) AD patient population ( $p=0.036$ , All doses vs. placebo), which was evident at week 1 and sustained through the 12-week treatment period.

The key secondary endpoint for KARE was the assessment of the proportion of patients achieving an improvement from baseline of  $\geq 4$  points with respect to the weekly mean of the daily 24-hour Itch NRS score at week 12 (4-point Responder Analysis). No dose group met this endpoint for the ITT population.

A prespecified analysis by disease severity indicated a statistically significant improvement in the 4-point Responder Analysis in the mild-to-moderate (BSA  $<10\%$ ) AD patient population with 33% of difelikefalin-treated patients achieving a  $\geq 4$ -point reduction in NRS at Week 12 vs. 19% in the placebo group for the 0.5 mg dose ( $p=0.046$ ). All doses performed similarly (0.25 mg, 0.5 mg, and 1 mg) vs. placebo. Oral difelikefalin was generally well-tolerated across all doses.

In the first quarter of 2022, we initiated a Phase 3 program for the treatment of moderate-to-severe pruritus in AD patients. The pivotal Phase 3 program for difelikefalin in AD comprises two studies: KIND 1 and KIND 2 and will investigate the use of oral difelikefalin as adjunctive treatment to topical corticosteroids. The KIND 1 study will be composed of two parts: Part A and Part B.

KIND 1 and KIND 2 will be double-blind, controlled, 12-week studies with patients allowed to roll-over into open label 52-week extensions. Part A of KIND 1, the dose finding portion of the trial, is expected to include 280 patients who will be randomized equally to four arms (0.25 mg BID + TCS, 0.5 mg BID + TCS, placebo BID + TCS, placebo BID + vehicle). At the end of the 12-week treatment period in Part A of KIND 1, we expect to have an internal data readout targeted for the fourth quarter of 2023. This readout will provide key information, specifically the dose and the sample size to initiate Part B of KIND 1 and KIND 2. Part B and KIND 2 will be identical in design. They will be double-blind, controlled, 12-week studies with patients randomized 1:1 to either difelikefalin or matching placebo as adjunct treatment to topical corticosteroids. The difelikefalin dose is expected to be based on the results from Part A of

KIND 1. The primary endpoint will be the proportion of patients with a  $\geq 4$ -point improvement at Week 12 from baseline in the worst itch NRS.

The studies will include adult patients with AD whose chronic pruritus has not been adequately controlled by topical therapy alone and who have had chronic pruritus of moderate-to-severe intensity for  $\geq 6$  weeks (worst itch NRS of  $\geq 5$ ). Patients must have an Investigator Global Assessment  $\geq 2$  and a BSA  $\leq 20\%$ . We will stratify patients to a BSA  $< 10\%$  or  $\geq 10\%$  with the aim to enroll 85% of patients with a BSA  $< 10\%$ .

We expect to release top-line results for both KIND 1 Part B and KIND 2 in the first half of 2025.

### ***Oral Difelikefalin for Treatment of Moderate-to-Severe Pruritus Associated with Notalgia Paresthetica (NP)***

In June 2022, we announced positive top-line results from the proof-of-concept Phase 2 KOMFORT trial of oral difelikefalin for the treatment of pruritus in patients with NP.

KOMFORT was a Phase 2 randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of oral difelikefalin for moderate-to-severe pruritus in 125 adult patients with NP and moderate-to-severe pruritus. Patients were randomized to receive oral difelikefalin 2 mg twice daily (BID) vs. matching placebo for eight weeks followed by a 4-week open-label active extension period and follow-up visit approximately 14 days after the last dose of the study drug.

KOMFORT's primary efficacy endpoint was the change from baseline in the weekly mean of the daily 24-hour worst itch NRS score at week 8 of the treatment period. Patients treated with oral difelikefalin achieved the primary endpoint (-4.0 difelikefalin vs. -2.4 placebo,  $p=0.001$ ) with statistically significant improvement observed as early as Week 1 and sustained through Week 8.

Other endpoints included a  $\geq 4$ -point improvement in worst itch NRS, complete response in worst itch NRS, and safety assessments. A statistically significantly greater proportion of patients treated with oral difelikefalin achieved a  $\geq 4$ -point improvement in worst itch NRS score at Week 8 vs. placebo (41% difelikefalin vs. 18% placebo,  $p=0.007$ ). In addition, oral difelikefalin met the complete response endpoint, defined as a worst itch NRS score of 0 or 1 for 70% of the daily non-missing worst itch NRS scores for the week. At Week 8, a significantly greater proportion of patients receiving oral difelikefalin vs. placebo achieved a complete response (22% difelikefalin vs. 5% placebo,  $p<0.01$ ).

Oral difelikefalin was generally well tolerated, with all AEs in difelikefalin-treated patients reported as mild or moderate in severity. Nausea, headache, dizziness, constipation, and increased urine output were more commonly reported in patients on difelikefalin.

In November 2022, we had a positive interaction with the FDA leading to the initiation of a Phase 2/3 program for the treatment of chronic pruritus associated with NP. In February 2023, the results of our KOMFORT Phase 2 trial were published in the *New England Journal of Medicine*.

In the first quarter of 2023, we initiated a Phase 2/3 program for the treatment of moderate-to-severe pruritus in NP patients. The Phase 2/3 program for difelikefalin in NP will comprise two studies: KOURAGE 1 and KOURAGE 2. The KOURAGE 1 study will be composed of two parts: Part A and Part B.

KOURAGE 1 and KOURAGE 2 will be double-blind, placebo-controlled, 8-week studies with patients allowed to roll-over into open label 52-week extensions. Part A of KOURAGE 1, the dose finding portion of the trial, is expected to include 200 patients who will be randomized equally to four arms (0.25 mg BID, 1.0 mg BID, 2.0 mg BID, placebo BID). At the end of the 8-week treatment period in Part A of KOURAGE 1, we expect to have an internal data read out targeted for the second half of 2024. This readout will provide key information, specifically the dose and the sample size to initiate Part B of KOURAGE 1 and KOURAGE 2. Part B and KOURAGE 2 will be identical in design. They will be double-blind, placebo-controlled, 8-week studies with patients randomized 1:1 to either difelikefalin or matching placebo. The difelikefalin dose is expected to be based on the results from Part A of KOURAGE 1. The primary endpoint will be the proportion of patients with a  $\geq 4$ -point improvement at Week 8 from baseline in the worst itch NRS.



The studies will include adult patients with NP who have had chronic pruritus of moderate-to-severe intensity for  $\geq 6$  months (worst itch NRS of  $\geq 5$ ).

We expect to release top-line results for both KOURAGE 1 Part B and KOURAGE 2 in the first half of 2026.

## **Collaboration and License Agreements**

### *Vifor (International) Ltd., or Vifor International*

In October 2020, we entered into a license agreement with Vifor International, or Vifor Agreement No. 1, under which we granted Vifor International an exclusive license solely in the United States to use, distribute, offer for sale, promote, sell and otherwise commercialize KORSUVA (difelikefalin) injection for all therapeutic uses relating to the inhibition, prevention or treatment of itch associated with pruritus in hemodialysis and peritoneal dialysis patients in the United States. Under Vifor Agreement No. 1, we retain all rights with respect to the clinical development of, and activities to gain regulatory approvals of, KORSUVA (difelikefalin) injection in the United States.

Under the terms of Vifor Agreement No. 1, we received from Vifor International an upfront payment of \$100.0 million and an additional payment of \$50.0 million for the purchase of an aggregate of 2,939,552 shares of our common stock at a price of \$17.0094 per share, which represents a premium over a pre-determined average closing price of our common stock. The purchase of our common stock was governed by a separate stock purchase agreement, or the Vifor Stock Purchase Agreement.

After U.S. regulatory approval of KORSUVA injection in August 2021, we received an additional \$50.0 million in October 2021 for the purchase of an aggregate of 3,282,391 shares of our common stock at a price of \$15.23 per share, which represents a 20% premium to the 30-day trailing average price of our common stock. The purchase of our common stock was governed by the Vifor Stock Purchase Agreement. The excess of the stock purchase price over the cost of the purchased shares at the closing price of our common stock on the date of the achievement of the milestone of \$5.0 million was included as license and milestone fees revenue for accounting purposes. In addition, pursuant to Vifor Agreement No. 1, we are eligible to receive payments of up to \$240.0 million upon the achievement of certain sales-based milestones.

In connection with Vifor Agreement No. 1, we also have a related supply agreement with Vifor International, or Vifor International Supply Agreement, pursuant to which we retain the right to make and have made KORSUVA injection, on a non-exclusive basis, worldwide for commercial sale of KORSUVA injection for use in all therapeutic uses to prevent, inhibit or treat itch associated with pruritus in hemodialysis and peritoneal-dialysis patients and for supply of difelikefalin injection, or Licensed Product, to Vifor International. The supply price is our cost of goods sold, or COGS, as calculated under GAAP, plus an agreed upon margin. The Vifor International Supply Agreement will co-terminate with Vifor Agreement No. 1.

Vifor Agreement No. 1 provides full commercialization rights in dialysis clinics to Vifor International in the United States under a profit-sharing arrangement. Pursuant to the profit-sharing arrangement, we are generally entitled to 60% of the net profits (as defined in Vifor Agreement No. 1) from sales of KORSUVA injection in the United States and Vifor International is entitled to 40% of such net profits (excluding sales to Fresenius Medical Center dialysis clinics, compensation for which is governed by Vifor Agreement No. 2, as defined below), subject to potential temporary adjustment in future years based on certain conditions. Under Vifor Agreement No. 1, in consideration of Vifor International's conduct of the marketing, promotion, selling and distribution of KORSUVA injection in the United States, we pay a marketing and distribution fee to Vifor International based on the level of annual net sales. This fee as well as Vifor International's COGS are deducted from net sales in calculating the net profits that are subject to the profit-sharing arrangement under Vifor Agreement No. 1.

In May 2022, Vifor International assigned its rights and obligations under the license agreement and a supply agreement, as permitted under the agreements, to Vifor Fresenius Medical Care Renal Pharma Ltd. Our rights and obligations under these agreements were unaffected by this assignment, and the assignment did not affect our economic rights under the agreements with Vifor International.



In August 2022, Vifor Pharma Group (which includes Vifor International) was acquired by CSL Limited and subsequently renamed CSL Vifor as part of the acquisition. The acquisition of Vifor Pharma Group did not affect any of the Company's rights and obligations pursuant to these agreements.

*Vifor Fresenius Medical Care Renal Pharma Ltd.*

In May 2018, we entered into a license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd., or Vifor Agreement No. 2, under which we have granted Vifor Fresenius Medical Care Renal Pharma Ltd. a license to seek regulatory approval to commercialize, import, export, use, distribute, offer for sale, promote, sell and otherwise commercialize KORSUVA (difelikefalin) injection for all therapeutic uses to prevent, inhibit or treat itch associated with pruritus in hemodialysis and peritoneal-dialysis patients worldwide (excluding the United States, Japan and South Korea). We retained full development and commercialization rights for KORSUVA injection for the treatment of CKD-aP in dialysis patients in the United States except in the dialysis clinics of Fresenius Medical Care North America, or FMCNA, where Vifor Fresenius Medical Care Renal Pharma Ltd. will promote KORSUVA injection under a profit-sharing arrangement.

Upon entry into Vifor Agreement No. 2, we received a non-refundable, non-creditable \$50.0 million upfront payment for the purchase of an aggregate of 1,174,827 shares of our common stock at a price of \$17.024 per share, which represented a premium over a pre-determined average closing price of our common stock. The purchase of our common stock was governed by the Vifor Stock Purchase Agreement.

As a result of the European Commission's regulatory approval of Kapruvia in April 2022, we received a \$15.0 million regulatory milestone payment from Vifor Fresenius Medical Care Renal Pharma Ltd.

After U.S. regulatory approval of KORSUVA injection in August 2021, we received a \$15.0 million regulatory milestone payment.

We are eligible to receive from CSL Vifor commercial milestone payments in the aggregate of up to \$440.0 million, all of which milestones are sales related. We are also eligible to receive tiered double-digit royalty payments based on annual net sales, as defined, of KORSUVA (difelikefalin) injection in the licensed territories. In the United States, CSL Vifor will promote KORSUVA (difelikefalin) injection in the dialysis clinics of FMCNA under a profit-sharing arrangement (subject to the terms and conditions of the Vifor Agreement No. 2) based on net FMCNA clinic sales (as defined in Vifor Agreement No. 2) and Vifor Fresenius Medical Care Renal Pharma Ltd. is entitled to 50% of such net profits, subject to potential adjustments in a calendar year based on certain conditions.

In connection with Vifor Agreement No. 2, we also have a related supply agreement with Vifor Fresenius Medical Care Renal Pharma Ltd., or the Vifor Fresenius Medical Care Renal Pharma Ltd. Supply Agreement, pursuant to which we retain the right to make and have made KORSUVA (difelikefalin) injection worldwide (excluding the United States, Japan and South Korea), or the Territory, for commercial sale by Vifor Fresenius Medical Care Renal Pharma Ltd. in or outside the Territory, and for supply of KORSUVA (difelikefalin) injection to Vifor Fresenius Medical Care Renal Pharma Ltd. The supply price is our COGS, as calculated under GAAP, plus an agreed upon margin. The Vifor Fresenius Medical Care Renal Pharma Ltd. Supply Agreement will co-terminate with Vifor Agreement No. 2.

In January 2023, Vifor Fresenius Medical Care Renal Pharma Ltd. and Winhealth Pharma signed a long-term exclusive licensing agreement for the co-development and commercialization of KORSUVA injection for the treatment of moderate-to-severe pruritus in adult patients undergoing hemodialysis in China.

*Maruishi Pharmaceutical Co., Ltd., or Maruishi*

In April 2013, we entered into a license agreement with Maruishi, or the Maruishi Agreement, under which we granted Maruishi an exclusive license to develop, manufacture and commercialize drug products containing difelikefalin in Japan in the acute pain and uremic pruritus fields. Maruishi has a right of first negotiation for any other indications for which we develop difelikefalin and, under certain conditions, Maruishi may substitute another pruritus indication for the

uremic pruritus indication originally included in its license from us. Maruishi is required to use commercially reasonable efforts, at its expense, to develop, obtain regulatory approval for and commercialize difelikefalin in Japan. We are required to use commercially reasonable efforts, at our expense, to develop, obtain regulatory approval for and commercialize difelikefalin in the United States.

In January 2022, Maruishi and its sublicensee Kissei confirmed the primary endpoint was achieved in a Japanese Phase 3 clinical study (double-blind, placebo-controlled period) of difelikefalin injection for the treatment of pruritus in hemodialysis patients. In the Phase 3 study, 178 patients were administered difelikefalin or placebo for 6 weeks followed by an open-label extension period of difelikefalin administration for 52 weeks. The primary endpoint, change in itch NRS score, and the secondary endpoint, change in itching scores of Shiratori severity criteria, were significantly improved from baseline compared to the placebo group. Difelikefalin was well-tolerated.

In September 2022, Maruishi submitted a New Drug Application in Japan for approval of difelikefalin injection for the treatment of pruritus in hemodialysis patients. A final decision on the application is expected in the second half of 2023.

Under the terms of the Maruishi Agreement, we received a non-refundable and non-creditable upfront license fee of \$15.0 million and are eligible to receive up to an aggregate of \$10.5 million in clinical development and regulatory milestones (before contractual foreign currency exchange adjustments). As of the date of this filing, we have received \$4.5 million (before contractual foreign currency exchange adjustments) of clinical development and regulatory milestones from Maruishi. We are also eligible to receive a one-time sales milestone of one billion Yen when a certain sales level is attained. We also receive a mid-double-digit percentage of all non-royalty payments received by Maruishi from its sublicensees, if any, and tiered royalties based on net sales, if any, with minimum royalty rates in the low double digits and maximum royalty rates in the low twenties. Maruishi's obligation to pay us royalties continues, on a product-by-product basis, until the expiration of the last-to-expire licensed patent covering such product or the later expiration of any market exclusivity period.

*Chong Kun Dang Pharmaceutical Corporation, or CKDP*

In April 2012, we entered into a license agreement with CKDP, or the CKDP Agreement, under which we granted CKDP an exclusive license to develop, manufacture and commercialize drug products containing difelikefalin in South Korea. CKDP is required to use commercially reasonable efforts, at its expense, to develop, obtain regulatory approval for and commercialize difelikefalin in South Korea. We are required to use commercially reasonable efforts, at our expense, to develop, obtain regulatory approval for and commercialize difelikefalin in the United States.

Under the terms of the CKDP Agreement, we received a non-refundable and non-creditable \$0.6 million upfront payment and are eligible to receive up to an aggregate of \$3.8 million in development and regulatory milestones (before South Korean withholding taxes). As of the date of this filing, we have received \$2.3 million (before South Korean withholding tax) of development and regulatory milestones. We are also eligible to receive a mid-double-digit percentage of all non-royalty payments received by CKDP from its sublicensees, if any, and tiered royalties ranging from the high single digits to the high teens based on net sales, if any. CKDP's obligation to pay us royalties continues, on a product-by-product basis, until the expiration of the last-to-expire licensed patent covering such product or the later expiration of any market exclusivity period.

**Manufacturing and License Agreements**

*Polypeptide Laboratories S.A. (PPL)*

In July 2021, we entered into an API Commercial Supply Agreement with Polypeptide Laboratories S.A., or PPL, that defines each party's responsibilities with respect to PPL's manufacture and supply of active pharmaceutical ingredient, or API, for the difelikefalin injection product candidate. Under the API Commercial Supply Agreement, PPL shall manufacture API at its facility for sale and supply to us, in the amounts as set forth in purchase orders to be provided by us. We will be required to purchase our requirements of API for each year of the term of the agreement, based on internal forecasts.

The API Commercial Supply Agreement will continue until the fifth anniversary of the approval by the FDA of the NDA for KORSUVA injection, unless the API Commercial Supply Agreement is earlier terminated, and will automatically be extended for successive five-year periods unless either party gives notice to the other party of its intention to terminate.

*Enteris Biopharma, Inc. (Enteris)*

In August 2019, we entered into a license agreement with Enteris, or the Enteris License Agreement. Pursuant to the Enteris License Agreement, Enteris granted us a non-exclusive, royalty-bearing license, including the right to grant sublicenses, under certain proprietary technology and patent rights related to or covering formulations for oral delivery of peptide active pharmaceutical ingredients with functional excipients to enhance permeability and/or solubility, known as Enteris's Peptelligence<sup>®</sup> technology, to develop, manufacture and commercialize products using such technology worldwide, excluding Japan and South Korea.

As consideration for the licensed rights under the Enteris License Agreement, we paid an upfront fee equal to \$8.0 million, consisting of \$4.0 million in cash and \$4.0 million in shares of our common stock.

We are also obligated, pursuant to the Enteris License Agreement, to pay Enteris (1) milestone payments upon the achievement of certain development, regulatory and commercial milestones and (2) low-single digit royalty percentages on net sales of licensed products, subject to reductions in specified circumstances. During the three months ended March 31, 2023 and 2022, no milestone payments or royalties were paid to Enteris by us in relation to the Enteris License Agreement.

The Enteris License Agreement will expire on a country-by-country, licensed product-by-licensed product basis upon the later of (1) the expiration (or invalidation) of all valid claims in licensed patent rights that cover such product in such country, (2) the end of the calendar quarter in which generic competition (as defined in the Enteris License Agreement) occurs for such product in such country and (3) ten years from the first commercial sale of such product.

*Patheon UK Limited (Patheon)*

In July 2019, we entered into a Master Services Agreement, or MSA, with Patheon UK Limited, or Patheon. The MSA governs the general terms under which Patheon, or one of its affiliates, will provide non-exclusive manufacturing services to us for the drug products specified by us from time to time. Pursuant to the MSA, we have agreed to order from Patheon at least a certain percentage of our commercial requirements for a product under a related Product Agreement. Each Product Agreement that we may enter into from time to time will be governed by the terms of the MSA, unless expressly modified in such Product Agreement.

The MSA has an initial term ending December 31, 2024, and will automatically renew after the initial term for successive terms of two years each if there is a Product Agreement in effect, unless either party gives notice of its intention to terminate the MSA at least 18 months prior to the end of the then current term.

Also in July 2019, we entered into two related Product Agreements under the MSA, one with each of Patheon and Patheon Manufacturing Services LLC, or Patheon Greenville, to govern the terms and conditions of the manufacture of commercial supplies of difelikefalin injection, our lead product candidate. Pursuant to the Product Agreements, Patheon and Patheon Greenville will manufacture commercial supplies of difelikefalin injection at the Monza, Italy and Greenville, North Carolina manufacturing sites, respectively, from API supplied by us. Patheon and Patheon Greenville will be responsible for supplying the other required raw materials and packaging components, and will also provide supportive manufacturing services such as quality control testing for raw materials, packaging components and finished product.

## Components of Operating Results

The following discussion sets forth certain components of our Condensed Statements of Comprehensive Loss as well as factors that impact those items.

### Revenue

We generate revenue primarily from (1) collaborative revenue from our share of the profit generated by KORSUVA injection sales in the United States; (2) commercial supply revenue from our sales of commercial product to CSL Vifor, which is subsequently sold to wholesalers; (3) royalty revenue in conjunction with the launch of Kapruvia in Europe; and (4) sales-based or regulatory milestone payments, which could be earned in the future in accordance with certain licensing agreements. As of March 31, 2023, we have not recorded any sales-based milestone payments.

To date, we have earned a total of \$122.7 million in clinical development or regulatory milestone payments, clinical compound and commercial compound sales from certain license agreements, collaborative revenue from our share of the profit generated by KORSUVA injection sales, and royalty revenue.

We commenced our commercial launch of KORSUVA injection for the treatment of pruritus in adult patients undergoing hemodialysis in the United States in April 2022 following FDA approval of KORSUVA injection in August 2021. We also commenced our commercial launch of Kapruvia in Europe in the third quarter of 2022. Commercial launches in Austria, Germany, Sweden, France, the Netherlands, Finland, and Switzerland have commenced. We expect additional commercial launches to commence over the next 12-18 months.

Revenue from sales of KORSUVA injection in future periods is subject to uncertainties and will depend on several factors, including the success of our and our commercial partners' commercialization efforts in the United States, the number of new patients switching to KORSUVA injection, patient retention and demand, the number of physicians prescribing KORSUVA injection, the rate of monthly prescriptions, reimbursement from third-party payors including the U.S. government, the conversion of patients from our clinical trials to commercial customers, and market trends. More specifically, in December 2021, CMS granted TDAPA to KORSUVA injection in the anti-pruritic functional category. TDAPA went into effect on April 1, 2022, for a minimum of two years. CMS expressed in its written communication to us and CSL Vifor, a continuing interest in engaging with the companies regarding potential post-TDAPA support to ensure all beneficiaries with ESRD have access to innovative products such as KORSUVA injection. However, there is no assurance that KORSUVA injection will be able to maintain its price established during the TDAPA period in the post-TDAPA timeframe, which could significantly impact our revenues in future periods.

In June 2022, in its Calendar Year 2023 ESRD PPS proposed rule, CMS issued a request for information, or RFI, to seek input on potential methodologies to add additional money through an add-on adjustment methodology for certain TDAPA drugs that enter the prospective payment system in an existing functional category. The options included in the RFI, if proposed and ultimately approved through Notice and Comment Rulemaking, could result in the provision of additional payments for KORSUVA injection post-TDAPA. Further, in November 2022, CMS published a Calendar Year 2023 ESRD PPS final rule that will, among others, update Medicare payment policies and rates for renal dialysis services. This final rule rebases and revises ESRD bundled market basket to a 2020 base year, updates the labor-related share, changes the ESRD PPS methodology for calculating the outlier threshold for adult patients, applies a permanent 5% cap on decreases in the ESRD PPS wage index, and increases the wage index floor. Also in the final rule, with regard to the RFI in the June 2022 proposed rule, CMS noted that most commenters expressed support for an add-on payment adjustment for new renal dialysis drugs to improve patient access to innovative drugs and that CMS intends to take the received comments into consideration during potential future policy development. As this is an RFI, these provisions have not been proposed or implemented as a rule and there is no guarantee that CMS will formally propose a change in policy in the form presented in the RFI.

As of March 31, 2023, Vifor International owned 7,396,770, or 13.7%, of our common stock. CSL Vifor and its affiliates are considered related parties as of March 31, 2023 and December 31, 2022 (see Note 17 of Notes to Condensed Financial Statements, *Related Party Transactions*, in this Quarterly Report on Form 10-Q).

### **Cost of Goods Sold (COGS)**

COGS includes costs related to sales of our commercial product, KORSUVA injection, to CSL Vifor. Costs related to the sales of KORSUVA injection are generally recognized upon receipt of shipment by CSL Vifor. Our COGS for KORSUVA injection include the cost of producing commercial product that correspond with commercial supply revenue, such as third-party supply and overhead costs, as well as certain period costs related to freight, packaging, stability, and quality testing. The related COGS for CSL Vifor associated with the net profit share arrangement as well as the marketing and distribution fee for the applicable period reduces our profit share revenue for the period.

In January 2022, we recorded commercial supply revenue of \$2.3 million, with no associated COGS as all inventory costs were incurred prior to receipt of regulatory approval of KORSUVA injection and, accordingly, were expensed as incurred. In March 2022, we recorded commercial supply revenue of \$2.5 million, with associated COGS of \$2.1 million as these inventory costs were incurred subsequent to the receipt of regulatory approval of KORSUVA injection and, accordingly, were capitalized as inventory. During the three months ended March 31, 2023, we recorded commercial supply revenue of \$3.2 million, with associated COGS of \$2.6 million. We expect our COGS to increase as CSL Vifor generates additional sales of KORSUVA injection in the future.

### **Research and Development (R&D)**

Our R&D expenses relate primarily to the development of difelikefalin. R&D expenses consist of expenses incurred in performing R&D activities, including compensation and benefits for full-time R&D employees, clinical trial and related clinical manufacturing expenses, third-party formulation expenses or milestone payments, fees paid to CROs and other consultants, stock-based compensation for R&D employees and consultants, and other outside expenses. Our R&D expenses also included expenses related to preclinical activities for our earlier stage programs in prior periods and may include such expenses in the future.

R&D costs are expensed as incurred. Non-refundable advance payments for goods or services to be received in the future for use in R&D activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Most of our R&D costs have been external costs, which we track on a program-by-program basis. Our internal R&D costs are primarily compensation expenses for our full-time R&D employees. We do not track internal R&D costs on a program-by-program basis.

R&D activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Based on our current development plans, we presently expect that our R&D expenses for 2023 will be higher than 2022. However, it is difficult to determine with certainty the duration and completion costs of our current or future nonclinical and clinical studies of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors including, but not limited to:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;

- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

#### ***General and Administrative (G&A)***

General and administrative, or G&A, expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, legal, business development, information technology, or IT, human resources, project management, alliance management, and procurement functions. Other costs include facility costs not otherwise included in R&D expenses, legal fees, insurance costs, investor relations costs, patent costs and fees for accounting and consulting services.

We anticipate that our G&A expenses for 2023 will be consistent with 2022 to support our continued R&D activities and for our product candidates. These expenses will likely include costs related to the hiring of additional personnel, fees to outside consultants, lawyers, and accountants. In addition, if oral difelikefalin or any future product candidate obtains regulatory approval for marketing, we may incur expenses associated with building sales and marketing, commercial operations, and market access teams.

Our license agreements with CSL Vifor provide full U.S. commercialization rights of KORSUVA injection to CSL Vifor under profit-sharing arrangements. Under these profit-sharing arrangements, in consideration of CSL Vifor's conduct of the marketing, promotion, selling and distribution of KORSUVA injection in the United States, we pay a marketing and distribution fee to CSL Vifor based on the level of annual net sales. This fee as well as CSL Vifor's COGS are deducted from product sales in calculating the net profits that are subject to the profit-sharing arrangement (see Note 11 of Notes to Condensed Financial Statements, *Collaboration and Licensing Arrangements*, in this Quarterly Report on Form 10-Q).

#### ***Other Income, Net***

Other income, net consists of interest and dividend income earned on our cash, cash equivalents, and marketable securities, realized gains and losses on the sale of marketable securities and property and equipment, as well as accretion of discounts/amortization of premiums on purchases of marketable securities. In the event we record a credit loss expense on our available-for-sale debt securities, those expenses would be offset against other income.

#### ***Income Taxes***

Historically, our benefit from income taxes related to state R&D tax credits exchanged for cash pursuant to the Connecticut R&D Tax Credit Exchange Program, which permits qualified small businesses engaged in R&D activities within Connecticut to exchange their unused R&D tax credits for a cash amount equal to 65% of the value of the exchanged credits.

The Inflation Reduction Act of 2022 included tax legislation that became effective during the three months ended March 31, 2023. Significant legislation for corporate taxpayers includes a corporate alternative minimum tax of 15.0%

for companies with \$1.0 billion or more in average net financial statement profits over the three previous years, as well as a 1.0% indirect excise tax on the repurchase of shares by a publicly traded company. We do not expect this legislation to have an effect on our tax provision as of March 31, 2023; however, we will continue to evaluate the effect on the tax provision each reporting period.

## Results of Operations

### Comparison of the Three Months Ended March 31, 2023 and 2022

#### Revenue

	Three Months Ended March 31,		% change
	2023	2022	
	Dollar amounts in thousands		
Collaborative revenue	\$ 2,750	\$ —	N/A
Commercial supply revenue	3,191	4,790	-33%
Royalty revenue	125	—	N/A
Clinical compound revenue	99	—	N/A
Total revenue	<u>\$ 6,165</u>	<u>\$ 4,790</u>	29%

#### Collaborative Revenue

We recognized collaborative revenue of \$2.8 million for the three months ended March 31, 2023 and no collaborative revenue for the three months ended March 31, 2022. This increase in collaborative revenue was related to our share of the profit from CSL Vifor's sales of KORSUVA injection to third parties in the United States, which commercially launched in April 2022.

#### Commercial Supply Revenue

We recognized commercial supply revenue of \$3.2 million and \$4.8 million for the three months ended March 31, 2023 and 2022, respectively. This decrease was related to sales of KORSUVA injection to CSL Vifor, as we and CSL Vifor began commercializing KORSUVA injection in the United States in December 2021 and commercial launch began in April 2022.

#### Royalty revenue

We recognized royalty revenue of approximately \$125,000 for the three months ended March 31, 2023 and no royalty revenue for the three months ended March 31, 2022. This increase was related to sales of Kaprivia in Europe, which commercially launched in the third quarter of 2022.

#### Clinical compound revenue

We recognized clinical compound revenue of approximately \$99,000 for the three months ended March 31, 2023 and no clinical compound revenue for the three months ended March 31, 2022. This increase was related to sales of clinical compound to Maruishi.

#### Cost of Goods Sold (COGS)

	Three Months Ended March 31,		% change
	2023	2022	
	Dollar amounts in thousands		
Cost of Goods Sold	\$ 2,590	\$ 2,081	24%

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The increase of \$0.5 million in COGS to \$2.6 million for the three months ended March 31, 2023 compared to \$2.1 million for the three months ended March 31, 2022, was related to commercial supply revenue for KORSUVA injection sales to CSL Vifor. There was no associated COGS recorded for commercial supply revenue of \$2.3 million recognized in January 2022 as all inventory costs associated with commercial supply revenue were incurred prior to receipt of regulatory approval of KORSUVA injection, and accordingly, were expensed as incurred.

### Research and Development Expense

	Three Months Ended March 31,		% change
	2023	2022	
	Dollar amounts in thousands		
Direct clinical trial costs	\$ 13,749	\$ 11,566	19%
Consultant services in support of clinical trials	1,071	1,349	-21%
Stock-based compensation	1,659	2,084	-20%
Depreciation and amortization	29	31	-6%
Other R&D operating expenses	7,826	6,243	25%
Total R&D expense	<u>\$ 24,334</u>	<u>\$ 21,273</u>	14%

For the three months ended March 31, 2023 compared to the three months ended March 31, 2022, the \$2.2 million increase in direct clinical trial costs was primarily due to the increases in clinical trial spend related to our three late-stage oral difelikefalin programs. These increases were partially offset by a decrease related to the Phase 2 efficacy trial for pruritus associated with NP, and other general costs associated with our oral programs. The \$1.6 million increase in other R&D operating expenses was primarily related to increases in payroll-related costs and travel costs.

The following table summarizes our R&D expenses by program for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		% change
	2023	2022	
	Dollar amounts in thousands		
External research and development expenses:			
KORSUVA (difelikefalin) injection - Pruritus	\$ —	\$ 3,103	-100%
Oral difelikefalin - Pruritus	14,806	10,011	48%
Internal research and development expenses	9,528	8,159	17%
Total research and development expenses	<u>\$ 24,334</u>	<u>\$ 21,273</u>	14%

### General and Administrative Expenses

	Three Months Ended March 31,		% change
	2023	2022	
	Dollar amounts in thousands		
Professional fees and public/investor relations	\$ 1,644	\$ 1,935	-15%
Stock-based compensation	1,694	3,620	-53%
Depreciation and amortization	29	32	-9%
Other G&A operating expenses	3,524	3,760	-6%
Total G&A expense	<u>\$ 6,891</u>	<u>\$ 9,347</u>	-26%



The decrease of \$1.9 million in stock-based compensation expense for the three months ended March 31, 2023 compared to the three months ended March 31, 2022 was primarily related to higher expenses recorded during the three months ended March 31, 2022 for the modification of our former CEO's equity awards, and certain performance-based restricted stock units that vested during the three months ended March 31, 2022. The \$0.2 million decrease in other G&A operating expenses was primarily the result of decreases in payroll-related costs.

### Other Income, Net

	Three Months Ended March 31,		% change
	2023	2022	
	Dollar amounts in thousands		
Other income, net	\$ 985	\$ 162	510%

For the three months ended March 31, 2023 compared to the three months ended March 31, 2022, the increase in other income, net was primarily due to an increase in interest income resulting from a higher yield on our portfolio of investments during the three months ended March 31, 2023 and an increase in accretion income from our available-for-sale marketable securities.

### Benefit from Income Taxes

We were not eligible to exchange our R&D tax credit for cash during the three months ended March 31, 2023 and 2022, therefore there was no benefit from income taxes for each of the three months ended March 31, 2023 and 2022. As of March 31, 2023, we recorded \$0.7 million within income tax receivable which related to the 2020 R&D credit.

We recognized a full valuation allowance against deferred tax assets at March 31, 2023 and December 31, 2022. The tax benefit related to the exercise of stock options is recognized as a deferred tax asset that is offset by a corresponding valuation allowance. As such, our effective tax rate is zero for each of the three months ended March 31, 2023 and 2022.

### Capital Requirements, Liquidity, and Capital Resources

#### Short-Term and Long-Term Cash Requirements

Our primary uses of capital have been, and we expect will continue to be, compensation and related expenses, third-party clinical R&D services, and clinical costs related to the oral difelikefalin program.

As of March 31, 2023, we have no commitments for capital expenditures in either the short-term or long-term. The following discussion summarizes our current and long-term material cash requirements as of March 31, 2023, which we expect to fund primarily with current unrestricted cash and cash equivalents and available-for-sale marketable securities:

	Material Cash Requirements		
	Total	Less than 1 Year	1 Year or More
Operating lease obligations <sup>(1)</sup>	\$ 1,498	\$ 1,498	\$ —
Manufacturing purchase obligations <sup>(2)</sup>	7,668	7,668	—
Other obligations <sup>(3)</sup>	408	408	—
Total	<u>\$ 9,574</u>	<u>\$ 9,574</u>	<u>\$ —</u>

(1) Operating lease obligations relate to our Stamford operating leases entered into in December 2015 and amended in June 2020 and continue through December 2023. See Note 16 of Notes to Condensed Financial Statements, *Commitments and Contingencies*, in this Quarterly Report on Form 10-Q for details about our operating lease obligations.

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- (2) Based on our MSA with Patheon that we entered into in July 2019, we have a purchase capacity reservation through December 31, 2023. We expect the majority of this capacity reservation will be reimbursed in accordance with the supply agreement with CSL Vifor. See Note 16 of Notes to Condensed Financial Statements, *Commitments and Contingencies*, in this Quarterly Report on Form 10-Q for details about our MSA with Patheon. We have no other material non-cancelable purchase commitments with any other contract manufacturers or service providers, as we have generally contracted on a cancelable purchase order basis.
- (3) We are required to maintain a stand-by letter of credit as a security deposit under our leases for office space in Stamford, Connecticut. See Note 6 of Notes to Condensed Financial Statements, *Restricted Cash*, in this Quarterly Report on Form 10-Q for details about our letter of credit associated with our Stamford operating leases.

As we anticipate revenue increasing in the short-term and long-term with the commercialization of KORSUVA injection and Kapruvia, our costs of manufacturing will also increase.

Based on the Enteris License Agreement that we entered into in August 2019, we are obligated to pay (1) milestone payments upon the achievement of certain development, regulatory and commercial milestones and (2) low-single digit royalty percentages on net sales of licensed products, subject to reductions in specified circumstances. As these milestone payments may or may not be achieved, and royalties may or may not be owed depending on our future commercial success, there were no future potential payments that were considered cash requirements in the table above as of March 31, 2023. During the three months ended March 31, 2023 and 2022, there were no milestone payments made to Enteris. See Note 16 of Notes to Condensed Financial Statements, *Commitments and Contingencies*, in this Quarterly Report on Form 10-Q for details about our Enteris License Agreement.

We do not have any other requirements or off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, cash requirements or capital resources.

Since inception, we have incurred significant operating and net losses. We incurred net losses of \$26.7 million and \$27.7 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of \$592.9 million. We expect to continue to incur significant expenses and operating and net losses in the foreseeable future, as we and our partner CSL Vifor expand the commercial launch of KORSUVA injection and Kapruvia and to develop and seek marketing approval for oral difelikefalin. However, we will not incur any material commercial costs on KORSUVA injection and Kapruvia due to the licensing agreement with CSL Vifor. Our financial results may fluctuate significantly from quarter to quarter and year to year, depending on the success of our commercialization efforts, timing of our clinical trials, the receipt of additional milestone payments, if any, under our licensing and collaborations with CSL Vifor, Maruishi and CKDP, the receipt of payments under any future collaborations and/or licensing agreements we may enter into, and our expenditures on other R&D activities.

We anticipate that our expenses will increase as we:

- continue the development of oral difelikefalin for pruritus associated with AD, NDD-CKD, and NP;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any other products for which we may obtain regulatory approval;
- maintain, expand and protect our global intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development and potential future commercialization efforts.

The successful commercialization of KORSUVA injection and Kaprivia and the successful development of any of our other product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to successfully commercialize KORSUVA injection and Kaprivia, complete the development of oral difelikefalin or our other current and future programs. We are also unable to predict when, if ever, we will generate any further material net cash inflows from difelikefalin. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- successful enrollment in, and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- achieving meaningful penetration in the markets which we seek to serve; and
- obtaining adequate coverage or reimbursement by third parties, such as commercial payers and government healthcare programs, including Medicare and Medicaid.

A change in the outcome of any of these variables with respect to the development of oral difelikefalin or any of our future product candidates would significantly change the costs and timing associated with the development of that product candidate. Further, the timing of any of the above may be impacted by the COVID-19 pandemic, introducing additional uncertainty.

Commercial launch of KORSUVA injection began in the United States in April 2022, and commercial launch of Kaprivia has commenced in the EU in Austria, Germany, Sweden, France, the Netherlands, and Finland. In August 2022, as part of the Access Consortium, difelikefalin injection was approved in Switzerland under the brand name Kaprivia, as well as Singapore and Canada under the brand name KORSUVA. Commercial launch in Switzerland has also commenced. We expect additional commercial launches to commence over the next 12-18 months. Our other product candidates are still in clinical development and since the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the commercialization of KORSUVA injection and Kaprivia and the development and commercialization of our other product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements, including our existing licensing and collaboration agreements with CSL Vifor, Maruishi and CKDP.

We will require additional capital beyond our current balances of cash and cash equivalents and available-for-sale marketable securities and anticipated amounts as described above, and this additional capital may not be available when needed, on reasonable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and continuing disruptions to and volatility in the credit and equity markets in the United States and worldwide, including impacts from the COVID-19 pandemic or future public health crises, geopolitical tensions, such as the ongoing military conflict between Russia and Ukraine and related sanctions against Russia, decades-high inflation, rising interest rates, uncertainty and liquidity concerns in the broader financial services industry, such as those caused by certain recent banking failures, and a potential recession in the United States. If we are not able to do so, we could be required to postpone, scale back or eliminate some, or all, of these objectives. To the extent that we raise additional capital through the future sale of equity or convertible debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt

securities, these securities could contain covenants that would restrict our operations. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

### **Sources of Liquidity**

Since our inception to date, we have raised an aggregate of \$890.6 million to fund our operations, including (1) net proceeds of \$446.3 million from the sale of shares of our common stock in five public offerings, including our initial public offering; (2) proceeds of \$73.3 million from the sale of shares of our convertible preferred stock and from debt financings prior to our initial public offering; (3) payments of \$253.6 million under our license and supply agreements (including commercial supply sales and royalty payments), primarily with CSL Vifor, Maruishi, CKDP, and an earlier product candidate for which development efforts ceased in 2007; (4) our share of the profit generated by KORSUVA injection sales of \$19.3 million; and (5) net proceeds of \$98.0 million from the purchase of our common stock in relation to the license agreements with CSL Vifor (see Note 11 of Notes to Condensed Financial Statements, *Collaboration and Licensing Agreements*, in this Quarterly Report on Form 10-Q).

In order to fund our future operations, including our planned clinical trials, on March 1, 2022, we filed a universal shelf registration statement, or the Shelf Registration Statement, which provides for aggregate offerings of up to \$300.0 million of common stock, preferred stock, debt securities, warrants or any combination thereof. The Shelf Registration Statement was declared effective by the Securities and Exchange Commission on May 11, 2022. The securities registered under the Shelf Registration Statement include \$154.5 million of unsold securities that had been registered under our previous Registration Statement on Form S-3 (File No. 333-230333) that was declared effective on April 4, 2019. We believe that our Shelf Registration Statement will provide us with the flexibility to raise additional capital to finance our operations as needed.

On March 1, 2022, we entered into an open market sales agreement, or the Sales Agreement, with Jefferies LLC, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to \$80.0 million in an at-the-market offering. Jefferies is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. The common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. No shares were sold under the Sales Agreement during the three months ended March 31, 2023 and 2022.

We may offer additional securities under our Shelf Registration Statement from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders.

Under Vifor Agreement No. 1, we are eligible to receive commercial milestone payments in the aggregate of up to \$240.0 million upon the achievement of certain sales-based milestones. In October 2021, we received a \$50.0 million milestone payment from Vifor International in exchange for the issuance of 3,282,391 shares of our common stock to Vifor International as a result of the regulatory approval of KORSUVA injection in August 2021. As of March 31, 2023, we have received \$50.0 million of regulatory milestones from Vifor International.

Under Vifor Agreement No. 2, we are eligible to receive commercial milestone payments in the aggregate of up to \$440.0 million, all of which are sales-related. We are also eligible to receive tiered double-digit royalty payments based on annual net sales, as defined in Vifor Agreement No. 2, of difelikefalin injection in the licensed territories. In June 2022, we received a \$15.0 million milestone payment from Vifor Fresenius Medical Care Renal Pharma Ltd. as a result of the regulatory approval of Kapruvia by the European Commission in April 2022. In October 2021, we received a \$15.0 million milestone payment from Vifor Fresenius Medical Care Renal Pharma Ltd. as a result of the regulatory approval of KORSUVA injection in August 2021. As of March 31, 2023, we have received \$30.0 million of regulatory milestones from Vifor Fresenius Medical Care Renal Pharma Ltd.

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Under the Maruishi Agreement, we are also potentially eligible to earn up to an aggregate of \$6.0 million in clinical development milestones and \$4.5 million in regulatory milestones, before any foreign exchange adjustment, as well as tiered royalties, with percentages ranging from the low double digits to the low twenties, based on net sales of products containing difelikefalin in Japan, if any, and share in any sub-license fees. As of the date of this filing, we have received \$4.5 million (before contractual foreign currency exchange adjustments) of clinical development and regulatory milestone from Maruishi.

Under the CKDP Agreement, we are potentially eligible to earn up to an aggregate of \$2.3 million in clinical development milestones and \$1.5 million in regulatory milestones, before South Korean withholding tax, as well as tiered royalties with percentages ranging from the high single digits to the high teens, based on net sales of products containing difelikefalin in South Korea, if any, and share in any sub-license fees. As of the date of this filing, \$2.3 million (before South Korean withholding tax) of development and regulatory milestones have been received under the CKDP Agreement.

In December 2021, CMS granted TDAPA designation to KORSUVA injection in the anti-pruritic functional category. TDAPA went into effect on April 1, 2022, for a minimum of two years. CMS expressed in its written communication to us and CSL Vifor, a continuing interest in engaging with the companies regarding potential post-TDAPA support to ensure all beneficiaries with ESRD have access to innovative products such as KORSUVA injection. Commercial launch of KORSUVA injection commenced in April 2022 and we began recording associated profit-sharing revenues in the second quarter of 2022. As a result of the European Commission's approval of Kapruvia in April 2022, the commercial launch of Kapruvia in the EU has commenced in Austria, Germany, Sweden, France, the Netherlands, and Finland. Commercial launch has also commenced in Switzerland, and we expect additional commercial launches to commence over the next 12-18 months.

Our ability to earn these payments and their timing is dependent upon the outcome of oral difelikefalin development activities and successful commercialization of KORSUVA injection and Kapruvia. However, our receipt of any further such amounts is uncertain at this time and we may never receive any more of these amounts.

### **Outlook**

We expect that our current unrestricted cash and cash equivalents and available-for-sale marketable securities, including collaborative revenue from our share of the profit from KORSUVA injection, will be sufficient to fund our currently anticipated operating plan into the second half of 2024. Our anticipated operating expenses include contractually committed costs as well as non-contractually committed clinical trial costs for trials that may be delayed or not initiated and other non-committed controllable costs. Because the process of testing product candidates in clinical trials is costly and the timing of progress in these trials is uncertain, it is possible that the assumptions upon which we have based this estimate may prove to be wrong, and we could use our capital resources sooner than we presently expect.

### **Cash Flows**

The following is a summary of the net cash flows provided by (used in) our operating, investing and financing activities for the three months ended March 31, 2023 and 2022:

	Three Months Ended	
	March 31,	
	2023	2022
	Dollar amounts in thousands	
Net cash used in operating activities	\$ (34,618)	\$ (25,525)
Net cash provided by investing activities	17,708	33,431
Net cash provided by financing activities	560	3
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (16,350)	\$ 7,909

### ***Net cash used in operating activities***

Net cash used in operating activities for the three months ended March 31, 2023 consisted primarily of a net loss of \$26.7 million and a \$11.6 million cash outflow from net changes in operating assets and liabilities, partially offset by a \$3.7 million cash inflow from net non-cash charges. The change in operating assets and liabilities primarily consisted of cash outflows of \$6.3 million from an increase in accounts payable and accrued expenses primarily relating to increased payments made in the first quarter of 2023, an increase of \$2.8 million in accounts receivable, net – related party primarily relating to amounts due from CSL Vifor from our share of the profit generated by KORSUVA injection sales and for commercial supply of KORSUVA injection to CSL Vifor, an increase in inventory, net of \$1.1 million, an increase in prepaid expenses of \$0.9 million, primarily related to an increase in prepaid clinical costs, and a cash outflow of \$0.5 million relating to operating lease liabilities associated with our lease agreements for our operating facility in Stamford, Connecticut. Net non-cash charges primarily consisted of stock-based compensation expense of \$3.4 million, and the amortization expense component of lease expense of \$0.4 million relating to our Stamford operating leases.

Net cash used in operating activities for the three months ended March 31, 2022 consisted primarily of a net loss of \$27.7 million and a \$4.2 million cash outflow from net changes in operating assets and liabilities, partially offset by a \$6.4 million cash inflow from net non-cash charges. The change in operating assets and liabilities primarily consisted of an increase in prepaid expenses of \$2.6 million, primarily related to an increase in prepaid clinical costs, an increase of \$2.5 million in accounts receivable, net – related party relating to amounts due from CSL Vifor for sales of KORSUVA injection during the three months ended March 31, 2022, and a cash outflow of \$0.4 million relating to operating lease liabilities associated with our lease agreements for our operating facility in Stamford, Connecticut, partially offset by a decrease in inventory of \$0.7 million and a cash inflow of \$0.6 million from an increase in accounts payable and accrued expenses. Net non-cash charges primarily consisted of stock-based compensation expense of \$5.7 million, which includes incremental expense related to the modification of our former CEO's equity awards in 2021 of \$1.6 million, the amortization expense component of lease expense of \$0.3 million relating to our Stamford operating leases, and the amortization of available-for-sale marketable securities, net of \$0.3 million.

### ***Net cash provided by investing activities***

Net cash provided by investing activities was \$17.7 million for the three months ended March 31, 2023, which primarily included cash inflows of \$33.5 million from maturities and redemptions of available-for-sale marketable securities, partially offset by cash outflows of \$15.8 million for the purchases of available-for-sale marketable securities.

Net cash provided by investing activities was \$33.4 million for the three months ended March 31, 2022, which primarily included cash inflows of \$44.0 million from maturities of available-for-sale marketable securities, partially offset by cash outflows of \$10.5 million for the purchases of available-for-sale marketable securities.

### ***Net cash provided by financing activities***

Net cash provided by financing activities for the three months ended March 31, 2023 and 2022 consisted of proceeds of approximately \$560,000 and \$3,000, respectively, received from the exercise of stock options.

### **Recent Accounting Pronouncements**

Please refer to Note 2 of Notes to Condensed Financial Statements, *Basis of Presentation*, in this Quarterly Report on Form 10-Q.

### **Critical Accounting Estimates**

The preparation of our condensed financial statements and related disclosures in conformity with U.S. GAAP and our discussion and analysis of financial condition and results of operations require us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable

under the circumstances at the time such estimates are made. Actual results and outcomes may differ materially from our estimates, judgments, and assumptions. We periodically review our estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates are reflected in the condensed financial statements prospectively from the date of the change in estimate. Note 2 of Notes to Financial Statements, *Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2022, or Annual Report, describes the significant accounting policies and methods used in the preparation of our condensed financial statements.

We define our critical accounting estimates as those subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations as well as the specific manner in which we apply U.S. GAAP. Our critical accounting policies that require significant judgments and estimates are more fully described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates” in our Annual Report and in Note 2 to our audited financial statements contained in our Annual Report. There have been no significant changes to our critical accounting policies that require significant judgments and estimates from those disclosed in our Annual Report.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

*Interest Rate Risk*

As of March 31, 2023, we invested a majority of our cash reserves in a variety of available-for-sale marketable securities, including investment-grade debt instruments, principally corporate bonds, commercial paper, municipal bonds and direct obligations of the U.S. government and U.S. government-sponsored entities, and in cash equivalents. See Note 3 of Notes to Condensed Financial Statements, *Available-for-Sale Marketable Securities*, in this Quarterly Report on Form 10-Q for details about our available-for-sale marketable securities.

As of March 31, 2023, we had invested \$76.0 million of our cash reserves in such marketable securities. Those marketable securities included \$76.0 million of investment grade debt instruments with a yield of approximately 2.07% and maturities through November 2024. As of December 31, 2022, we had invested \$93.0 million of our cash reserves in such marketable securities. Those marketable securities included \$93.0 million of investment grade debt instruments with a yield of approximately 2.01% and maturities through November 2024.

We maintain an investment portfolio in accordance with our investment policy, which includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity and to meet operating needs. Our investments are subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, we do not believe we are materially exposed to changes in interest rates related to our investments. As a result, we do not currently use interest rate derivative instruments to manage exposure to interest rate changes.

Duration is a sensitivity measure that can be used to approximate the change in the fair value of a security that will result from a change in interest rates. Applying the duration model, a hypothetical 100 basis point, or 1%, increase in interest rates as of March 31, 2023 and December 31, 2022, would have resulted in immaterial decreases in the fair values of our portfolio of marketable securities at those dates.

*Credit Quality Risk*

Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. As of March 31, 2023 and December 31, 2022, the aggregate unrealized losses on our available-for-sale marketable securities were \$1.1 million and \$1.7 million, respectively. For each of the three months ended March 31, 2023 and 2022, we did not record any charges to credit loss expense for our available-for-sale securities. Refer to Note 3 of Notes to Condensed Financial Statements, *Available-for-Sale Marketable Securities*, in this Quarterly Report on Form 10-Q.



As of March 31, 2023 and December 31, 2022, we had accounts receivable, net - related party from CSL Vifor of \$6.1 million and \$3.3 million, respectively, primarily for our share of the profit generated by KORSUVA injection sales and commercial supply revenue. We believe that credit risk associated with CSL Vifor is not significant. We review the need for an allowance for credit losses for any receivable based on various factors including payment history and historical bad debt experience. We had an insignificant allowance for credit losses as of March 31, 2023 and December 31, 2022.

**Item 4. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of March 31, 2023. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2023, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

*Changes in Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

*Limitations on Controls and Procedures*

Management, including our Chief Executive Officer and Chief Financial Officer, recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Because of the inherent limitations of the effectiveness of all control systems, no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, within Cara Therapeutics, Inc. have been detected.



**PART II**  
**OTHER INFORMATION**

**Item 1.      *Legal Proceedings***

From time to time, we may become subject to arbitration, litigation or claims arising in the ordinary course of business. We are not currently a party to any arbitration or legal proceeding that, if determined adversely to us, would have a material adverse effect on our business, operating results or financial condition. The results of any future claims or proceedings cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and litigation costs, diversion of management resources, and other factors.

**Item 1A.     *Risk Factors***

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and trading price of our securities. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors described in Part I, Item 1A. “Risk Factors” of our Annual Report. We may disclose changes to risk factors or disclose additional factors from time to time in our future filings with the SEC. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

**Item 2.      *Unregistered Sales of Equity Securities and Use of Proceeds.***

None.

**Item 3.      *Defaults upon Senior Securities.***

None.

**Item 4.      *Mine Safety Disclosures.***

Not applicable.

**Item 5.      *Other Information.***

On May 11, 2023, we entered into a lease agreement, or the New Lease, with 400 Atlantic Joint Venture LLC and SLJ Atlantic Stamford LLC (tenants-in-common), or the Landlord, for the lease of 26,374 square feet of office space located at 400 Atlantic Street, Stamford, Connecticut 06901 for our principal executive offices. The initial term of the New Lease commences on the earlier to occur of (a) the date we first occupy the premises for the regular conduct of our business therein, and (b) the date the Landlord delivers the premises to us in the condition required under the terms of the New Lease, provided that such date shall be no sooner than November 1, 2023, or the Commencement Date, and will expire on the last day of the calendar month in which occurs the tenth anniversary of the Rent Commencement Date, as defined below, or the Term.

The annual fixed rent rate under the New Lease will initially be \$1.3 million, commencing on the date which is the later to occur of (a) the date which is 12 months after the Commencement Date and (b) November 1, 2024, or the Rent Commencement Date, and will escalate 2.5% annually thereafter.

We will also be responsible for the payment of Additional Rent, as defined in the New Lease, including our share of the complex operating and tax expenses for the building. We will have the option to extend the Term under the New Lease for an additional five years on the same terms and conditions (other than with respect to the annual fixed rent at the annual fair market rental rate, as defined in the New Lease) as set forth in the New Lease.

The foregoing description of the New Lease does not purport to be complete and is qualified in its entirety by reference to the full text of the New Lease, a copy of which is to be filed as an exhibit to our next periodic report filed with the SEC.

**Item 6. Exhibits.**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>	<b>Form</b>	<b>File No.</b>	<b>Incorporated by Reference</b>	
				<b>Exhibit No.</b>	<b>Date Filed</b>
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	001-36279	3.1	February 7, 2014
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	001-36279	3.2	February 7, 2014
31.1†	<a href="#">Certification of Chief Executive Officer of Cara Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.</a>				
31.2†	<a href="#">Certification of Chief Financial Officer of Cara Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.</a>				
32.1†*	<a href="#">Certifications of Chief Executive Officer and Chief Financial Officer of Cara Therapeutics, Inc. pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				
101.CAL†	Inline XBRL Taxonomy Extension Calculation Linkbase.				
101.INS†	Inline XBRL Instance Document.				
101.LAB†	Inline XBRL Taxonomy Extension Label Linkbase.				
101.PRE†	Inline XBRL Taxonomy Extension Presentation Linkbase.				
101.SCH†	Inline XBRL Taxonomy Extension Schema Linkbase.				
101.DEF†	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
104†	Cover page interactive data file (formatted as Inline XBRL and contained in Exhibit 101).				

† Filed herewith.

\* This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CARA THERAPEUTICS, INC.

Date: May 15, 2023

By /s/ CHRISTOPHER POSNER  
Christopher Posner  
President, Chief Executive Officer, and Director  
*(Principal Executive Officer)*

Date: May 15, 2023

By /s/ RYAN MAYNARD  
Ryan Maynard  
Chief Financial Officer  
*(Principal Financial and Accounting Officer)*

**Certification of Chief Executive Officer Pursuant to  
Rule 13a-14(a) under the Securities Exchange Act  
of 1934, as Adopted Pursuant to  
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Christopher Posner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cara Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2023

By: /s/ Christopher Posner  
CHRISTOPHER POSNER  
CHIEF EXECUTIVE OFFICER  
(Principal Executive Officer)

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**Certification of Chief Financial Officer Pursuant to  
Rule 13a-14(a) under the Securities Exchange Act  
of 1934, as Adopted Pursuant to  
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Ryan Maynard, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cara Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2023

By: /s/ Ryan Maynard  
RYAN MAYNARD  
CHIEF FINANCIAL OFFICER  
(Principal Financial Officer)

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**CERTIFICATIONS OF  
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
OF CARA THERAPEUTICS, INC.  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Cara Therapeutics, Inc. (the "Company") for the quarter ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Christopher Posner, as Chief Executive Officer of the Company, and Ryan Maynard, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, based upon a review of the Report:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ CHRISTOPHER POSNER

Name: Christopher Posner  
Title: Chief Executive Officer  
(Principal Executive Officer)  
Date: May 15, 2023

/s/ RYAN MAYNARD

Name: Ryan Maynard  
Title: Chief Financial Officer  
(Principal Financial Officer)  
Date: May 15, 2023

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