Table of Contents

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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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	**75-3175693**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4 Stamford Plaza **107 Elm Street, 9th Floor** **Stamford, Connecticut**	**06902**
(Address of registrant's principal executive offices)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 November 9, 2023 was: 54,480,704.

CARA THERAPEUTICS, INC.

INDEX TO FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023

PART I –FINANCIAL INFORMATION

PART I
FINANCIAL INFORMATION

Item 1. ***Financial Statements*.**

CARA THERAPEUTICS, INC.

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 62,875	$ 63,741
Marketable securities	15,666	81,658
Accounts receivable, net - related party	3,351	3,260
Inventory, net	3,266	2,383
Income tax receivable	697	697
Other receivables	1,682	496
Prepaid expenses	12,658	16,267
Restricted cash	408	408
Total current assets	100,603	168,910
Operating lease right-of-use assets	7,108	1,551
Marketable securities, non-current	4,747	11,350
Property and equipment, net	1,380	426
Restricted cash, non-current	1,500	—
Total assets	$ 115,338	$ 182,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,384	$ 21,540
Operating lease liabilities, current	497	1,918
Total current liabilities	22,881	23,458
Operating lease liabilities, non-current	6,815	—
Commitments and contingencies (Note 16)	—	—
Stockholders' equity:		
Preferred stock; $0.001 par value; 5,000,000 shares authorized at September 30, 2023 and December 31, 2022, zero shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock; $0.001 par value; 100,000,000 shares authorized at September 30, 2023 and December 31, 2022, 54,471,829 shares and 53,797,341 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	54	53
Additional paid-in capital	738,435	726,630
Accumulated deficit	(652,408)	(566,232)
Accumulated other comprehensive loss	(439)	(1,672)
Total stockholders' equity	85,642	158,779
Total liabilities and stockholders' equity	$ 115,338	$ 182,237

See Notes to Condensed Financial Statements.

CARA THERAPEUTICS, INC.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenue:				
Collaborative revenue	$ 2,471	$ 7,443	$ 10,631	$ 15,446
Commercial supply revenue	1,252	3,370	5,843	8,160
Royalty revenue	167	—	415	—
License and milestone fees	910	—	910	15,000
Clinical compound revenue	66	—	165	—
Total revenue	4,866	10,813	17,964	38,606
Operating expenses:				
Cost of goods sold	1,558	3,055	5,566	5,136
Research and development	25,451	24,691	80,095	65,869
General and administrative	6,755	6,912	21,191	23,829
Total operating expenses	33,764	34,658	106,852	94,834
Operating loss	(28,898)	(23,845)	(88,888)	(56,228)
Other income, net	866	665	2,712	1,093
Net loss	$ (28,032)	$ (23,180)	$ (86,176)	$ (55,135)
Net loss per share:				
Basic and Diluted	$ (0.52)	$ (0.43)	$ (1.59)	$ (1.03)
Weighted average shares:				
Basic and Diluted	54,235,695	53,726,123	54,038,239	53,616,753
Other comprehensive income (loss), net of tax of $0:				
Change in unrealized gains (losses) on available-for-sale marketable securities	291	(101)	1,233	(1,790)
Total comprehensive loss	$ (27,741)	$ (23,281)	$ (84,943)	$ (56,925)

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	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2022	53,797,341	$ 53	$ 726,630	$ (566,232)	$ (1,672)	$ 158,779
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	53,974,352	$ 54	$ 730,542	$ (592,897)	$ (1,101)	$ 136,598
Stock-based compensation expense	—	—	3,116	—	—	3,116
Shares issued upon vesting of restricted stock units	94,454	—	326	—	—	326
Net loss	—	—	—	(31,479)	—	(31,479)
Other comprehensive income	—	—	—	—	371	371
Balance at June 30, 2023	54,068,806	$ 54	$ 733,984	$ (624,376)	$ (730)	$ 108,932
Net proceeds from sales of common stock under open market sales agreement	386,881	—	1,117	—	—	1,117
Stock-based compensation expense	—	—	3,171	—	—	3,171
Shares issued upon vesting of restricted stock units	16,142	—	163	—	—	163
Net loss	—	—	—	(28,032)	—	(28,032)
Other comprehensive income	—	—	—	—	291	291
Balance at September 30, 2023	54,471,829	$ 54	$ 738,435	$ (652,408)	$ (439)	$ 85,642

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(amounts in thousands except share and per share data)
(unaudited)

	Common Stock		Additional Paid-In		Accumulated Other	Total
	Shares	Amount	Capital	Accumulated Deficit	Comprehensive Loss	Stockholders' Equity
Balance at December 31, 2021	53,480,812	$ 53	$ 708,585	$ (480,758)	$ (358)	$ 227,522
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	53,591,225	$ 53	$ 714,292	$ (508,507)	$ (1,723)	$ 204,115
Stock-based compensation expense	—	—	4,232	—	—	4,232
Shares issued upon exercise of stock options	30,000	—	182	—	—	182
Shares issued upon vesting of restricted stock units	89,075	—	423	—	—	423
Net loss	—	—	—	(4,206)	—	(4,206)
Other comprehensive loss	—	—	—	—	(324)	(324)
Balance at June 30, 2022	53,710,300	$ 53	$ 719,129	$ (512,713)	$ (2,047)	$ 204,422
Stock-based compensation expense	—	—	3,520	—	—	3,520
Shares issued upon exercise of stock options	15,807	—	104	—	—	104
Shares issued upon vesting of restricted stock units	7,500	—	55	—	—	55
Net loss	—	—	—	(23,180)	—	(23,180)
Other comprehensive loss	—	—	—	—	(101)	(101)
Balance at September 30, 2022	53,733,607	$ 53	$ 722,808	$ (535,893)	$ (2,148)	$ 184,820

See Notes to Condensed Financial Statements.

CARA THERAPEUTICS, INC.

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

	Nine Months Ended	
	September 30, 2023	**September 30, 2022**
Operating activities		
Net loss	$ (86,176)	$ (55,135)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,129	13,933
Depreciation and amortization	177	187
Noncash lease expense	1,221	1,055
(Accretion)/amortization of available-for-sale marketable securities, net	(159)	498
Changes in operating assets and liabilities:		
Accounts receivable, net - related party	(91)	(9,623)
Inventory, net	(883)	749
Other receivables	(1,186)	4
Prepaid expenses	3,609	(16,043)
Accounts payable and accrued expenses	37	10,455
Operating lease liabilities	(1,278)	(1,300)
Other	(108)	—
Net cash used in operating activities	(74,708)	(55,220)
Investing activities		
Proceeds from maturities of available-for-sale marketable securities	118,590	162,185
Proceeds from redemptions of available-for-sale marketable securities, at par	4,000	—
Purchases of available-for-sale marketable securities	(48,601)	(77,858)
Purchases of property and equipment	(323)	(43)
Net cash provided by investing activities	73,666	84,284
Financing activities		
Net proceeds from sales of common stock under open market sales agreement	1,117	—
Proceeds from the exercise of stock options	559	289
Net cash provided by financing activities	1,676	289
Net increase in cash, cash equivalents and restricted cash	634	29,353
Cash, cash equivalents and restricted cash at beginning of period	64,149	13,861
Cash, cash equivalents and restricted cash at end of period	$ 64,783	$ 43,214
Noncash investing and financing activities		
Accrual for leasehold improvements	$ 807	$ —

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. Difelikefalin injection was also approved in the United Arab Emirates, Kuwait, Israel, and Japan under the brand name KORSUVA in January 2023, May 2023, June 2023, and September 2023, respectively. The Company expects additional approvals and commercial launches over the next 12-18 months. On November 1, 2023, the Company entered into a Purchase and Sale Agreement, or the HCR Agreement, with HCRX Investments Holdco, L.P. and Healthcare Royalty Partners IV, L.P., or collectively HCR, where HCR will receive future royalty payments for Kapruvia and KORSUVA (ex U.S. only) up to certain capped amounts in exchange for certain payments to the Company (see Note 18, *Subsequent Event)*.

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

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
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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).*

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 2023, Maruishi received manufacturing and marketing approval from Japan's Ministry of Health, Labour and Welfare for KORSUVA IV Injection Syringe for the treatment of pruritus in hemodialysis patients. In conjunction with the approval, the Company earned a $1,449 milestone payment per the terms of the licensing agreement (see Note 11, *Collaboration and Licensing Agreements* and Note 12, *Revenue Recognition).*

As of September 30, 2023, the Company had raised aggregate net proceeds of approximately $520,700 from several rounds of equity financing, including its initial public offering, or IPO, which closed in February 2014, four follow-on public offerings of common stock, which closed in July 2019, July 2018, April 2017 and August 2015, respectively, the issuance of common stock pursuant to its open market sales agreement with Jefferies LLC as sales agent, or the Sales Agreement, in 2023, 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 $284,800 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 September 30, 2023, the Company had unrestricted cash and cash equivalents and marketable securities of $83,288 and an accumulated deficit of $652,408. 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 $28,032 and $23,180 for the three months ended September 30, 2023 and 2022, respectively, and $86,176 and $55,135 for the nine months ended September 30, 2023 and 2022, respectively, and had net cash used in operating activities of $74,708 and $55,220 for the nine months ended September 30, 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

CARA THERAPEUTICS, INC.

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

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 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 amount of lease incentives, as applicable, and 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, the conflict between Israel and Hamas, and government actions implemented as a result of either of the foregoing, high rates of 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.

CARA THERAPEUTICS, INC.

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

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 September 30, 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.

The following tables summarize the Company's available-for-sale marketable securities by major type of security as of September 30, 2023 and December 31, 2022:

As of September 30, 2023

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agency obligations	$ 9,500	$ —	$ (397)	$ 9,103
Corporate bonds	9,327	—	(42)	9,285
Municipal bonds	2,025	—	—	2,025
Total available-for-sale marketable securities	$ 20,852	$ —	$ (439)	$ 20,413

As of December 31, 2022

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
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 September 30, 2023 and December 31, 2022:

As of September 30, 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	$ —	$ —	$ 9,103	$ (397)	$ 9,103	$ (397)
Corporate bonds	1,826	—	7,459	(42)	9,285	(42)
Total	$ 1,826	$ —	$ 16,562	$ (439)	$ 18,388	$ (439)

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)
Total	$ 18,358	$ (48)	$ 62,181	$ (1,626)	$ 80,539	$ (1,674)

As of September 30, 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 September 30, 2023 and December 31, 2022, the Company held a total of 7 out of 9 positions and 35 out of 39 positions, respectively, that were in an unrealized loss position, 6 of which had been in an unrealized loss position for 12 months or greater as of September 30, 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 September 30, 2023.

Corporate bonds and municipal bonds. The unrealized losses on the Company's investments in corporate bonds 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 4 out of 4 positions for its corporate bonds, and 0 out of 2 positions for its municipal bonds, that were in unrealized loss positions as of September 30, 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 September 30, 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:

	As of September 30, 2023		As of December 31, 2022	
Contractual maturity	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	$ 15,852	$ 15,666	$ 82,678	$ 81,658
One year to two years	5,000	4,747	12,002	11,350
Total	$ 20,852	$ 20,413	$ 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 each of the three and nine months ended September 30, 2023 and 2022.

As of September 30, 2023 and December 31, 2022, accrued interest receivables on the Company's available-for-sale debt securities were $232 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 nine months ended September 30, 2023 and 2022, respectively.

	Total Accumulated Other Comprehensive Loss
Balance, December 31, 2022	$ (1,672)
Other comprehensive income before reclassifications	1,233
Amount reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive income	1,233
Balance, September 30, 2023	$ (439)
Balance, December 31, 2021	$ (358)
Other comprehensive loss before reclassifications	(1,790)
Amount reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive loss	(1,790)
Balance, September 30, 2022	$ (2,148)

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 each of the three and nine months ended September 30, 2023 and 2022.

CARA THERAPEUTICS, INC.

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

5. Fair Value Measurements

As of September 30, 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 September 30, 2023 or December 31, 2022.

The following tables summarize the Company's financial assets measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022.

Fair value measurement as of September 30, 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)
Cash and cash equivalents:				
Money market funds and checking accounts	$ 62,875	$ 62,875	$ —	$ —
Available-for-sale marketable securities:				
U.S. government agency obligations	9,103	—	9,103	—
Corporate bonds	9,285	—	9,285	—
Municipal bonds	2,025	—	2,025	—
Restricted cash:				
Commercial money market account	1,908	1,908	—	—
Total financial assets	$ 85,196	$ 64,783	$ 20,413	$ —

CARA THERAPEUTICS, INC.

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

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)
Cash and cash equivalents:				
Money market funds and checking accounts	$ 63,741	$ 63,741	$ —	$ —
Available-for-sale marketable securities:				
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	—
Restricted cash:				
Commercial money market account	408	408	—	—
Total financial assets	$ 157,157	$ 64,149	$ 93,008	$ —

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 each of the three and nine months ended September 30, 2023 and 2022. There were no transfers of financial assets into or out of Level 3 classification during each of the three and nine months ended September 30, 2023 and 2022.

6. Restricted Cash

In May 2023, the Company entered into a lease agreement 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 its new principal executive offices, or the New Lease. The Company is required to maintain a stand-by letter of credit as a security deposit under the New Lease and its existing leases for its office spaces in Stamford, Connecticut (refer to Note 16, *Commitments and Contingencies: Leases*). The fair value of the letters 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 letters of credit issued to the landlords by the bank. As of September 30, 2023, the restricted cash balances for the New Lease and the existing leases were invested in a commercial money market account.

As of September 30, 2023, the Company had $408 of restricted cash related to its existing leases in current assets and $1,500 of restricted cash related to the New Lease in long-term assets. After the first and second anniversaries of the rent commencement date, the face amount of the letter of credit relating to the New Lease can be reduced by $500 each period if the Company is not in default of its lease obligations. As of December 31, 2022, the Company had $408 of restricted cash related to its existing leases in current assets.

CARA THERAPEUTICS, INC.

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

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.

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 62,875	$ 63,741
Restricted cash, current assets	408	408
Restricted cash, long-term assets	1,500	—
Total cash, cash equivalents, and restricted cash shown in the Condensed Statements of Cash Flows	$ 64,783	$ 64,149

7. Inventory, net

Inventory, net consists of the following:

	September 30, 2023	December 31, 2022
Raw materials	$ 2,692	$ 1,918
Work-in-process	607	499
Finished goods	4	—
	3,303	2,417
Less Inventory Reserve for Obsolescence	(37)	(34)
Total	$ 3,266	$ 2,383

As of September 30, 2023 and December 31, 2022, inventory balances include inventory costs subsequent to regulatory approval of KORSUVA injection on August 23, 2021.

8. Prepaid expenses

As of September 30, 2023, prepaid expenses were $12,658, consisting of $11,133 of prepaid R&D clinical costs, $865 of prepaid insurance and $660 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:

	September 30, 2023	December 31, 2022
Accounts payable	$ 7,978	$ 9,604
Accrued research projects	6,304	5,200
Accrued compensation and benefits	5,370	5,219
Accrued professional fees and other	2,732	1,517
Total	$ 22,384	$ 21,540

CARA THERAPEUTICS, INC.

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

10. Stockholders' Equity

In August 2023, as a result of completion of the vesting period for restricted stock units granted in October 2022, an aggregate of 7,267 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In July 2023, as a result of completion of the quarterly vesting period for restricted stock units granted in October 2021, an aggregate of 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 June 2023, as a result of completion of the final vesting period for restricted stock units granted in December 2021, an aggregate of 26,199 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In June 2023, as a result of the completion of the one-year vesting period, an aggregate of 59,380 restricted stock units of members of the Board of Directors vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In April 2023, as a result of completion of the quarterly vesting period for restricted stock units granted in October 2021, an aggregate of 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 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*).

In January 2023, as a result of completion 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 September 2022, as a result of the appointment of the Company's new Chief Financial Officer, or CFO, 7,500 time-based restricted stock units held by the Company's interim principal financial and accounting officer vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In June 2022, as a result of the accelerated vesting of restricted stock units associated with the former Chief Executive Officer's, or CEO's, modification of equity awards, an aggregate of 33,999 restricted stock units vested and were settled in shares of the Company's common stock (see Note 14, *Stock-Based Compensation*).

In June 2022, as a result of the completion of the one-year vesting period, an aggregate of 43,200 restricted stock units of members of the Board of Directors vested and were settled in shares of the Company's common stock. Also in

CARA THERAPEUTICS, INC.

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

June 2022, the Company granted 11,876 fully vested restricted stock units, which were immediately settled in shares of the Company's common stock, to the Company's chairman in consideration of his effort in connection with the Company's CEO transition in 2021 (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 the Sales Agreement, 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. During the three months ended September 30, 2023, 386,881 shares were sold under the Sales Agreement and the Company received net proceeds of $1,117.

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

CARA THERAPEUTICS, INC.

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

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.

CARA THERAPEUTICS, INC.

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

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. In September 2023, Maruishi received manufacturing and marketing approval from Japan's Ministry of Health, Labour and Welfare for KORSUVA IV Injection Syringe for the treatment of pruritus in hemodialysis patients. In conjunction with the approval, the Company earned a $1,449 milestone payment per the terms of the licensing agreement (see Note 12, *Revenue Recognition)*.

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.

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

12. Revenue Recognition

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 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 September 30, 2023, the Company has not earned any sales-based milestones under its collaboration agreements.

As of September 30, 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 and nine months ended September 30, 2023 and 2022, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaborative revenue				
CSL Vifor (KORSUVA injection profit sharing)	$ 1,932	$ 7,443	$ 10,092	$ 15,446
Maruishi	539	—	539	—
Total collaborative revenue	$ 2,471	$ 7,443	$ 10,631	$ 15,446
Commercial supply revenue				
CSL Vifor* (KORSUVA injection)	$ 1,252	$ 3,370	$ 5,843	$ 8,160
Total commercial supply revenue	$ 1,252	$ 3,370	$ 5,843	$ 8,160
Royalty revenue				
CSL Vifor (Kapruvia ex U.S.)	$ 167	$ —	$ 415	$ —
Total royalty revenue	$ 167	$ —	$ 415	$ —
License and milestone fees				
Vifor Fresenius Medical Care Renal Pharma Ltd.	$ —	$ —	$ —	$ 15,000
Maruishi	910	—	910	—
Total license and milestone fees	$ 910	$ —	$ 910	$ 15,000
Clinical compound revenue				
Maruishi	$ 66	$ —	$ 165	$ —
Total clinical compound revenue	$ 66	$ —	$ 165	$ —

* 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

CARA THERAPEUTICS, INC.

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

collaborative revenue. During the three and nine months ended September 30, 2023, the Company recorded $1,932 and $10,092, respectively, as collaborative revenue for its profit-share from the sales of KORSUVA injection in the United States. During the three and nine months ended September 30, 2022, the Company recorded $7,443 and $15,446, respectively, as collaborative revenue for its profit-share from the sales of KORSUVA injection in the United States.

The Company's distinct performance obligations under the Maruishi Agreement include transfer of the license to the Company's intellectual property, which allowed Maruishi to develop and commercialize difelikefalin, for acute pain and uremic pruritus indications in Japan, which occurred at inception of the contract in 2013 (considered license and milestone fees revenue), and performance of R&D services, which occurred from 2013 to 2015 (considered collaborative revenue), as those services were rendered. The Company agreed to conduct limited work on an oral tablet formulation of difelikefalin and to conduct Phase 1 and proof-of-concept Phase 2 clinical trials of an intravenous formulation of difelikefalin to be used to treat patients with uremic pruritus. The Company agreed to transfer the data and information from such development to Maruishi for its efforts to obtain regulatory approval in Japan. These activities are referred to as R&D services and are included as collaborative revenue.

During each of the three and nine months ended September 30, 2023, the criteria for revenue recognition for a regulatory milestone event set forth in the Maruishi Agreement was achieved, and the Company earned $1,449, of which $539 was recorded as collaborative revenue based on the relative standalone selling prices described at contract inception. This regulatory milestone payment was considered variable consideration due to the uncertainty of occurrence of this event as specified at inception of the agreement. Therefore, this potential regulatory milestone payment was not included in the transaction price at the inception of the agreement. There was no collaborative revenue recognized under the Maruishi Agreement during the three and nine months ended September 30, 2022.

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 $1,252 and $5,843 for the three and nine months ended September 30, 2023, respectively, with associated COGS of $1,558 and $5,566, respectively. The Company had commercial supply revenue of $3,370 for the three months ended September 30, 2022 with associated COGS of $3,055. The Company had commercial supply revenue of $8,160 for the nine months ended September 30, 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 $5,865 was recognized with associated COGS of $5,136 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 Kapruvia 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 and nine months ended September 30, 2023, the Company recorded $167 and $415, respectively, as royalty revenue based on net sales of Kapruvia. There was no royalty revenue for the three and nine months ended September 30, 2022.

CARA THERAPEUTICS, INC.

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

License and milestone fees revenue

Under Vifor Agreement No. 2, the Company's performance obligations of granting a license to allow Vifor Fresenius Medical Care Renal Pharma Ltd. to commercialize difelikefalin injection worldwide, except in the United States, Japan and South Korea, which occurred at inception of the contract in May 2018, and performing R&D services by the Company to obtain sufficient clinical data which were shared with Vifor Fresenius Medical Care Renal Pharma Ltd. to allow them to receive regulatory approval to sell difelikefalin in the licensed territory, were not distinct, and were accounted for as a single performance obligation during the period the that the R&D services were rendered (see Note 11, *Collaboration and Licensing Agreements*).

Revenue related to achievement of milestone events is recognized when the Company has determined that it is probable that a milestone event will be achieved and there will not be a significant reversal of revenue in future periods. Upon probability of achievement of a milestone event, the most likely amount of variable consideration is included in the transaction price. Subsequent changes to the transaction price, after contract initiation, are allocated to the performance obligations in the contract on the same basis as at contract inception. Revenue for variable consideration is recognized in the same manner (point in time or over time) as for the performance obligations to which the payment amounts were allocated.

During each of the three and nine months ended September 30, 2023, the criteria for revenue recognition for a regulatory milestone event set forth in the Maruishi Agreement was achieved and the Company earned $1,449, of which $910 was recorded as license and milestone fees revenue based on the relative standalone selling prices described at contract inception. This regulatory milestone payment was considered variable consideration due to the uncertainty of occurrence of this event as specified at inception of the agreement. Therefore, this potential regulatory milestone payment was not included in the transaction price at the inception of the agreement. There was no license and milestone fees revenue recognized under the Maruishi Agreement during the three and nine months ended September 30, 2022.

As a result of the European Commission's regulatory approval of Kapruvia in April 2022, the Company achieved a $15,000 regulatory milestone payment from Vifor Fresenius Medical Care Renal Pharma Ltd. under Vifor Agreement No. 2, which was recorded as license and milestone fees revenue for the nine months ended September 30, 2022. This regulatory milestone payment was considered variable consideration due to the uncertainty of occurrence of this event as specified at inception of the agreement. Therefore, this potential regulatory milestone payment was not included in the transaction price at the inception of the agreement.

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 and nine months ended September 30, 2023, the Company recognized clinical compound revenue of $66 and $165, respectively, from the sale of clinical compound to Maruishi. There were no sales of clinical compound during the three and nine months ended September 30, 2022.

Contract balances

As of September 30, 2023 and December 31, 2022, respectively, the Company recorded accounts receivable, net – related party of $3,351 and $3,260 which primarily related to its profit-sharing revenue from sales of KORSUVA injection in the United States by CSL Vifor, its commercial supply of KORSUVA injection to CSL Vifor, and royalty revenue from CSL Vifor relating to sales of Kapruvia outside of the United States. The Company also recorded $1,449 within other receivables for the regulatory milestone payment earned from Maruishi as of September 30, 2023. There

CARA THERAPEUTICS, INC.

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

were no other contract assets or contract liabilities related to the CSL Vifor, Maruishi and CKDP agreements as of September 30, 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 September 30, 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 each of the three and nine months ended September 30, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Basic:				
Weighted average common shares outstanding	54,235,695	53,726,123	54,038,239	53,616,753
Diluted:				
Weighted average common shares outstanding - Basic	54,235,695	53,726,123	54,038,239	53,616,753
Common stock equivalents*	—	—	—	—
Denominator for diluted net loss per share	54,235,695	53,726,123	54,038,239	53,616,753

* 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss - basic and diluted	$ (28,032)	$ (23,180)	$ (86,176)	$ (55,135)
Weighted-average common shares outstanding:				
Basic and diluted	54,235,695	53,726,123	54,038,239	53,616,753
Net loss per share, basic and diluted:	$ (0.52)	$ (0.43)	$ (1.59)	$ (1.03)

As of September 30, 2023, 8,040,891 stock options and 775,711 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 September 30, 2022, 7,654,523 stock options and 640,950 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.

CARA THERAPEUTICS, INC.

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

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

Pursuant to the Company's non-employee director compensation policy, an aggregate of 194,172 restricted stock units were granted to non-employee directors on June 1, 2023, the date of the Company's 2023 Annual Meeting of Stockholders, under the 2014 Plan with a grant date fair value of $3.09 per share. The restricted stock units will vest on the earlier of (i) June 1, 2024 and (ii) immediately prior to the Company's next Annual Meeting of Stockholders

CARA THERAPEUTICS, INC.

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

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 and nine months ended September 30, 2023, stock compensation expense associated with these awards of $151 and $199, respectively, was recognized in general and administrative expense, or G&A expense. As of September 30, 2023, 194,172 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.

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 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 each of the three and nine months ended September 30, 2023, no stock compensation expense relating to these restricted stock units was recognized. As of September 30, 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 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 vested on August 31, 2023. For the three and nine months ended September 30, 2023, the Company recognized $13 and $51, respectively, of stock compensation expense associated with these awards, all of which was recorded within G&A expense. As of September 30, 2023, none of these restricted stock units were outstanding as these restricted stock units vested fully in August 2023.

On June 15, 2022, the Compensation Committee approved and granted a total of 7,500 time-based restricted stock units to the Company's interim principal financial officer and principal accounting officer, as a result of his assuming the responsibilities of the Company's former Chief Financial Officer on an interim basis, under the 2014 Plan with a grant date fair value of $7.94 per share. As a result, the Company recognized compensation expense associated with these restricted stock units ratably over the vesting period following the grant date. For the three and nine months ended September 30, 2022, the Company recognized $55 and $60, respectively, of stock compensation expense associated with these awards, all of which were recorded within G&A expense. As of September 30, 2023, none of these restricted stock units were outstanding as these restricted stock units vested fully in September 2022.

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. These restricted stock unit grants fully vested on June 2, 2023. For the nine months ended September 30, 2023, stock compensation expense associated with these awards of $209 was recognized in G&A expense. There was no stock compensation expense associated with these restricted stock units during the three months ended September 30, 2023. For the three and nine months ended September 30, 2022, stock compensation expense of $126 and $164, respectively, was recognized in G&A expense. As of September 30, 2023, none of these restricted stock units were outstanding as these restricted stock units vested fully on June 2, 2023. Also in June 2022, the Company granted 11,876 fully vested restricted stock units, which were immediately settled in shares of common stock, to the Company's chairman in consideration of his effort in connection with the Company's CEO transition in 2021. For the nine months ended September 30, 2022, stock compensation expense of $100 was recognized in G&A expense associated with this award.

On February 25, 2022, the Compensation Committee also approved and granted a total of 243,000 restricted stock units to certain employees under the 2014 Plan with a grant date fair value of $10.46 per share. Vesting of the restricted

CARA THERAPEUTICS, INC.

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

stock units is contingent on the achievement of certain performance targets related to commercial 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 are probable of achievement and the employee has met the service conditions. For each of the three and nine months ended September 30, 2023 and 2022, no stock compensation expense relating to these restricted stock units was recognized. In June 2022, 29,000 of these restricted stock units were forfeited as a result of the resignation of our former CFO. In December 2022, 214,000 of these restricted stock units were cancelled as the performance targets associated with them were not achieved. As of September 30, 2023, none of these restricted stock units were outstanding as the remaining restricted stock units were cancelled in 2022.

Additionally, 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 April 2023, 3,585 of these restricted stock units were forfeited. 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 and nine months ended September 30, 2023, the Company recognized $103 and $303, respectively, of stock compensation expense associated with these awards, with $35 recorded in R&D expense and $68 recorded in G&A expense for the three months ended September 30, 2023, and $100 recorded in R&D expense and $203 recorded in G&A expense for the nine months ended September 30, 2023. For the three and nine months ended September 30, 2022, the Company recognized $116 and $274, respectively, of stock compensation expense associated with these awards, with $48 recorded in R&D expense and $68 recorded in G&A expense for the three months ended September 30, 2022, and $113 recorded in R&D expense and $161 recorded in G&A expense for the nine months ended September 30, 2022. In June 2022, 20,000 of these restricted stock units were forfeited as a result of the resignation of the Company's former CFO. As of September 30, 2023, 78,665 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 vested in two equal installments on December 15, 2022 and June 15, 2023. As a result, the Company recognized compensation expense associated with these restricted stock units ratably over the 18-month vesting period following the grant date. On June 15, 2023, the remaining 26,199 of these restricted stock units fully vested and were settled in shares of the Company's common stock. In June 2022, 11,170 of these restricted stock units were forfeited as a result of the resignation of the Company's former CFO. For the nine months ended September 30, 2023, the Company recognized $199 of stock compensation expense associated with these awards, with $96 recorded in R&D expense and $103 recorded in G&A expense. There was no stock compensation expense recognized for these restricted stock awards for the three months ended September 30, 2023. For the three and nine months ended September 30, 2022, the Company recognized $110 and $323, respectively, of stock compensation expense associated with these awards, with $53 recorded in R&D expense and $57 recorded in G&A expense for the three months ended September 30, 2022, and $157 recorded in R&D expense and $166 recorded in G&A expense for the nine months ended September 30, 2022. As of September 30, 2023, none of these restricted stock units were outstanding as the remaining restricted stock units fully vested in June 2023.

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 vested 25% on the first anniversary of the date of grant and the balance vests quarterly over the next 36 months. As a result, 35,500 of these restricted stock units vested and were settled in shares of the Company's common stock in October 2022. The second tranche of 5,942 restricted

CARA THERAPEUTICS, INC.

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

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 July 2023, April 2023 and January 2023, 8,875 of these restricted stock units vested each period and were settled in shares of the Company's common stock in satisfaction of the quarterly periods of vesting. For the three and nine months ended September 30, 2023, stock compensation expense associated with these awards of $150 and $446, respectively, was recognized in G&A expense. For the three and nine months ended September 30, 2022, stock compensation expense associated with these awards of $151 and $506, respectively, was recognized in G&A expense. As of September 30, 2023, 79,875 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 nine months ended September 30, 2022, stock compensation expense associated with these awards of $239 was recognized in G&A expense for these restricted stock units. There was no stock compensation expense recognized for the three months ended September 30, 2022. As of September 30, 2023, none of these restricted stock units were outstanding as the remaining restricted stock units fully vested in June 2022.

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 March 2022, 93,999 restricted stock units were forfeited as a result of not achieving certain defined performance targets of the awards. 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 each of the three and nine months ended September 30, 2023, there was no stock compensation expense recognized as all of these restricted stock units either vested or were forfeited prior to these periods. For the nine months ended September 30, 2022, the Company recognized $729 of stock compensation expense associated with these awards in G&A expense. G&A amounts recorded for the nine months ended September 30, 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). There was no stock compensation expense recognized for the three months ended September 30, 2022. As of September 30, 2023, none of these restricted stock units were outstanding as the remaining restricted stock units either fully vested or were forfeited in prior periods.

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 June 2022, 17,333 of these restricted stock units vested and were settled in shares of the Company's common stock in accordance with the acceleration of vesting provisions relating to the modification of certain of these restricted stock units on November 1, 2021. In June 2022, 17,333 restricted stock units were forfeited as a result of the completion of the consulting agreement in relation to the modification of certain of these restricted stock units on November 1, 2021 (see *Stock Award Modifications* below). In March 2022, 33,336 of these restricted stock units vested and were settled in shares of the Company's common stock in

CARA THERAPEUTICS, INC.

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

satisfaction of the first year of vesting. For the three and nine months ended September 30, 2023, the Company recognized $83 and $246, respectively, of stock compensation expense associated with these awards, with $55 recorded in R&D expense and $28 in G&A expense for the three months ended September 30, 2023, and $164 recorded in R&D expense and $82 in G&A expense for the nine months ended September 30, 2023. For the three and nine months ended September 30, 2022, the Company recognized $83 and $563, respectively, of stock compensation expense associated with these awards, with $55 recorded in R&D expense and $28 in G&A expense for the three months ended September 30, 2022, and $164 recorded in R&D expense and $399 in G&A expense for the nine months ended September 30, 2022. G&A amounts recorded for the nine months ended September 30, 2022 included $317 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 September 30, 2023, 15,999 restricted stock units were outstanding and available to vest and settle in shares of the Company's common stock.

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 vested in three equal installments annually from the date of the grant. As a result, the Company recognized 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 nine months ended September 30, 2023, the Company recognized $39 of stock compensation expense associated with these awards, with $26 recorded in R&D expense and $13 in G&A expense. There was no associated stock compensation expense for the three months ended September 30, 2023 as these restricted stock units were fully vested in the prior period. For the three and nine months ended September 30, 2022, the Company recognized $66 and $460, respectively, of stock compensation expense associated with these awards, with $44 recorded in R&D expense and $22 in G&A expense for the three months ended September 30, 2022, and $131 recorded in R&D expense and $329 in G&A expense for the nine months ended September 30, 2022. G&A amounts recorded for the nine months ended September 30, 2022 included $264 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 September 30, 2023, none of these restricted stock units were outstanding as the remaining restricted stock units were fully vested in February 2023.

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 nine months ended September 30, 2023 is presented below:

	Number of Units	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2022	372,513	$ 13.20
Awarded	601,172	7.81
Vested and released	(194,389)	12.26
Forfeited	(3,585)	10.46
Outstanding, September 30, 2023	775,711	$ 9.27
Restricted stock units exercisable (vested and deferred), September 30, 2023	—	

CARA THERAPEUTICS, INC.

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

Stock Options

Under the 2014 Plan, the Company granted 155,747 and 437,500 stock options during the three months ended September 30, 2023 and 2022, respectively, and 1,954,668 and 1,739,919 stock options during the nine months ended September 30, 2023 and 2022, respectively. No stock options were granted under the 2019 Inducement Plan during the three and nine months ended September 30, 2023 and 2022. The fair values of stock options granted during the three and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Risk-free interest rate	4.20%	2.65% - 4.09%	3.38% - 4.22%	1.70% - 4.09%
Expected volatility	80.8%	77.7% - 78.2%	76.3% - 81.3%	77.7% - 81.9%
Expected dividend yield	0%	0%	0%	0%
Expected life of employee and Board options (in years)	6.25	6.25	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 September 30, 2023 and 2022 was $2.24 and $7.37, respectively, and during the nine months ended September 30, 2023 and 2022 was $5.86 and $7.27, respectively. No options were granted to non-employee consultants during the three and nine months ended September 30, 2023 and 2022.

During the three and nine months ended September 30, 2023 and 2022, the Company recognized compensation expense relating to stock options as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 1,387	$ 1,719	$ 4,314	$ 5,380
General and administrative	1,447	1,149	4,122	5,137
Total stock option expense	$ 2,834	$ 2,868	$ 8,436	$ 10,517

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 $90 in R&D expense and $259 in G&A expense for the three months ended September 30, 2023, and $385 in R&D expense and $899 in G&A expense for the nine months ended September 30, 2023; (ii) the vesting of certain employees' restricted stock units for $200 in R&D expense and $381 in G&A expense for the three months ended September 30, 2022, and $565 in R&D expense and $2,350 in G&A expense for the nine months ended September 30, 2022; (iii) compensation expense relating to the Board of Directors' restricted stock units for $151 and $409 in G&A expense for the three and nine months ended September 30, 2023, respectively; and (iv) compensation expense relating to the Board of Directors' restricted stock units for $126 and $503 in G&A expense for the three and nine months ended September 30, 2022, respectively.

CARA THERAPEUTICS, INC.

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

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 nine months ended September 30, 2023 is presented below:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2022	7,689,449	$ 14.35
Granted	1,954,668	8.31
Exercised	(93,218)	6.00
Forfeited	(177,085)	11.19
Expired	(1,332,923)	14.48
Outstanding, September 30, 2023	8,040,891	$ 13.03
Options exercisable, September 30, 2023	4,583,227	

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 nine months ended September 30, 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.

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 through June 30, 2022.

During the nine months ended September 30, 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 $2,563, which was included in G&A expense for the nine months ended September 30, 2022. Of this total amount, $1,679 was included in G&A expense in the stock option compensation expense table above for the nine months ended September 30, 2022. There was no incremental stock compensation expense related to the modifications of stock options, time-

CARA THERAPEUTICS, INC.

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

based and performance-based restricted stock units for the three months ended September 30, 2022, as a result of the consulting period ending on June 30, 2022.

15. Income Taxes

The Company has recognized a full tax valuation allowance against its deferred tax assets as of September 30, 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 each of the three and nine months ended September 30, 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 and nine months ended September 30, 2023 and 2022, therefore there was no benefit from income taxes for the three and nine months ended September 30, 2023 and 2022. As of September 30, 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 early in 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 September 30, 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 enhance permeability and/or solubility, known as Enteris's Peptelligence® 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 and nine months ended September 30, 2023, no milestone payments or royalties were paid to Enteris by the Company in relation to the Enteris License Agreement. During the three months ended September 30, 2022, Enteris earned a $5,000 milestone payment based on the first patient dosing in a Phase 3 trial, which was subsequently paid in October 2022. This milestone payment to Enteris was recorded in R&D expense for the three and nine months ended September 30, 2022.

CARA THERAPEUTICS, INC.

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

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 (Original Corporate Headquarters in 2015 & Amendment for Additional Space in 2020)

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 $1,220 of operating lease cost, or lease expense, was recognized for the three and nine months ended September 30, 2023, respectively, consisting of $285 relating to R&D lease expense and $122 relating to G&A lease expense for the three months ended September 30, 2023, and $854 relating to R&D lease expense and $366 relating to G&A lease expense for the nine months ended September 30, 2023. For the three and nine months ended September 30, 2022, $406 and $1,218, respectively, of lease expense was recognized, consisting of $284 relating to R&D lease expense and $122 relating to G&A lease expense for the three months ended September 30, 2022, and $853 relating to R&D lease expense and $365 relating to G&A lease expense for the nine months ended September 30, 2022.

Lease (*New Corporate Headquarters in May 2023*)

On May 11, 2023, the Company entered into the New Lease for the Company's new principal executive offices. The initial term of the New Lease commences on the earlier to occur of (a) the date the Company first occupies the premises for the regular conduct of its business therein, and (b) the date the Landlord delivers the premises to the Company in the condition required under the terms of the New Lease, provided that such date shall be no sooner than November 1, 2023,

CARA THERAPEUTICS, INC.

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

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 (considered by the Company to be at market rate as of the signing of the New Lease), 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 increase 2.5% annually thereafter. The Company expects to begin paying rent in November 2024.

The Company is also responsible for the payment of Additional Rent, as defined in the New Lease, including its share of the operating and tax expenses for the building. As a result, the New Lease contains both a lease (the right to use the asset) and a non-lease component (common area maintenance services) which are accounted for separately. The Company allocates the consideration to the lease and non-lease component on a relative standalone price basis.

The Company 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. This renewable term is not included as part of the lease term as defined in ASC 842 since it is not reasonably certain that the Company will exercise that option on the Commencement Date.

Since the New Lease does not provide an implicit interest rate, the Company used an incremental borrowing rate equal to the 3-month Secured Overnight Financing Rate, or SOFR, plus 7.75% per annum subject to a 3-month SOFR floor of 2.75%, which is based on the rate that the Company could obtain in the market for a fully collateralized loan equal to the term of the New Lease, or 12.83%.

On July 28, 2023, the Company recorded a lease liability and a right-of-use asset, or the ROU asset, for the New Lease since it obtained control of the premises to begin work on its leasehold improvements prior to the Commencement Date. The initial lease liability of $6,672 was recorded as the sum of the present value of the future minimum lease payments over the term of the lease. Lease incentives of $2,900 were not included within lease payments since the timing of these costs being incurred and reimbursed to the Company was uncertain, and they are neither paid nor payable as of July 28, 2023. These lease incentives will reduce the lease liability and ROU asset by the costs incurred once the Company actually incurs the costs and the amounts qualify for reimbursement. The reduction to the lease liability will be reversed once the Company is reimbursed for the qualified costs. The reduction to the ROU asset will be recognized prospectively over the remainder of the lease term. The ROU asset of $6,779 was initially recorded as the amount of the lease liability plus prepaid rent paid in May 2023. During the three months ended September 30, 2023, the Company did not incur any costs that qualified for reimbursement as a lease incentive.

Beginning on July 28, 2023 and during the entire term of the New Lease, interest expense is calculated using the effective interest method and the ROU asset (including prepaid rent) will be amortized on a straight-line basis over the lease term, and both will be recorded as lease expense. As a result, lease expense of $214 for the New Lease was recorded for each of the three and nine months ended September 30, 2023, consisting of $150 relating to R&D lease expense and $64 relating to G&A lease expense.

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)
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Other information related to the leases (both existing and new) was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash outflows relating to operating leases	$ 500	$ 491	$ 1,489	$ 1,463
ROU assets obtained in exchange for new operating lease liabilities	$ 6,779	$ —	$ 6,779	$ —
Weighted average remaining lease term - operating leases (years)	10.4	1.3	10.4	1.3
Weighted average discount rate - operating leases	12.4 %	7.0 %	12.4 %	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 September 30, 2023, were as follows:

Year Ending December 31,	
2023 (Excluding the nine months ended September 30, 2023)	$ 503
2024	108
2025	1,298
2026	1,330
2027	1,363
2028	1,398
Thereafter	8,874
Total future minimum lease payments, undiscounted	14,874
Less imputed interest	(7,562)
Total	$ 7,312
Operating lease liabilities reported as of September 30, 2023:	
Operating lease liabilities - current	$ 497
Operating lease liabilities - non-current	6,815
Total	$ 7,312

17. Related Party Transactions

As of September 30, 2023, Vifor International owned 7,396,770, or 13.6%, of the Company's common stock. CSL Vifor and its affiliates are considered related parties as of September 30, 2023 and December 31, 2022 (see Note 11, *Collaboration and Licensing Agreements*).

As of September 30, 2023 and December 31, 2022, amounts due from CSL Vifor of $3,351 and $3,260, respectively, primarily relating to the Company's share of the profit generated by sales of KORSUVA injection in the United States by CSL Vifor, its commercial supply of KORSUVA injection to CSL Vifor, and royalty revenue from CSL Vifor relating to sales of Kapruvia outside of the United States were included within accounts receivable, net – related party.

The Company's collaborative revenue of $1,932 and $10,092 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 and nine

CARA THERAPEUTICS, INC.

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

months ended September 30, 2023, respectively. The Company's collaborative revenue of $7,443 and $15,446 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 and nine months ended September 30, 2022.

Sales of KORSUVA injection to CSL Vifor of $1,252 and $5,843 were included within commercial supply revenue for the three and nine months ended September 30, 2023, respectively. The associated COGS for the Company's commercial supply revenue from CSL Vifor was $1,558 and $5,566 for the three and nine months ended September 30, 2023, respectively. Sales of KORSUVA injection to CSL Vifor of $3,370 and $8,160 were also included within commercial supply revenue for the three and nine months ended September 30, 2022, respectively, with an associated COGS for the Company's commercial supply revenue from CSL Vifor of $3,055 and $5,136 for the three and nine months ended September 30, 2022, respectively.

The Company recorded $15,000 as license and milestone fee revenue from Vifor Fresenius Medical Care Renal Pharma Ltd. for the nine months ended September 30, 2022, as a result of the European Commission's regulatory approval of Kapruvia in April 2022.

The Company recorded $167 and $415 as royalty revenue based on net sales of Kapruvia outside of the United States during the three and nine months ended September 30, 2023.

18. Subsequent Event

On November 1, 2023, the Company, through its wholly-owned subsidiary Cara Royalty Sub, LLC, a Delaware limited liability company, or Royalty Sub, entered into the HCR Agreement, with HCRX Investments Holdco, L.P., a Delaware limited partnership and Healthcare Royalty Partners IV, L.P., a Delaware limited partnership, or collectively HCR, pursuant to which Royalty Sub sold, or agreed to sell, to HCR certain of its rights to receive royalty payments, or the Royalties, due and payable to Royalty Sub (as assignee of the Company) under the Maruishi Agreement and Vifor Agreement No. 2., collectively the Covered License Agreements, in exchange for up to $40,000. Vifor Agreement No. 2 and the Royalties thereunder shall be retained by the Company until the Company has received the First Milestone Payment (as defined below). The Company has retained all of its right, title and interest in, to and under the Covered License Agreements that relate to any non-intravenous formulation of difelikefalin.

Under the terms of the HCR Agreement, Royalty Sub received an upfront payment of $17,500, less certain expenses. The terms of the HCR Agreement provide for an additional (a) $20,000 milestone payment, or the First Milestone Payment, to Royalty Sub if, prior to December 31, 2023, pricing for Kapruvia® (difelikefalin) in Germany is approved above a certain threshold amount per dose and (b) $2,500 milestone payment to Royalty Sub upon achievement of a 2024 sales milestone of KORSUVA in Japan.

The HCR Agreement will automatically expire, and the payment of Royalties to HCR will cease, when HCR has received payments of Royalties equal to two times the aggregate amount of payments made by HCR under the HCR Agreement, or the 2029 Threshold, if the 2029 Threshold is achieved on or prior to December 31, 2029, or 2.8 times the aggregate amount of payments made by HCR under the HCR Agreement, if the 2029 Threshold is not achieved on or prior to December 31, 2029. After the HCR Agreement expires, all rights to receive the Royalties return to Royalty Sub.

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, Singapore, the United Arab Emirates, or UAE, Kuwait, Israel, and Japan, or Kapruvia® (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;

- our ability to obtain and maintain coverage and adequate reimbursement for KORSUVA injection or Kapruvia in markets around the world;

- 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;

- the performance of third-party manufacturers, clinical research organizations, or CROs, and other vendors;

- risks relating to KORSUVA injection's and Kapruvia's market acceptance, competition, reimbursement and regulatory actions;

- 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 pruritus associated with advanced chronic kidney disease, or 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;
- our receipt of payments from HCRX Investments Holdco, L.P., and Healthcare Royalty Partners IV, L.P., or collectively HCR, under that certain Purchase and Sale Agreement with HCR;
- 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 advanced 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 advanced 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 advanced CKD in adults undergoing hemodialysis in the United States. In December 2021, the U.S. Centers for Medicare & Medicaid Services, or 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. On June 26, 2023, CMS issued the Calendar Year, or CY, 2024 end-stage renal disease, or ESRD, Prospective Payment System, or PPS, proposed rule to update Medicare payment policies and rates for renal dialysis services including a proposed methodology for post-TDAPA reimbursement for TDAPA designated products in existing functional categories. On October 27, 2023, CMS published the final CY 2024 rule, which finalized the post-TDAPA add-on as proposed in the draft CY 2024 rule. Under the final rule, TDAPA drugs in existing functional categories will receive a post-TDAPA add-on payment set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment adjustment will be applied to all ESRD PPS payments and paid for 3 years, adjusted annually. The add-on payments for KORSUVA injection will commence on April 1, 2024. 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 advanced 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. Difelikefalin injection was also approved in the UAE, Kuwait, Israel, and Japan under the brand

name KORSUVA in January 2023, May 2023, June 2023, and September 2023, respectively. We expect additional approvals and commercial launches 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 advanced 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 Kapruvia. 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) advanced 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 advanced 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.

Recent Developments

Royalty Financing Agreement

On November 1, 2023, we, through our wholly-owned subsidiary Cara Royalty Sub, LLC, a Delaware limited liability company, or Royalty Sub, entered into a Purchase and Sale Agreement, or the HCR Agreement, with HCR pursuant to which Royalty Sub sold, or agreed to sell, to HCR certain of its rights to receive royalty payments, or the Royalties, due and payable to Royalty Sub (as our assignee) under the Maruishi Agreement (as defined below), and Vifor Agreement No. 2. (as defined below), collectively the Covered License Agreements, in exchange for up to $40.0 million. Vifor Agreement No. 2 and the Royalties thereunder shall be retained by us until we have received the First Milestone Payment (as defined below). We have retained all of our right, title and interest in, to and under the Covered License Agreements that relate to any non-intravenous formulation of difelikefalin.

Under the terms of the HCR Agreement, Royalty Sub received an upfront payment of $17.5 million, less certain expenses. The terms of the HCR Agreement provide for an additional (a) $20.0 million milestone payment, or the First Milestone Payment, to Royalty Sub if, prior to December 31, 2023, pricing for Kapruvia® (difelikefalin) in Germany is approved above a certain threshold amount per dose and (b) $2.5 million milestone payment to Royalty Sub upon achievement of a 2024 sales milestone of KORSUVA in Japan. All such payments, once received, will be paid by Royalty Sub to us.

The HCR Agreement will automatically expire, and the payment of Royalties to HCR will cease, when HCR has received payments of Royalties equal to two times the aggregate amount of payments made by HCR under the HCR Agreement, or the 2029 Threshold, if the 2029 Threshold is achieved on or prior to December 31, 2029, or 2.8 times the aggregate amount of payments made by HCR under the HCR Agreement, if the 2029 Threshold is not achieved on or prior to December 31, 2029. After the HCR Agreement expires, all rights to receive the Royalties return to Royalty Sub.

Appointment

We appointed Helen M. Boudreau to our Board of Directors in August 2023 and she will serve as Chair of the Audit Committee.

Retirement

Harrison M. Bains has retired from our Board of Directors.

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	• FDA approved in August 2021 • EMA MAA approved in April 2022 (Kapruvia) • UK MAA approved in April 2022 (Kapruvia) • Switzerland (Kapruvia), Canada (KORSUVA) and Singapore (KORSUVA) MAAs approved in August 2022 • Australia (KORSUVA) approved in November 2022 • U.S. commercial launch commenced in April 2022 • EU commercial launch commenced in third quarter of 2022 • UAE, Kuwait, and Israel (KORSUVA) approved in January 2023, May 2023, and June 2023, respectively • Japan manufacturing and marketing approval (KORSUVA) in September 2023	CSL Vifor (Worldwide, other than Japan and South Korea); Maruishi (Japan); CKDP (South Korea)
	Oral difelikefalin	Pruritus AD-aP	• Phase 3 program initiated in first quarter of 2022	Cara (Worldwide, other than South Korea); CKDP (South Korea)
	Oral difelikefalin	Pruritus advanced CKD-aP	• Phase 3 program initiated in first quarter of 2022	Cara (Worldwide, other than Japan and South Korea); Maruishi (Japan); CKDP (South Korea)
	Oral difelikefalin	Pruritus NP	• Phase 2 trial reported in second quarter of 2022 • Phase 2/3 program initiated in first quarter of 2023	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 advanced 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. On June 26, 2023, CMS issued the CY 2024 ESRD PPS proposed rule to update Medicare payment policies and rates for renal dialysis services including a proposed methodology for post-TDAPA reimbursement for TDAPA designated products in existing functional

categories. On October 27, 2023, CMS published the final CY 2024 rule, which finalized the post-TDAPA add-on as proposed in the draft CY 2024 rule. Under the final rule, TDAPA drugs in existing functional categories will receive a post-TDAPA add-on payment set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment adjustment will be applied to all ESRD PPS payments and paid for 3 years, adjusted annually. The add-on payments for KORSUVA injection will commence on April 1, 2024. We are partnering with CSL Vifor to commercialize KORSUVA injection in dialysis patients with advanced CKD-aP worldwide, excluding Japan (Maruishi/sub-licensee Kissei), and South Korea (CKDP). For the three and nine months ended September 30, 2023, CSL Vifor recorded net sales of KORSUVA injection in the United States of approximately $4.4 million and $21.5 million, respectively, and we recorded associated collaborative revenue of $1.9 million and $10.1 million, respectively, 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 advanced 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. Difelikefalin injection was also approved in the UAE, Kuwait, Israel, and Japan under the brand name KORSUVA in January 2023, May 2023, June 2023, and September 2023, respectively. We expect additional approvals and commercial launches over the next 12-18 months. For the three and nine months ended September 30, 2023, we recorded royalty revenue of approximately $167,000 and $415,000, respectively, which represented our royalties on net sales of Kapruvia in Europe.

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. In September 2023, Maruishi received manufacturing and marketing approval from Japan’s Ministry of Health, Labour and Welfare for KORSUVA IV Injection Syringe for the treatment of pruritus in hemodialysis patients. In conjunction with the approval, we earned a $1.4 million milestone payment per the terms of the licensing agreement.

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 advanced 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 (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= 0.000019). 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= 0.000032), 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. During the three and nine months ended September 30, 2023, KORSUVA injection generated net sales of $4.4 million and $21.5 million, respectively, and we recorded collaborative revenue of $1.9 million and $10.1 million, respectively, which represented our share of the profit from sales of KORSUVA injection. Wholesalers shipped 90,828 and 203,400 vials to dialysis centers, the majority of which were Fresenius clinics, during the three and nine months ended September 30, 2023, respectively. Vial orders grew 36% quarter to quarter. However, FMC recently decided to reallocate remaining inventory that was shipped in the third quarter of 2022 within its network of clinics. As a result, we expect shipments from CSL Vifor to wholesalers to be small in the fourth quarter of 2023 and in the first quarter of 2024 translating into minimal revenues accrued to us in these quarters.

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 and nine months ended September 30, 2023, we recorded collaborative revenue of approximately $1.9 million and $10.1 million, respectively, 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 and nine months ended September 30, 2023, we recorded commercial supply revenue of approximately $1.3 million and $5.8 million, respectively.

- Royalty revenue in conjunction with the launch of Kapruvia in Europe. For the three and nine months ended September 30, 2023, we recorded royalty revenue of approximately $167,000 and $415,000, respectively.

- Sales-based or regulatory milestone payments, which could be earned in the future in accordance with certain licensing agreements. For the three and nine months ended September 30, 2023, we earned regulatory milestone revenue of $1.4 million related to the manufacturing and marketing approval in Japan under the Maruishi Agreement, but 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 and nine months ended September 30, 2023, CSL Vifor recorded net sales of KORSUVA injection in the United States of approximately $4.4 million and $21.5 million, respectively.

- Our share of profit from KORSUVA injection that we record as collaborative revenue. For the three and nine months ended September 30, 2023, we recorded collaborative revenue of approximately $1.9 million and $10.1 million, respectively, related to our share of the profit.

- Shipments of KORSUVA injection vials from wholesalers to the dialysis clinics. For the three and nine months ended September 30, 2023, 90,828 and 203,400, respectively, of KORSUVA injection vials were shipped from wholesalers to the dialysis clinics.

Oral Difelikefalin for Treatment of Advanced Chronic Kidney Disease Associated Pruritus (CKD-aP)

In December 2019, we announced top-line data from our Phase 2 trial of oral difelikefalin for the treatment of pruritus in advanced 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 ≥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 advanced 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 advanced 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, including patients on dialysis. The primary endpoint will be the proportion of patients with a ≥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 ≥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 ≥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. Enrollment for Part A of KIND 1, the dose finding portion of the trial, has been completed and includes 287 patients who were 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 a data read-out. We expect to release topline data from this readout in December 2023. Furthermore, 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 ≥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 ≥6 weeks (worst itch NRS of ≥ 5). Patients must have an Investigator Global Assessment ≥ 2 and a BSA ≤20%. We will stratify patients to a BSA <10% or ≥ 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 Day 1 and sustained through Week 8.

Other endpoints included a ≥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 ≥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 a 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 ≥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 ≥6 months (worst itch NRS of ≥ 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 advanced 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's right of first negotiation has expired for the indications of pruritus associated with AD and pruritus associated with NP. 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. In September 2023, Maruishi received manufacturing and marketing approval from Japan's Ministry of Health, Labour and Welfare for KORSUVA IV Injection Syringe for the treatment of pruritus in hemodialysis patients. In conjunction with the approval, we earned a $1.4 million milestone payment per the terms of the licensing agreement (see Item 2. *Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations*).

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 $6.5 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® 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 and nine months ended September 30, 2023, no milestone payments or royalties were paid to Enteris by us in relation to the Enteris License Agreement. During the three months ended September 30, 2022, Enteris earned a $5.0 million milestone payment based on the first patient dosing in a Phase 3 trial, which was subsequently paid in October 2022. This milestone payment to Enteris was recorded in R&D expense for the three and nine months ended September 30, 2022.

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 September 30, 2023, we have not recorded any sales-based milestone payments (see Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – *Recent Developments – Royalty Financing*).

To date, we have earned a total of $134.5 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 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 adopting or switching to KORSUVA injection, patient retention and sustained 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. On June 26, 2023,

CMS issued the CY 2024 ESRD PPS proposed rule to update Medicare payment policies and rates for renal dialysis services including a proposed methodology for post-TDAPA reimbursement for TDAPA designated products in existing functional categories. The proposed rule provides for additional funding per dialysis treatment outside the bundle rate for a 3-year post-TDAPA period starting immediately upon the expiration of the TDAPA period. On October 27, 2023, CMS published the final CY 2024 rule, which finalized the post-TDAPA add-on as proposed in the draft CY 2024 rule. Under the final rule, TDAPA drugs in existing functional categories will receive a post-TDAPA add-on payment set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment adjustment will be applied to all ESRD PPS payments and paid for 3 years, adjusted annually. The add-on payments for KORSUVA injection will commence on April 1, 2024. There is no assurance that the final CY 2024 rule provides for sufficient funding to maintain or grow KORSUVA patient volume post the TDAPA period which could significantly impact our revenues in future periods.

In addition, FMC recently decided to reallocate remaining inventory that was shipped in the third quarter of 2022 within its network of clinics. As a result, we expect shipments from CSL Vifor to wholesalers to be small in the fourth quarter of 2023 and in the first quarter of 2024 translating into minimal revenues accrued to us in these quarters.

As of September 30, 2023, Vifor International owned 7,396,770, or 13.6%, of our common stock. CSL Vifor and its affiliates are considered related parties as of September 30, 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).

On November 1, 2023, Royalty Sub entered into the HCR Agreement pursuant to which Royalty Sub sold, or agreed to sell, to HCR its (as our assignee) right to receive all royalty payments made pursuant to the Covered License Agreements (see Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – *Recent Developments – Royalty Financing*).

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.

During the three and nine months ended September 30, 2023, we recorded commercial supply revenue of $1.3 million and $5.8 million, respectively, with associated COGS of $1.6 million and $5.6 million, respectively. During the three and nine months ended September 30, 2022, we recorded commercial supply revenue of $3.4 million and $8.2 million, respectively, with associated COGS of $3.1 million and $5.1 million, respectively. 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. We expect our COGS to be reflective of future KORSUVA injection sales.

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 will increase in the future. 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 will stay consistent in the future 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, C*ollaboration 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 early in 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 September 30, 2023; however, we will continue to evaluate the effect on the tax provision each reporting period.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2023 and 2022

Revenue

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% change	2023	2022	% change
	Dollar amounts in thousands			Dollar amounts in thousands		
Collaborative revenue	$ 2,471	$ 7,443	-67%	$ 10,631	$ 15,446	-31%
Commercial supply revenue	1,252	3,370	-63%	5,843	8,160	-28%
Royalty revenue	167	—	N/A	415	—	N/A
License and milestone fees	910	—	N/A	910	15,000	-94%
Clinical compound revenue	66	—	N/A	165	—	N/A
Total revenue	$ 4,866	$ 10,813	-55%	$ 17,964	$ 38,606	-53%

Collaborative Revenue

We recognized collaborative revenue of $2.5 million and $10.6 million for the three and nine months ended September 30, 2023, respectively, and $7.4 million and $15.4 million for the three and nine months ended September 30, 2022, respectively. This change in collaborative revenue for each period 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, as well as $0.5 million earned in conjunction with the regulatory approval of KORSUVA injection in Japan for a milestone payment we earned in September 2023 from Maruishi that was allocated to the R&D services performance obligation under the Maruishi Agreement (see Notes 11 and 12 of Notes to Condensed Financial Statements, *Collaboration and Licensing Agreements and Revenue Recognition*, respectively, in this Quarterly Report on Form 10-Q).

Commercial Supply Revenue

We recognized commercial supply revenue of $1.3 million and $5.8 million for the three and nine months ended September 30, 2023, respectively, and $3.4 million and $8.2 million for the nine months ended September 30, 2022, respectively. This change in commercial supply revenue 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 $167,000 and $415,000 for the three and nine months ended September 30, 2023, respectively, and no royalty revenue for the three and nine months ended September 30, 2022, respectively. This increase in royalty revenue was related to sales of Kapruvia in Europe, which commercially launched in the third quarter of 2022.

License and milestone fees revenue

We recognized license and milestone fees revenue of $0.9 million for each of the three and nine months ended September 30, 2023, in conjunction with the regulatory approval of KORSUVA injection in Japan for a milestone payment we earned in September 2023 from Maruishi that was allocated to the license and milestone fee performance obligation under the Maruishi Agreement.

License and milestone fees revenue of $15.0 million for the nine months ended September 30, 2022 was related to the regulatory milestone payment earned from Vifor Fresenius Medical Care Renal Pharma Ltd. for the approval of Kapruvia by the European Commission in April 2022. There was no license and milestone fees revenue for the three months ended September 30, 2022 (see Notes 11 and 12 of Notes to Condensed Financial Statements, *Collaboration and Licensing Agreements* and *Revenue Recognition*, respectively, in this Quarterly Report on Form 10-Q).

Clinical compound revenue

We recognized clinical compound revenue of approximately $66,000 and $165,000 for the three and nine months ended September 30, 2023, respectively, which was related to sales of clinical compound to Maruishi. There was no clinical compound revenue for the three and nine months ended September 30, 2022.

Cost of Goods Sold (COGS)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% change	2023	2022	% change
	Dollar amounts in thousands			Dollar amounts in thousands		
Cost of Goods Sold	$ 1,558	$ 3,055	-49%	$ 5,566	$ 5,136	8%

During the three and nine months ended September 30, 2023, we recorded COGS of $1.6 million and $5.6 million, respectively, which was related to our commercial supply revenue for KORSUVA injection sales to CSL Vifor.

During the three and nine months ended September 30, 2022, we recorded COGS of $3.1 million and $5.1 million, respectively, which was related to our commercial supply revenue for KORSUVA injection sales to CSL Vifor. All COGS incurred through February 2022 were expensed as incurred since they were incurred prior to regulatory approval.

Research and Development Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% change	2023	2022	% change
	Dollar amounts in thousands			Dollar amounts in thousands		
Direct clinical trial costs	$ 16,210	$ 10,181	59%	$ 50,496	$ 32,613	55%
Consultant services in support of clinical trials	1,381	1,710	-19%	3,810	4,380	-13%
Stock-based compensation	1,477	1,919	-23%	4,699	5,945	-21%
Depreciation and amortization	28	30	-6%	86	91	-6%
Other R&D operating expenses	6,355	10,851	-41%	21,004	22,840	-8%
Total R&D expense	$ 25,451	$ 24,691	3%	$ 80,095	$ 65,869	22%

For the three months ended September 30, 2023 compared to the three months ended September 30, 2022, the $6.0 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, and other general costs associated with our oral programs. These increases were partially offset by decreases related to the Phase 2 efficacy trial for pruritus associated with NP, and lower costs associated with our prior difelikefalin injection trials. The decrease in stock compensation expense is primarily related to lower grant date fair values for new option grants in 2023 as compared to the prior period, fewer stock options granted during the three months ended September 30, 2023 as compared to the prior period, and lower stock compensation expense related to time-based restricted stock units that fully vested in February 2023. The $4.5 million decrease in other R&D operating expenses was primarily related to the recognition of a $5.0 million milestone payment due to Enteris during the three months ended September 30, 2022, partially offset by increases in payroll-related costs.

For the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, the $17.9 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 decreases related to the Phase 2 efficacy trial for pruritus associated with NP, costs associated with our prior difelikefalin injection trials, and other general costs associated with our oral programs. The decrease in stock compensation expense is primarily related to lower grant date fair values for new option grants during the nine months ended September 30, 2023, and lower stock compensation expense related to time-based restricted stock units that fully vested in February 2023. The $1.8 million decrease in other R&D operating expenses was primarily related to the recognition of a $5.0 million milestone payment due to Enteris during the nine months ended September 30, 2022, partially offset by increases in payroll-related costs.

The following table summarizes our R&D expenses by program for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% change	2023	2022	% change
	Dollar amounts in thousands			Dollar amounts in thousands		
External research and development expenses:						
KORSUVA (difelikefalin) injection - Pruritus	$ —	$ 1,254	-100%	$ —	$ 6,057	-100%
Oral difelikefalin - Pruritus	17,564	10,611	66%	54,239	31,110	74%
Internal research and development expenses/milestone payments[1]	7,887	12,826	-39%	25,856	28,702	-10%
Total research and development expenses	$ 25,451	$ 24,691	3%	$ 80,095	$ 65,869	22%

[1] Includes a milestone payment of $5.0 million earned by Enteris for the three and nine months ended September 30, 2022, based on the first patient dosing in a Phase 3 trial.

General and Administrative Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% change	2023	2022	% change
	Dollar amounts in thousands			Dollar amounts in thousands		
Professional fees and public/investor relations	$ 1,485	$ 1,364	9%	$ 4,925	$ 4,768	3%
Stock-based compensation	1,857	1,656	12%	5,429	7,988	-32%
Depreciation and amortization	31	32	-4%	91	96	-5%
Other G&A operating expenses	3,382	3,860	-12%	10,746	10,977	-2%
Total G&A expense	$ 6,755	$ 6,912	-2%	$ 21,191	$ 23,829	-11%

For the three months ended September 30, 2023 compared to the three months ended September 30, 2022, the increase in stock-based compensation expense was primarily related to a full quarter of stock compensation expense related to option grants to the new CFO that began in September 2022. The decrease in other G&A operating expenses was primarily the result of decreases in franchise taxes, recruiting expenses, and insurance costs, partially offset by increases in payroll-related costs.

For the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, the decrease in stock-based compensation expense was primarily related to higher expenses recorded during the nine months ended September 30, 2022 for the modification of our former CEO's equity awards, and certain performance-based restricted stock units that vested during the nine months ended September 30, 2022. The decrease in other G&A operating expenses was primarily the result of decreases in franchise taxes, recruiting expenses, and insurance costs, partially offset by increases in payroll-related costs.

Other Income, Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% change	2023	2022	% change
	Dollar amounts in thousands			Dollar amounts in thousands		
Other income, net	$ 866	$ 665	30%	$ 2,712	$ 1,093	148%

For the three months ended September 30, 2023 compared to the three months ended September 30, 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 September 30, 2023 and an increase in accretion income from our available-for-sale marketable securities.

For the nine months ended September 30, 2023 compared to the nine months ended September 30, 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 nine months ended September 30, 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 and nine months ended September 30, 2023 and 2022, therefore there was no benefit from income taxes for each of the three and nine months ended September 30, 2023 and 2022. As of September 30, 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 September 30, 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 and nine months ended September 30, 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 September 30, 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 September 30, 2023, which we expect to fund primarily with current unrestricted cash and cash equivalents and available-for-sale marketable securities (see Item 2. *Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments – Royalty Financing*):

	Material Cash Requirements *(amounts in thousands)*							
	Total	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**Thereafter**
Operating lease obligations[1]	$ 14,874	$ 503	$ 108	$ 1,298	$ 1,330	$ 1,363	$ 1,398	$ 8,874
Manufacturing purchase obligations[2]	6,402	6,402	—	—	—	—	—	—
Other obligations[3]	1,908	408	—	—	—	—	—	1,500
Total	$ 23,184	$ 7,313	$ 108	$ 1,298	$ 1,330	$ 1,363	$ 1,398	$ 10,374

(1) Operating lease obligations in 2023 relate to our Stamford operating leases entered into in December 2015, and amended in June 2020 (which continue through December 2023). Operating lease obligations in 2024 and beyond relate to our new lease entered into in May 2023 for our new principal executive offices, for which rent payments are expected to begin in late 2024. 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.

(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 a portion 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. Obligations in 2023 relate to our existing leases that terminate in December 2023. Obligations after 2028 relate to our stand-by letter of credit for our new lease for our new principal executive offices. 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 and new lease for our new principal executive offices in May 2023.

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 September 30, 2023. During the three and nine months ended September 30, 2023, there were no milestone payments earned by Enteris. During each of the three and nine months ended September 30, 2022, Enteris earned a $5.0 million milestone payment based on the first patient dosing in a Phase 3 trial, which was paid in October 2022. 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 $28.0 million and $23.2 million for the three months ended September 30, 2023 and 2022, respectively, and net losses of $86.2 million and $55.1 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $652.4 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, advanced 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 Kapruvia 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 Kapruvia, 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 Kapruvia 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 Kapruvia, as well as Singapore and Canada under the brand name KORSUVA. Commercial launch in Switzerland has also commenced. Difelikefalin injection was also approved under the brand name KORSUVA in the UAE, Kuwait, Israel, and Japan in January 2023, May 2023, June 2023, and September 2023, respectively. We expect additional commercial launches 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 Kapruvia 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, the conflict between Israel and

Hamas, and government actions implemented as a result of either of the foregoing, high rates of 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 through September 30, 2023, we have raised an aggregate of $903.5 million to fund our operations, including (1) net proceeds of $447.4 million from the sale of shares of our common stock in five public offerings, including our initial public offering; as well as the sale of our common stock under our open market sales agreement; (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) $258.1 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 $26.7 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).

On November 1, 2023, we, through Royalty Sub, entered into the HCR Agreement with HCR, pursuant to which Royalty Sub sold, or agreed to sell, to HCR the Royalties in exchange for up to $40.0 million. Vifor Agreement No. 2 and the Royalties thereunder shall be retained by us until we have received the First Milestone Payment. We have retained all of our right, title and interest in, to and under the Maruishi Agreement and Vifor Agreement No. 2. that relate to any non-intravenous formulation of difelikefalin.

Under the terms of the HCR Agreement, Royalty Sub received an upfront payment of $17.5 million, less certain expenses. The terms of the HCR Agreement provide for an additional (a) $20.0 million milestone payment, or the First Milestone Payment, to Royalty Sub if, prior to December 31, 2023, pricing for Kapruvia® (difelikefalin) in Germany is approved above a certain threshold amount per dose and (b) $2.5 million milestone payment to Royalty Sub upon achievement of a 2024 sales milestone of KORSUVA in Japan.

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. During the three months ended September 30, 2023, 386,881 shares were sold under the Sales Agreement and the Company received net proceeds of $1.1 million.

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 the date of this filing, 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 the date of this filing, we have received $30.0 million of regulatory milestones from Vifor Fresenius Medical Care Renal Pharma Ltd.

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 earned $6.5 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. On June 26, 2023, CMS issued the CY 2024 ESRD PPS proposed rule to update Medicare payment policies and rates for renal dialysis services including a proposed methodology for post-TDAPA reimbursement for TDAPA designated products in existing functional categories. The proposed rule provides for additional funding per dialysis treatment outside the bundle rate for a 3-year post-TDAPA period starting immediately upon the expiration of the TDAPA period. On October 27, 2023, CMS published the final CY 2024 rule, which finalized the post-TDAPA add-on as proposed in the draft CY 2024 rule. Under the final rule, TDAPA drugs in existing functional categories will receive a post-TDAPA add-on payment set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment adjustment will be applied to all ESRD PPS payments and paid for 3 years, adjusted annually. The add-on payments for KORSUVA injection will commence on April 1, 2024. There is no assurance that the final CY 2024 rule provides for sufficient funding to maintain or grow KORSUVA patient volume post the TDAPA period which could significantly impact our revenues in future periods. 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. We expect additional commercial launches 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 and the proceeds from our recently announced royalty financing, will be sufficient to fund our currently anticipated operating plan into 2025. 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 nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	2022
	Dollar amounts in thousands	
Net cash used in operating activities	$ (74,708)	$ (55,220)
Net cash provided by investing activities	73,666	84,284
Net cash provided by financing activities	1,676	289
Net increase in cash, cash equivalents and restricted cash	$ 634	$ 29,353

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2023 consisted primarily of a net loss of $86.2 million, partially offset by a $11.4 million cash inflow from net non-cash charges and a $0.1 million cash inflow from net changes in operating assets and liabilities. Net non-cash charges primarily consisted of stock-based compensation expense of $10.1 million, and the noncash lease expense of $1.2 million relating to our Stamford operating leases. The change in operating assets and liabilities primarily consisted of cash inflows from a decrease in prepaid expenses of $3.6 million, primarily related to prepaid clinical costs, partially offset by a cash outflow of $1.3 million relating to operating lease liabilities associated with our existing lease agreements for our operating facility in Stamford, Connecticut, a cash outflow of $1.2 million for an increase in other receivables, primarily due to the regulatory milestone payment earned from Maruishi in September 2023, and an $0.9 million cash outflow for an increase in inventory.

Net cash used in operating activities for the nine months ended September 30, 2022 consisted primarily of a net loss of $55.1 million and a $15.8 million cash outflow from net changes in operating assets and liabilities, partially offset by a $15.7 million cash inflow from net non-cash charges. The change in operating assets and liabilities primarily consisted of an increase in prepaid expenses of $16.0 million, primarily related to an increase in prepaid clinical costs, an increase of $9.6 million in accounts receivable, net – related party relating to amounts due from Vifor from our profit sharing arrangements governing KORSUVA injection sales in the U.S. and for commercial supply of KORSUVA injection to Vifor, and a cash outflow of $1.3 million relating to operating lease liabilities associated with our lease agreements for our operating facility in Stamford, Connecticut, partially offset by cash inflows of $10.5 million from an increase in accounts payable and accrued expenses and a decrease of $0.7 million of inventory, net. Net non-cash charges primarily consisted of stock-based compensation expense of $13.9 million, which includes incremental expense of $2.6 million related to the modification of our former CEO’s equity awards in 2021 through the end of the consulting period on June 30, 2022, the noncash lease expense of $1.1 million relating to our Stamford operating leases, and the amortization of available-for-sale marketable securities, net of $0.5 million.

Net cash provided by investing activities

Net cash provided by investing activities was $73.7 million for the nine months ended September 30, 2023, which primarily included cash inflows of $122.6 million from maturities and redemptions of available-for-sale marketable securities, partially offset by cash outflows of $48.6 million for the purchases of available-for-sale marketable securities.

Net cash provided by investing activities was $84.3 million for the nine months ended September 30, 2022, which primarily included cash inflows of $162.2 million from maturities of available-for-sale marketable securities, partially offset by cash outflows of $77.9 million for the purchases of available-for-sale marketable securities.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2023 consisted of net proceeds of $1.1 million from the sales of common stock under our open market sales agreement and proceeds of $0.6 million received from the exercise of stock options. Net cash provided by financing activities for the nine months ended September 30, 2022 consisted of proceeds of $0.3 million 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 September 30, 2023, we invested a portion 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 September 30, 2023, we had invested $20.4 million of our cash reserves in such marketable securities. Those marketable securities included $20.4 million of investment grade debt instruments with a yield of approximately 1.50% 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 September 30, 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 September 30, 2023 and December 31, 2022, the aggregate unrealized losses on our available-for-sale marketable securities were $0.4 million and $1.7 million, respectively. For each of the three and nine months ended September 30, 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 September 30, 2023 and December 31, 2022, we had accounts receivable, net - related party from CSL Vifor of $3.4 million and $3.3 million, respectively, primarily for our share of the profit generated by KORSUVA injection sales, commercial supply revenue, and royalty revenue. We also had $1.4 million recorded within other receivables for a milestone payment earned from Maruishi as of September 30, 2023. We believe that credit risk associated with CSL Vifor and Maruishi are 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 September 30, 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 September 30, 2023. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 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 September 30, 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 risk factor set forth below and 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. There have been no material changes to our risk factors as presented in our Annual Report on Form 10-K for the year ended December 31, 2022, other than the risk factor set forth below:

Risks Related to Our Business and the Development and Commercialization of Our Product and Product Candidates

Our agreements with HCR contain various covenants and other provisions, which, if violated, could materially adversely affect our financial condition.

On November 1, 2023, we, through Royalty Sub, entered into the HCR Agreement with HCR, pursuant to which Royalty Sub sold, or agreed to sell, to HCR the Royalties under the Covered License Agreements, in exchange for up to $40.0 million. Vifor Agreement No. 2 and the Royalties thereunder shall be retained by us until we have received the First Milestone Payment. We have retained all of our right, title and interest in, to and under the Covered License Agreements that relate to any non-intravenous formulation of difelikefalin.

Under the terms of the HCR Agreement, Royalty Sub received an upfront payment of $17.5 million, less certain expenses. The terms of the Agreement provide for an additional (a) $20.0 million milestone payment, or the First Milestone Payment, to Royalty Sub if, prior to December 31, 2023, pricing for Kapruvia® (difelikefalin) in Germany is approved above a certain threshold amount per dose and (b) $2.5 million milestone payment to Royalty Sub upon achievement of a 2024 sales milestone of KORSUVA in Japan.

The HCR Agreement will automatically expire, and the payment of Royalties to HCR will cease, when HCR has received payments of Royalties equal to two times the aggregate amount of payments made by HCR under the HCR Agreement if the 2029 Threshold is achieved on or prior to December 31, 2029, or 2.8 times the aggregate amount of payments made by HCR under the HCR Agreement, if the 2029 Threshold is not achieved on or prior to December 31, 2029. After the HCR Agreement expires, all rights to receive the Royalties return to Royalty Sub.

In connection with the HCR Agreement we entered into a Contribution and Servicing Agreement which contains various representations and warranties, covenants, indemnification obligations and other provisions related to the contribution of the Covered License Agreement to Royalty Sub and the Company's maintenance and servicing obligations with respect to the Royalties and the Covered License Agreements. In the event we violate these covenants or provisions, we may lose the right to act as the servicer of the Royalty Sub and a third-party servicer may be appointed at Royalty Sub's expense. Our replacement as servicer, if it were to occur, could have a material adverse effect on our financial condition as HCR, by virtue of owning Royalty Sub, would own the Royalties.

In connection with the HCR Agreement we also entered into a Pledge and Security Agreement containing various representations, warranties and covenants, and a limited recourse guaranty of Royalty Sub's obligations under the Purchase and Sale Agreement which is secured by the pledge in favor of HCR all of the capital stock of Royalty Sub. HCR is entitled to foreclose on the capital stock of Royalty Sub following the occurrence of certain remedies events, including, without limitation, a bankruptcy of us or the failure of us to perform our obligations under the Contribution and Servicing Agreement. Such foreclosure, if it were to occur, could have a material adverse effect on our financial condition as HCR, by virtue of owning Royalty Sub, would own the Royalties.

Risks Related to Legal and Compliance Matters

If the government or other third-party payers fail to provide coverage and adequate reimbursement and payment rates for KORSUVA injection or Kapruvia or any of our other current or future product candidates, if any, or if providers choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

In both U.S. and international markets, sales of KORSUVA injection, Kapruvia and our future products (if approved) will depend in part upon the availability of coverage and reimbursement from third-party payers. Such third-party payers include government health programs such as Medicare and Medicaid in the United States, managed care providers, private health insurers and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. In the United States, KORSUVA injection for the treatment of pruritus in adult hemodialysis patients is expected to be designated as a component of the government's bundled reimbursement for end stage renal disease treatment after the expiration of the TDAPA period.

On October 31, 2019, CMS issued a final rule that revises payment policies and rates under the ESRD PPS for renal dialysis services furnished to beneficiaries on or after January 1, 2020. The final rule also updates the TDAPA. In the final rule, CMS revised ESRD PPS eligibility to focus on innovative drugs and excluded certain drugs from being eligible for the TDAPA. CMS will pay the revised TDAPA adjustment, which is called the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies , or TPNIES, for equipment and supplies that: (1) have been designated by CMS as a renal dialysis service, (2) are new, meaning granted marketing authorization by FDA on or after January 1, 2020, (3) are commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, (4) have a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year, (5) are innovative, meaning they meet the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System regulations and related guidance, and (6) are not capital-related assets. TDAPA went into effect on April 1, 2022, for a minimum of two years, for KORSUVA injection. However, there is no assurance that KORSUVA injection will be able to maintain its price established in the TDAPA period in the post-TDAPA timeframe.

On November 2, 2020, CMS issued a final rule outlining its payment policies and rates under the ESRD PPS for the 2021 calendar year. In addition to the annual technical updates to the ESRD PPS, the final rule, among other things, expands eligibility under the TPNIES. In particular, the final rule provided for biannual coding cycles for new HCPCS Level II code applications, revised the definition of "new" to be three (3) years beginning on the date of FDA marketing authorization, and expanded eligibility under the TPNIES to include certain home dialysis capital-related assets. Additionally, in October 2021, CMS issued a final rule that updates the ESRD PPS for calendar year 2022. Further, on June 28, 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, on November 7, 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. On June 26, 2023, CMS issued the Calendar Year 2024 ESRD PPS proposed rule to update Medicare payment policies and rates for renal dialysis services including a proposed methodology for post-TDAPA reimbursement for TDAPA designated products in existing functional categories. The proposed rule provides for additional funding per dialysis treatment outside the bundle rate for a 3-year post-TDAPA period starting immediately upon the expiration of the TDAPA period. On October 27, 2023, CMS published the final CY 2024 rule, which finalized the post-TDAPA add-on as proposed in the draft CY 2024 rule. Under the final rule, TDAPA drugs in existing functional categories will receive a post-TDAPA add-on payment set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment adjustment will be applied to all ESRD PPS payments and paid for 3 years, adjusted annually. The add-on payments for KORSUVA injection will commence on April 1, 2024. There is no assurance that the final CY 2024 rule provides for sufficient funding to maintain or grow KORSUVA patient volume post the TDAPA period which could significantly impact our revenues in future periods.

Additionally, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform, or a pre-determined rate for all hospital inpatient care provided as payment in full. Because, in these instances, the amount of reimbursement that such providers receive may not be based on the actual expenses the provider incurs, providers may choose to use therapies which are less expensive when compared to our product candidates. Accordingly, KORSUVA injection or any of our other current or future product candidates, if approved, will face competition from other therapies and drugs for these limited provider financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payers. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Third-party coverage and adequate reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Third-party payers, whether U.S. or international, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the U.S. and international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the U.S. or international markets, which could have a negative effect on our business, results of operations, financial condition, and prospects.

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

None.

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

None.

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

Not applicable.

Item 5. ***Other Information.***

None.

Item 6. ***Exhibits.***

Exhibit No.	Description of Exhibit	Incorporated by Reference			
		Form	File No.	Exhibit No.	Date Filed
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-36279	3.1	February 7, 2014
3.2	Amended and Restated Bylaws.	8-K	001-36279	3.2	February 7, 2014
31.1†	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.				
31.2†	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.				
32.1†*	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.				
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: November 13, 2023

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

Date: November 13, 2023

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

EXHIBIT 31.1

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 (the registrant’s fourth fiscal quarter in the case of an annual report) 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: November 13, 2023

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

EXHIBIT 31.2

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 (the registrant’s fourth fiscal quarter in the case of an annual report) 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: November 13, 2023

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

EXHIBIT 32.1

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 September 30, 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 the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, ("the Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), 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 Exchange Act; 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: November 13, 2023

/s/ RYAN MAYNARD
Name: Ryan Maynard
Title: Chief Financial Officer
(Principal Financial Officer)
Date: November 13, 2023