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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 MARCH 31, 2024

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.)**
400 Atlantic Street Suite 500 Stamford, Connecticut	
(Address of registrant's principal executive offices)	**06901 (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 May 9, 2024 was: 54,675,954.

CARA THERAPEUTICS, INC.

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FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2024

PART I –FINANCIAL INFORMATION

PART I
FINANCIAL INFORMATION

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

CARA THERAPEUTICS, INC.

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 46,996	$ 51,775
Marketable securities	22,777	48,983
Accounts receivable, net - related party	1,718	2,765
Inventory, net	2,741	2,821
Income tax receivable	697	697
Other receivables	506	555
Prepaid expenses	5,790	8,154
Restricted cash	—	408
Total current assets	81,225	116,158
Operating lease right-of-use assets	3,826	4,864
Property and equipment, net	3,548	3,322
Restricted cash, non-current	1,500	1,500
Total assets	$ 90,099	$ 125,844
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,875	$ 25,592
Operating lease liability, current	220	—
Total current liabilities	15,095	25,592
Liability related to sales of future royalties and milestones, net	38,376	37,079
Operating lease liability, non-current	6,825	6,088
Total liabilities	60,296	68,759
Commitments and contingencies (Note 17)	—	—
Stockholders' equity:		
Preferred stock; $0.001 par value; 5,000,000 shares authorized at March 31, 2024 and December 31, 2023, zero shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock; $0.001 par value; 100,000,000 shares authorized at March 31, 2024 and December 31, 2023, 54,667,079 shares and 54,480,704 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	54	54
Additional paid-in capital	745,381	742,036
Accumulated deficit	(715,441)	(684,745)
Accumulated other comprehensive loss	(191)	(260)
Total stockholders' equity	29,803	57,085
Total liabilities and stockholders' equity	$ 90,099	$ 125,844

See Notes to Condensed Consolidated Financial Statements.

CARA THERAPEUTICS, INC.

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

	Three Months Ended	
	March 31, 2024	March 31, 2023
Revenue:		
Collaborative revenue	$ 788	$ 2,750
Commercial supply revenue	640	3,191
Royalty revenue	—	125
Clinical compound revenue	84	99
Other revenue	623	—
Total revenue	2,135	6,165
Operating expenses:		
Cost of goods sold	620	2,590
Research and development	21,964	24,334
General and administrative	6,816	6,891
Restructuring	2,401	—
Total operating expenses	31,801	33,815
Operating loss	(29,666)	(27,650)
Other income, net	952	985
Non-cash interest expense on liability related to sales of future royalties and milestones	(1,982)	—
Net loss	$ (30,696)	$ (26,665)
Net loss per share:		
Basic and Diluted	$ (0.56)	$ (0.49)
Weighted average shares:		
Basic and Diluted	54,588,090	53,872,038
Other comprehensive income, net of tax of $0:		
Change in unrealized gains on available-for-sale marketable securities	69	571
Total comprehensive loss	$ (30,627)	$ (26,094)

See Notes to Condensed Consolidated Financial Statements.

CARA THERAPEUTICS, INC.

CONDENSED CONSOLIDATED 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, 2023	54,480,704	$ 54	$ 742,036	$ (684,745)	$ (260)	$ 57,085
Stock-based compensation expense	—	—	1,660	—	—	1,660
Shares issued upon vesting of restricted stock units	186,375	—	1,685	—	—	1,685
Net loss	—	—	—	(30,696)	—	(30,696)
Other comprehensive income	—	—	—	—	69	69
Balance at March 31, 2024	54,667,079	$ 54	$ 745,381	$ (715,441)	$ (191)	$ 29,803

	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

See Notes to Condensed Consolidated Financial Statements.

CARA THERAPEUTICS, INC.

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

	Three Months Ended,	
	March 31, 2024	**March 31, 2023**
Operating activities		
Net loss	$ (30,696)	$ (26,665)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,345	3,353
Non-cash interest expense on liability related to sales of future royalties and milestones, net of issuance costs accretion	1,982	—
Depreciation and amortization	42	58
Noncash lease expense	269	375
Accretion of available-for-sale marketable securities, net	(510)	(94)
Changes in operating assets and liabilities:		
Accounts receivable, net - related party	1,047	(2,806)
Inventory, net	80	(1,132)
Other receivables	49	1
Prepaid expenses	2,364	(928)
Accounts payable and accrued expenses	(10,151)	(6,318)
Operating lease liability	—	(462)
Reimbursement of lease incentive	1,726	—
Net cash used in operating activities	(30,453)	(34,618)
Investing activities		
Proceeds from maturities of available-for-sale marketable securities	59,000	29,500
Proceeds from redemptions of available-for-sale marketable securities, at par	—	4,000
Purchases of available-for-sale marketable securities	(32,213)	(15,792)
Purchases of property and equipment	(836)	—
Net cash provided by investing activities	25,951	17,708
Financing activities		
Payments to royalty purchase and sale agreement	(685)	—
Proceeds from the exercise of stock options	—	560
Net cash (used in) provided by financing activities	(685)	560
Net decrease in cash, cash equivalents and restricted cash	(5,187)	(16,350)
Cash, cash equivalents and restricted cash at beginning of period	53,683	64,149
Cash, cash equivalents and restricted cash at end of period	$ 48,496	$ 47,799
Noncash investing and financing activities		
Accrual for leasehold improvements	$ 211	$ —

See Notes to Condensed Consolidated 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 development-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, Finland, and Norway 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, Japan, and Saudi Arabia under the brand name KORSUVA in January 2023, May 2023, June 2023, September 2023, and January 2024, 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, pursuant to which HCR will receive current and future royalty and milestone payments for Kapruvia and KORSUVA (ex U.S. only) up to certain capped amounts in exchange for certain payments made to the Company (see Note 10, *Royalty Purchase and Sale Agreement)*.

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 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 (see Note 12, *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.

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)
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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 (see Note 12, *Collaboration and Licensing Agreements)*. In the fourth quarter of 2023, the Company entered into the HCR Agreement pursuant to which HCR will receive current and future royalty and milestone payments for KORSUVA (Japan) up to certain capped amounts in exchange for certain payments to the Company (see Note 10, *Royalty Purchase and Sale Agreement)* .

As of March 31, 2024, the Company has 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 and 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. The Company has also earned approximately $288,600 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. Under the terms of the HCR Agreement, the Company received net proceeds of $36,474 for the sale of future ex-U.S. royalties and milestones under Vifor Agreement No. 2 and the Maruishi Agreement in November and December 2023. 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 license agreement with CSL Vifor (see Note 12, *Collaboration and Licensing Agreements*).

As of March 31, 2024, the Company had unrestricted cash and cash equivalents and marketable securities of $69,773 and an accumulated deficit of $ 715,441. 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 $30,696 and $26,665 for the three months ended March 31, 2024 and 2023, respectively, and had net cash used in operating activities of $30,453 and $34,618 for the three months ended March 31, 2024 and 2023, respectively.

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

2. Basis of Presentation

The Company's condensed consolidated financial statements include the results of the financial operations of Cara Therapeutics, Inc. and its wholly-owned subsidiary, Cara Royalty Sub, LLC, or Cara Royalty Sub, a Delaware limited liability company which was formed in November 2023 for the purpose of the transactions contemplated by the HCR Agreement described in Note 10, *Royalty Purchase and Sale Agreement* . All intercompany balances and transactions have been eliminated.

The unaudited interim condensed consolidated 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

CARA THERAPEUTICS, INC.

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

the opinion of management, these unaudited interim condensed consolidated 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 consolidated balance sheet data as of December 31, 2023 were derived from audited financial statements, but do not include all disclosures required by GAAP. These unaudited interim condensed consolidated 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, 2023.

Use of Estimates

The preparation of condensed consolidated 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 condensed consolidated 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 and future ex-U.S. royalties and milestones projected in relation to the HCR Agreement, 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, restructuring costs, 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 global health crises, geopolitical tensions, such as the ongoing conflicts between Russia and Ukraine, conflict in the Middle East, and increasing tensions between China and Taiwan, and government actions implemented as a result of the foregoing, fluctuations in inflation, rising interest rates, uncertainty and liquidity concerns in the broader financial services industry, 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 consolidated 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 consolidated financial statements as soon as they become known.

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

Significant Accounting Policies

There have been no material changes to the significant accounting policies previously disclosed in Note 2 to the Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
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Accounting Pronouncements Recently Adopted

In November 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* , or ASU 2023-07, which expanded the disclosures for reportable segments made by public entities. These amendments within ASU 2023-07 retained the existing disclosure requirements in ASC 280 and expanded upon them to require public entities to disclose significant expenses for reportable segments in both interim and annual reporting periods, as well as items that were previously disclosed only annually on an interim basis, including disclosures related to a reportable segment's profit or loss and assets. In addition, entities with a single reportable segment must provide all segment disclosures required in ASC 280, including the new disclosures for reportable segments under the amendments in ASU 2023-07. The amendments did not change the existing guidance on how a public entity identified and determined its reportable segments. A public entity should apply the amendments in ASU 2023-07 retrospectively to all prior periods presented in the financial statements. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. The amendments in ASU 2023-07 are effective for annual periods for all public entities in fiscal years beginning after December 15, 2023, and in interim periods within fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-07 on January 1, 2024, and will comply with any new applicable disclosures in its Annual Report on Form 10-K for the year ended December 31, 2024. The Company does not expect the adoption to have a material effect on its results of operations, financial position, and cash flows.

Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, or ASU 2023-09, which applies to all entities subject to income taxes. ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is intended to provide more detailed income tax disclosures. For public business entities (PBEs), the new requirements will be effective for annual periods beginning after December 15, 2024. ASU 2023-09 will be applied on a prospective basis with the option to apply the standard retrospectively. The Company expects to adopt ASU 2023-09 on January 1, 2025, and it does not expect the adoption to have a material effect on its results of operations, financial position, and cash flows.

3. Available-for-Sale Marketable Securities

As of March 31, 2024 and December 31, 2023, the Company's available-for-sale marketable securities consisted of debt securities issued by the U.S. Treasury, U.S. government-sponsored entities and investment grade institutions (corporate bonds).

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
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(unaudited)

The following tables summarize the Company's available-for-sale marketable securities by major type of security as of March 31, 2024 and December 31, 2023:

As of March 31, 2024

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 13,468	$ —	$ (1)	$ 13,467
U.S. government agency obligations	7,500	—	(190)	7,310
Corporate bonds	2,000	—	—	2,000
Total available-for-sale marketable securities	$ 22,968	$ —	$ (191)	$ 22,777

As of December 31, 2023

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 37,243	$ 3	$ —	$ 37,246
U.S. government agency obligations	7,500	—	(262)	7,238
Corporate bonds	4,500	—	(1)	4,499
Total available-for-sale marketable securities	$ 49,243	$ 3	$ (263)	$ 48,983

The following tables summarize the fair value and gross unrealized losses of the Company's available-for-sale marketable securities by investment category and disaggregated by the length of time that individual debt securities have been in a continuous unrealized loss position as of March 31, 2024 and December 31, 2023:

As of March 31, 2024

	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. Treasury securities	$ 13,467	$ (1)	$ —	$ —	$ 13,467	$ (1)
U.S. government agency obligations	—	—	7,310	(190)	7,310	(190)
Total	$ 13,467	$ (1)	$ 7,310	$ (190)	$ 20,777	$ (191)

As of December 31, 2023

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government agency obligations	$ —	$ —	$ 7,238	$ (262)	$ 7,238	$ (262)
Corporate bonds	—	—	2,000	(1)	2,000	(1)
Total	$ —	$ —	$ 9,238	$ (263)	$ 9,238	$ (263)

As of March 31, 2024 and December 31, 2023, 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:

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)
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As of March 31, 2024 and December 31, 2023, the Company held a total of 3 out of 4 positions and 3 out of 9 positions, respectively, that were in an unrealized loss position, 2 of which had been in an unrealized loss position for 12 months or greater as of March 31, 2024. 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. Treasury and U.S. government agency obligations. The unrealized losses on the Company's investments in direct obligations of the U.S. Treasury and U.S. 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 1 out of 1 position for its U.S. Treasury securities and 2 out of 2 positions for its U.S. government agency obligations, that were in unrealized loss positions as of March 31, 2024.

The Company classifies its marketable debt securities based on their contractual maturity dates. As of March 31, 2024, 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 March 31, 2024		As of December 31, 2023	
Contractual maturity	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	$ 22,968	$ 22,777	$ 49,243	$ 48,983
More than one year	—	—	—	—
Total	$ 22,968	$ 22,777	$ 49,243	$ 48,983

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 months ended March 31, 2024 and 2023.

As of March 31, 2024 and December 31, 2023, accrued interest receivables on the Company's available-for-sale debt securities were $160 and $139, respectively, and were included within other receivables.

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
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4. Accumulated Other Comprehensive Loss

The following table summarizes the changes in accumulated other comprehensive loss, net of tax, from unrealized gains on available-for-sale marketable securities, the Company's only component of accumulated other comprehensive loss, for the three months ended March 31, 2024 and 2023, respectively.

	Total Accumulated Other Comprehensive Loss
Balance, December 31, 2023	$ (260)
Other comprehensive income before reclassifications	69
Amount reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive income	69
Balance, March 31, 2024	$ (191)
Balance, December 31, 2022	$ (1,672)
Other comprehensive income before reclassifications	571
Amount reclassified from accumulated other comprehensive loss	—
Net current period other comprehensive income	571
Balance, March 31, 2023	$ (1,101)

Amounts reclassified out of accumulated other comprehensive loss into net loss are determined by specific identification. There were no reclassifications out of accumulated other comprehensive loss and into net loss for the three months ended March 31, 2024 and 2023.

5. Fair Value Measurements

As of March 31, 2024 and December 31, 2023, 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, and liability related to the sales of future royalties and milestones. 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. The fair value of the liability related to the sales of future royalties and milestones also approximates the carrying value. Available-for-sale marketable securities are reported at their fair values, based upon pricing of securities with the same or similar investment characteristics as provided by third-party pricing services.

The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods, obtaining market values from other pricing sources, and comparing them to the share prices presented by the third-party pricing services. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by its third-party pricing services as of March 31, 2024 or December 31, 2023.

The following tables summarize the Company's financial assets measured at fair value on a recurring basis as of March 31, 2024 and December 31, 2023.

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Fair value measurement as of March 31, 2024:

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	$ 46,996	$ 46,996	$ —	$ —
Available-for-sale marketable securities:				
U.S. Treasury securities	13,467	—	13,467	—
U.S. government agency obligations	7,310	—	7,310	—
Corporate bonds	2,000	—	2,000	—
Restricted cash:				
Commercial money market account	1,500	1,500	—	—
Total financial assets	$ 71,273	$ 48,496	$ 22,777	$ —

Fair value measurement as of December 31, 2023:

Financial assets Type of Instrument	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents:				
Money market funds and checking accounts	$ 51,775	$ 51,775	$ —	$ —
Available-for-sale marketable securities:				
U.S. Treasury securities	37,246	—	37,246	—
U.S. government agency obligations	7,238	—	7,238	—
Corporate bonds	4,499	—	4,499	—
Restricted cash:				
Commercial money market account	1,908	1,908	—	—
Total financial assets	$ 102,666	$ 53,683	$ 48,983	$ —

There were no purchases, sales or maturities of Level 3 financial assets and no unrealized gains or losses related to Level 3 available-for-sale marketable securities during the three months ended March 31, 2024 and 2023. There were no transfers of financial assets into or out of Level 3 classification during each the three months ended March 31, 2024 and 2023.

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 for its office space in Stamford, Connecticut (refer to Note 17, *Commitments and Contingencies: Leases*). The fair value of the letter of credit approximates its contract value. The Company's bank requires the Company to maintain a restricted cash balance to serve as collateral for the letter of credit issued to the landlords by the bank. As of March 31, 2024, the restricted cash balance for the New Lease was invested in a commercial money market account.

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As of March 31, 2024, the Company had $ 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, 2023, the Company had $408 of restricted cash related to its previous lease (which was terminated in December 2023 and became unrestricted in January 2024) in current assets and $1,500 of restricted cash related to the New Lease in long-term assets.

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

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 46,996	$ 51,775
Restricted cash, current assets	—	408
Restricted cash, long-term assets	1,500	1,500
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statements of Cash Flows	$ 48,496	$ 53,683

7. Inventory, net

Inventory, net consists of the following:

	March 31, 2024	December 31, 2023
Raw materials	$ 2,142	$ 2,639
Work-in-process	644	708
	2,786	3,347
Less Inventory Reserve for Obsolescence	(45)	(526)
Total	$ 2,741	$ 2,821

As of March 31, 2024 and December 31, 2023, inventory balances include inventory costs subsequent to regulatory approval of KORSUVA injection on August 23, 2021. There were no write-downs of commercial supply inventory during the three months ended March 31, 2024 and 2023.

8. Prepaid expenses

As of March 31, 2024, prepaid expenses were $5,790, consisting of $3,770 of prepaid R&D clinical costs, $1,548 of prepaid insurance and $472 of other prepaid costs. As of December 31, 2023, prepaid expenses were $ 8,154, consisting of $7,245 of prepaid R&D clinical costs, $492 of prepaid insurance, and $417 of other prepaid costs.

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9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2024	December 31, 2023
Accounts payable	$ 4,978	$ 11,583
Accrued research projects	5,895	4,343
Accrued compensation and benefits	2,064	6,519
Accrued professional fees and other	1,938	3,147
Total	$ 14,875	$ 25,592

10. Royalty Purchase and Sale Agreement

During the fourth quarter of 2023, the Company, through its wholly-owned subsidiary Cara Royalty Sub, entered into the HCR Agreement with HCR, pursuant to which Cara Royalty Sub sold, or agreed to sell, to HCR certain of its rights to receive royalty payments, or the Royalties, due and payable to Cara 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. The Company has retained all of its rights, 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, Cara Royalty Sub received an upfront payment of $ 16,915 in November 2023, representing the $17,500 to which the Company was initially entitled, net of advisory fees and certain of HCR's transaction-related expenses which the Company agreed to reimburse. In December 2023, Cara Royalty Sub received an additional payment of $19,770, representing the $20,000 milestone it achieved for Kapruvia (difelikefalin) pricing in Germany being approved above a certain threshold amount per dose, net of advisory fees. There were additional issuance costs of $211 related to the HCR Agreement resulting in aggregate net proceeds of $ 36,474. An additional $2,500 milestone payment is due to Cara 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 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 not achieved on or prior to December 31, 2029. After the HCR Agreement expires, all rights to receive the Royalties return to Cara Royalty Sub.

Issuance costs pursuant to the HCR Agreement consisting primarily of advisory and legal fees totaled $ 1,025 including the amount of HCR's transaction-related expenses that the Company reimbursed. The effective interest rate includes cash flow projections for future royalty and milestone payments, which are sensitive to certain assumptions, including market size, market penetration and sales price, that are forward looking and could be affected by future market conditions.

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The following table summarizes the activity of the HCR Agreement (in thousands):

Royalty purchase and sale agreement balance at December 31, 2023	$	37,079
Payments		(685)
Non-cash interest expense		1,982
Balance at March 31, 2024	$	38,376
Effective interest rate		22.56 %

11. Stockholders' Equity

During the three months ended March 31, 2024, an aggregate of 45,875 time-based restricted stock units of certain employees vested and were settled in shares of the Company's common stock (See Note 15, *Stock-Based Compensation*).

During the three months ended March 31, 2024, an aggregate of 140,500 performance-based restricted stock units of certain employees vested and were settled in shares of the Company's common stock (See Note 15, *Stock-Based Compensation*).

During the three months ended March 31, 2023, an aggregate of 83,793 time-based restricted stock units vested and were settled in shares of the Company's common stock (see Note 15, *Stock-Based Compensation*).

12. 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 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.

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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.

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

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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 November 2023, the Company entered into an API supply agreement with Maruishi for difelikefalin.

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.

13. Revenue Recognition

The Company has recognized revenue under its license and collaboration agreements from (1) its share of the profit generated by KORSUVA injection sales in the United States during the three months ended March 31, 2024 and 2023; (2) commercial supply revenue from the Company's sales of commercial product to CSL Vifor during the three months ended March 31, 2024 and 2023; (3) royalty revenue from net sales of Kapruvia in Europe during the three months ended March 31, 2023; (4) clinical compound sales from certain license agreements during the three months ended March 31, 2024 and 2023; and (5) other revenue which represents royalty payments earned by the Company under Vifor Agreement No. 2 and the Maruishi Agreement under the HCR Agreement during the three months ended March 31, 2024. As of March 31, 2024, the Company has not earned any sales-based milestones under its collaboration agreements.

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As of March 31, 2024, the Company had license and collaboration agreements with CSL Vifor, Maruishi and CKDP. The following table provides amounts included in the Company's Condensed Consolidated Statements of Comprehensive Loss as revenue for the three months ended March 31, 2024 and 2023, respectively:

	Three Months Ended March 31,	
	2024	2023
Collaborative revenue		
CSL Vifor (KORSUVA injection profit sharing)	$ 788	$ 2,750
Total collaborative revenue	$ 788	$ 2,750
Commercial supply revenue		
CSL Vifor* (KORSUVA injection)	$ 640	$ 3,191
Total commercial supply revenue	$ 640	$ 3,191
Royalty revenue		
CSL Vifor (Kapruvia ex-U.S.)	$ —	$ 125
Total royalty revenue	$ —	$ 125
Clinical compound revenue		
Maruishi	$ 84	$ 99
Total clinical compound revenue	$ 84	$ 99
Other revenue (non-cash)		
CSL Vifor (Kapruvia ex-U.S.)	$ 290	$ —
Maruishi	333	—
Total other revenue	$ 623	$ —

Collaborative revenue

Beginning in April 2022, the Company began recording its share of the profit generated by KORSUVA injection sales by CSL Vifor to third parties in the United States. Under the license agreements with CSL Vifor, KORSUVA injection net sales are calculated by CSL Vifor which are net of discounts, rebates, and allowances. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. The Company records its share of the net profits from the sales of KORSUVA injection in the United States on a net basis (since the Company is not the primary obligor and does not retain inventory risk) and presents the revenue earned each period as collaborative revenue. During the three months ended March 31, 2024 and 2023, the Company recorded $788 and $2,750, respectively, as collaborative revenue for its profit-share from the sales of KORSUVA injection in the United States.

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 $640 and $3,191 for the three months ended March 31, 2024 and 2023, respectively, with associated COGS of $620 and $2,590, respectively.

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. The Company recognized royalty revenue of approximately $125 for the three months ended March 31, 2023, which were related to the Company's royalties on the net sales of Kapruvia in Europe. Beginning on October 1, 2023, royalty revenue is no longer recognized until the Company has fulfilled its obligations under the HCR Agreement (see Note 10, *Royalty Purchase and Sale 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 months ended March 31, 2024 and 2023, the Company recognized clinical compound revenue of $84 and $99, respectively, from the sale of clinical compound to Maruishi.

Other revenue

The Company recorded other non-cash revenue of $ 623 which represents the royalty payments earned by the Company under Vifor Agreement No. 2 and the Maruishi Agreement during the three months ended March 31, 2024 in conjunction with ex-U.S. sales of KORSUVA/Kapruvia, which will be remitted to HCR under the terms of the HCR Agreement. This non-cash revenue will continue to be recorded until the Company has fulfilled its obligations under the HCR Agreement. There was no other revenue recorded for the three months ended March 31, 2023 as the HCR Agreement went into effect during the fourth quarter of 2023 (see Note 10, *Royalty Purchase and Sale Agreement*).

Contract balances

As of March 31, 2024 and December 31, 2023, the Company recorded accounts receivable, net – related party of $1,718 and $2,765, respectively, 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 payments from CSL Vifor. The Company also recorded $346 and $415 within other receivables which primarily related to royalty payments from Maruishi as of March 31, 2024 and December 31, 2023, respectively. There were no other contract assets or contract liabilities related to the CSL Vifor, Maruishi and CKDP agreements as of March 31, 2024 and December 31, 2023.

The Company routinely assesses the creditworthiness of its license and collaboration partners. The Company has not experienced any losses related to receivables from its license and collaboration partners as of March 31, 2024 and December 31, 2023.

14. Net Loss Per Share

The Company computes basic net loss per share by dividing net loss by the weighted-average number of shares of common stock outstanding. Diluted net 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 months ended March 31, 2024 and 2023, the Company excluded the effects of potentially dilutive shares that were outstanding during those respective periods from the denominator as their inclusion would be anti-dilutive due to the Company's net losses during those periods.

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

	Three Months Ended March 31,	
	2024	2023
Basic:		
Weighted average common shares outstanding	54,588,090	53,872,038
Diluted:		
Weighted average common shares outstanding - Basic	54,588,090	53,872,038
Common stock equivalents*	—	—
Denominator for diluted net loss per share	54,588,090	53,872,038

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

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

	Three Months Ended March 31,	
	2024	2023
Net loss - basic and diluted	$ (30,696)	$ (26,665)
Weighted-average common shares outstanding:		
Basic and diluted	54,588,090	53,872,038
Net loss per share, basic and diluted:	$ (0.56)	$ (0.49)

As of March 31, 2024, 8,816,532 stock options and 250,267 restricted stock units were outstanding, which could potentially dilute basic earnings per share in the future, but were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive as a result of the net loss for the period.

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

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15. 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 generally vest monthly over a period of four years from the grant date, or upon the probable achievement of corporate goals. 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 continued 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, 2024, the aggregate number of shares of common stock that may be issued pursuant to Stock Awards under the 2014 Plan automatically increased from 12,203,023 to 13,837,444. 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.

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Restricted Stock Units

Under the 2014 Plan, there were no restricted stock units granted during the three months ended March 31, 2024. During the three months ended March 31, 2023, the Company granted 407,000 restricted stock units. No restricted stock units were granted under the 2019 Inducement Plan during the three months ended March 31, 2024 and 2023.

The weighted-average grant date fair value per share of restricted stock units granted to employees during the three months ended March 31, 2023 was $10.06.

As of March 31, 2024, the Company's restricted stock units consist of time-based restricted stock units and performance-based restricted stock units. For time-based restricted stock units, the Company recognizes compensation expense associated with these restricted stock units ratably over the award's vesting period following the grant date. For performance-based restricted stock units, vesting 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 performance-based awards begins when, and to the extent, the performance criteria are probable of achievement and the employee has met the service conditions.

During the three months ended March 31, 2024 and 2023, the Company recognized compensation expense relating to restricted stock units as follows:

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 255	$ 179
General and administrative	1,357	453
Total restricted stock unit expense	$ 1,612	$ 632

A summary of restricted stock unit activity related to employees and non-employee members of the Company's Board of Directors as of and for the three months ended March 31, 2024 is presented below:

	Number of Units	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2023	566,324	$ 9.27
Awarded	—	—
Vested and released	(186,375)	11.04
Forfeited	(129,682)	10.57
Outstanding, March 31, 2024	250,267	$ 7.28
Restricted stock units exercisable (vested and deferred), March 31, 2024	—	

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(unaudited)

Stock Options

Under the 2014 Plan, the Company granted 1,875,125 and 1,449,154 stock options during the three months ended March 31, 2024 and 2023, respectively. No stock options were granted under the 2019 Inducement Plan during the three months ended March 31, 2024 and 2023. There was no stock compensation expense recognized for the stock options granted in the current period as these were performance-based options that were not probable of achievement as of March 31, 2024. The fair values of stock options granted during the three months ended March 31, 2024 and 2023 were estimated as of the dates of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended March 31,	
	2024	2023
Risk-free interest rate	4.12%	3.62% - 4.22%
Expected volatility	89.6%	76.3% - 81.3%
Expected dividend yield	0%	0%
Expected life of employee and Board options (in years)	6.25	6.25

The weighted-average grant date fair value per share of options granted to employees and non-employee members of the Company's Board of Directors for their Board service during the three months ended March 31, 2024 and 2023 was $0.76 and $7.08, respectively. No options were granted to non-employee consultants during the three months ended March 31, 2024 and 2023.

During the three months ended March 31, 2024 and 2023, the Company recognized compensation expense relating to stock options as follows:

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 504	$ 1,480
General and administrative	1,229	1,241
Total stock option expense	$ 1,733	$ 2,721

A summary of stock option award activity related to employees, non-employee members of the Company's Board of Directors and non-employee consultants as of and for the three months ended March 31, 2024 is presented below:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2023	7,897,647	$ 12.99
Granted	1,875,125	0.99
Exercised	—	—
Forfeited	(679,165)	10.87
Expired	(277,075)	13.36
Outstanding, March 31, 2024	8,816,532	$ 10.59
Options exercisable, March 31, 2024	4,827,562	

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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 each of the three months ended March 31, 2024 and 2023.

16. Income Taxes

The Company has recognized a full tax valuation allowance against its deferred tax assets as of March 31, 2024 and December 31, 2023. The tax benefit related to the exercise of stock options is recognized as a deferred tax asset that is offset by a corresponding valuation allowance. As such, the Company's effective tax rate is zero for the three months ended March 31, 2024 and 2023.

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. The Company has not exchanged its R&D tax credit for cash during the three months ended March 31, 2024, and it was not eligible to exchange its R&D tax credit for cash during the three months ended March 31, 2023. Therefore, there was no benefit from income taxes for either of the three months ended March 31, 2024 and 2023. As of March 31, 2024, 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 March 31, 2024; however, the Company will continue to evaluate the effect on the tax provision each reporting period.

17. 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 months ended March 31, 2024 and 2023, no milestone payments or royalties were paid to Enteris by the Company in relation to the Enteris License Agreement.

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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.

In December 2023, the Company entered into an agreement with Patheon to reimburse Patheon approximately $1,700 for forecasted manufacturing commitments that are no longer needed due to the reduced demand expectations of KORSUVA in the United States. As of March 31, 2024, $246 remained within accounts payable and accrued expenses on its Condensed Consolidated Balance Sheet. In connection with the agreement with Patheon, the Company agreed to schedule additional manufacturing commitments in 2024.

Restructuring Action

In January 2024, the Company announced a workforce reduction of up to 50% of its employees in order to reduce its operating expenses and focus its efforts on development of oral difelikefalin in chronic pruritus associated with notalgia paresthetica. As a result, the Company has made estimates and judgements regarding its future plans, including future employee termination costs to be incurred in conjunction with involuntary separations when such separations are probable and estimable. In the first quarter of 2024, the Company recorded a pre-tax severance expense of $2,401, which was included within restructuring expenses on the Condensed Consolidated Statements of Comprehensive Loss. The remaining amounts to be paid as of March 31, 2024 are included within accounts payable and accrued expenses on the Condensed Consolidated Balance Sheet.

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The detail of activity related to the Company's restructuring action is as follows:

Total expense recorded in the three months ended March 31, 2024	$	2,401
Payments made in the three months ended March 31, 2024		(1,702)
Remaining amounts to be paid as of March 31, 2024	$	699

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

Lease expense was recognized on a straight-line basis over the lease term of the Company's previous lease agreements for its original headquarters, and additional office space, in Stamford, Connecticut. As a result, $407 of operating lease cost, or lease expense, was recognized for the three months ended March 31, 2023, consisting of $284 relating to R&D lease expense and $123 relating to G&A lease expense. There was no lease expense recognized on these former lease agreements for the three months ended March 31, 2024 since these agreements terminated in December 2023.

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 commenced on November 1, 2023, or the Commencement Date, and will expire on the last day of the calendar month in which occurs the tenth anniversary of the Rent Commencement Date, as defined below, or the Term.

In connection with the signing of the New Lease, the Company entered into a standby letter of credit agreement for $1,500 which serves as a security deposit for the leased office space. This standby letter of credit is secured with restricted cash in a money market account and is included within long-term assets as of March 31, 2024 (refer to Note 6, *Restricted Cash*).

The annual fixed rent rate under the New Lease is initially $1.3 million (considered by the Company to be at market rate as of the signing of the New Lease), which will commence on 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 has 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

CARA THERAPEUTICS, INC.

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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. In January 2024, the Company incurred $778 of costs that qualified for reimbursement as lease incentives, which were fully reimbursed in February 2024. Also in January 2024, the Company was reimbursed $947 for qualified lease incentive costs that were incurred in November 2023.

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 $269 for the New Lease was recorded for the three months ended March 31, 2024, consisting of $173 relating to R&D lease expense and $ 96 relating to G&A lease expense.

Other information related to the leases (both previous and new) was as follows:

	Three Months Ended March 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows relating to operating leases	$ —	$ 494
ROU assets obtained in exchange for new operating lease liabilities	$ —	$ —
Remaining lease term - operating leases (years)	10.6	0.8
Discount rate - operating leases	12.8 %	7.0 %

Future minimum lease payments under non-cancellable operating leases, as well as a reconciliation of these undiscounted cash flows to the operating lease liabilities as of March 31, 2024, were as follows:

Year Ending December 31,	
2024 (Excluding the three months ended March 31, 2024)	$ 108
2025	1,298
2026	1,330
2027	1,363
2028	1,398
Thereafter	8,874
Total future minimum lease payments, undiscounted	14,371
Less imputed interest	(7,115)
Less lease incentive to be reimbursed	(211)
Total	$ 7,045
Operating lease liability reported as of March 31, 2024:	
Operating lease liability - current	$ 220
Operating lease liability - non-current	6,825
Total	$ 7,045

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18. Related Party Transactions

As of March 31, 2024, Vifor International owned 7,396,770, or 13.5%, of the Company's common stock. CSL Vifor and its affiliates are considered related parties as of March 31, 2024 and December 31, 2023 (see Note 12, *Collaboration and Licensing Agreements*).

As of March 31, 2024 and December 31, 2023, amounts due from CSL Vifor of $1,718 and $2,765, 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 payments from CSL Vifor were included within accounts receivable, net – related party.

The Company's collaborative revenue of $788 and $2,750 from its share of the profit generated by sales of KORSUVA injection in the United States by CSL Vifor was included within collaborative revenue for the three months ended March 31, 2024 and 2023, respectively.

Sales of KORSUVA injection to CSL Vifor of $ 640 and $3,191 were included within commercial supply revenue for the three months ended March 31, 2024 and 2023, respectively. The associated COGS for the Company's commercial supply revenue from CSL Vifor was $620 and $2,590 for the three months ended March 31, 2024 and 2023, respectively.

The Company recorded $125 as royalty revenue based on net sales of Kapruvia outside of the United States during the three months ended March 31, 2023. There was no royalty revenue recorded during the three months ended March 31, 2024.

The Company recorded $290 as other revenue from its royalty payments from CSL Vifor for the three months ended March 31, 2024. There was no other revenue recorded for the three months ended March 31, 2023.

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

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

Cautionary Note Regarding Forward-Looking Statements

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

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

- our plans to develop and commercialize oral difelikefalin for the treatment of pruritus associated with notalgia paresthetica, or NP, and any potential future product candidates;
- our ability to execute on our strategic plans, including efforts to focus our resources on the development of oral difelikefalin for the treatment of chronic pruritus associated with NP and significantly reduce our operating expenses;
- the timing of our clinical trials and reporting of our results from these trials, including our clinical trial programs for oral difelikefalin in chronic pruritus associated with NP;
- the potential results of ongoing and planned preclinical studies and clinical trials and future regulatory and development milestones for our product candidates;
- the performance of third-party manufacturers, clinical research organizations, or CROs, and other vendors;
- the size and growth of the potential markets for pruritus management, including the treatment of chronic pruritus associated with NP;
- 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 candidate, and the labeling under any approval we may obtain;
- the anticipated use of Enteris Biopharma, Inc.'s, or Enteris's, Peptelligence ® technology to develop, manufacture and commercialize oral difelikefalin;
- our ability to establish additional collaborations for our product candidates;
- the continued service of our key scientific or management personnel;

- our ability to establish commercialization and marketing capabilities for any approved products;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain coverage and adequate reimbursement from third-party payers and governments 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;
- the potential effects of any global health crises, geopolitical tensions and macroeconomic conditions on our business, operations and clinical development and regulatory timelines and plans; and
- the performance of our current and future collaborators and licensees, including CSL Vifor, 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.

You should refer to the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2023, or the Annual Report, 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 Consolidated Financial Statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (ii) our Annual Report.

Overview

Introduction

We are a development-stage biopharmaceutical company driving innovation in sizable, yet underserved diseases and conditions. Specifically, we are focused on leading a new treatment paradigm to improve the lives of patients suffering from chronic pruritus. We are developing an oral formulation of difelikefalin, a selective, predominantly peripherally acting, non-scheduled Kappa opioid receptor agonist, for the treatment of chronic neuropathic pruritus associated with NP, a common, underdiagnosed neuropathy affecting the upper back. We are conducting a Phase 2/3 program with topline results of the dose-finding portion expected by the end of the second quarter of 2024. We also developed an IV formulation of the same molecule, which is approved for the treatment of moderate-to-severe pruritus associated with advanced chronic kidney disease in adults undergoing hemodialysis in the United States, the European Union, or EU, and multiple other countries. The IV formulation is out-licensed worldwide.

Corporate History

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, sales of our royalties from ex-U.S. sales of our commercial product, and payments from license agreements.

NASDAQ Notice

On February 1, 2024, we received a letter from The Nasdaq Stock Market, or Nasdaq, notifying us that, for the previous 30 consecutive business day periods prior to the date of the letter, the closing bid price for our common stock was below $1.00. In accordance with Nasdaq Listing Rule 5810(c)(3)(A) we were provided an initial period of 180 calendar days, or until July 30, 2024, to regain compliance with Nasdaq's bid price requirement. If, at any time before July 30, 2024, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days, we would regain compliance with the bid price requirement, unless Nasdaq staff exercised its discretion to extend this 10-day period pursuant to Nasdaq rules. In the event we do not regain compliance with the minimum bid price requirement by July 30, 2024, we may be eligible for an additional 180-calendar day compliance period if we elect to transfer to The Nasdaq Capital Market to take advantage of the additional compliance period offered on that market. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the bid price deficiency during the second compliance period. Our failure to regain compliance during this period could result in delisting.

Our board of directors approved and has recommended for stockholder approval at our 2024 Annual Meeting of Stockholders a series of alternate amendments to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of our common stock and corresponding proportionate reduction in the total number of authorized shares of our common stock, where the board of directors will have the discretion to select the reverse stock split ratio from within a range between and including one-for-four and one-for-twelve. Such reverse stock split and corresponding reduction in authorized shares of common stock, and the reverse stock split ratio, will be at the sole discretion of the board of directors at any time prior to our 2025 Annual Meeting of Stockholders.

Our Product Portfolio

Product Candidate	Indication	Status	Next Milestone	Commercialization Rights
Oral difelikefalin	Pruritus NP	Phase 2/3 KOURAGE 1 ongoing Phase 3 KOURAGE 2 planned	Phase 2 KOURAGE 1 Topline 2Q2024	Cara (Worldwide excl. South Korea)
KORSUVA (difelikefalin) injection/Kapruvia	Pruritus CKD - Hemodialysis	Approved in the U.S. (08/2021) Approved in EU incl. UK (04/2022) Approved in Japan (09/2023) Other approvals: Switzerland, Canada, Singapore, Australia, Kuwait, Israel, UAE, Saudi Arabia		CSL Vifor (Worldwide excl. Japan and South Korea)*; Maruishi (Japan); CKDP (South Korea)

**We are party to two collaborations for the commercialization of KORSUVA (difelikefalin) injection/Kapruvia with a joint venture between CSL Vifor and Fresenius Medical Care. In this Quarterly Report, unless the context otherwise requires, "CSL Vifor" refers to CSL Vifor and its affiliated entities, including, where applicable, the joint venture.*

Oral Difelikefalin, Our Development Stage Product Candidate

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) or 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 numerical rating scale, or 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 adverse events, or 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. 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.

Part A of KOURAGE 1, the dose finding portion of the study, is a double-blind, placebo-controlled, 8-week study. In the first quarter of 2024, we completed enrollment with 214 patients who were randomized equally to four arms (0.25 mg BID, 1.0 mg BID, 2.0 mg BID, placebo BID). Part A is not powered for statistical significance. We expect to have topline efficacy and safety results from KOURAGE 1 Part A by the end of the second quarter of 2024. This readout will provide key information, specifically the dose and the sample size, to initiate the pivotal Phase 3 portions of the program - Part B of KOURAGE 1 and the second study KOURAGE 2.

Part B of KOURAGE 1 and KOURAGE 2, the pivotal studies, will be identical in design. They will likely be double-blind, placebo-controlled, 8-week studies with patients allowed to roll over into open label 52-week extensions. Patients will be randomized 1:1 to either difelikefalin or matching placebo. The primary endpoint will likely be the proportion of patients with a ≥4-point improvement at Week 8 from baseline in the worst itch NRS.

KOURAGE 1 and KOURAGE 2 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 final topline results from the first pivotal study KOURAGE 1 Part B by the end of 2025 with the second pivotal study KOURAGE 2 results in early 2026.

KORSUVA (difelikefalin) injection – Our Commercial Stage Product

Overview

We have out-licensed to CSL Vifor the commercialization of KORSUVA injection/Kapruvia in dialysis patients with advanced CKD-aP worldwide, excluding Japan (licensed to Maruishi/sub-licensee Kissei), and South Korea (licensed to CKDP).

On August 23, 2021, 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, 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 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 October 27, 2023, CMS published the final CY 2024 rule, which finalized the post-TDAPA add-on payment 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 the total trailing 12-months expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment will be applied to all End Stage Renal Disease, or ESRD, Prospective Payment System, or PPS, payments and paid for 3 years, adjusted annually. The add-on payments for KORSUVA injection commenced on April 1, 2024. The unfavorable CMS reimbursement codified in the final CY2024 rule has resulted in a lack of sequential revenues growth for KORSUVA injection since its launch. For the three months ended March 31, 2024 and 2023, CSL Vifor recorded net sales of KORSUVA injection in the United States of approximately $1.8 million and $5.7 million, respectively, and we recorded associated collaborative revenue of $0.8 million and $2.8 million, respectively, which represented our share of the profit from these sales. As a result of the final CY 2024 rule, we expect no meaningful revenue contribution from KORSUVA injection following the TDAPA period expiration.

In April 2022, the European Commission granted a 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. Difelikefalin injection was also approved in the UK (04/2022) and Switzerland (08/2022) under the brand name Kapruvia as well as Singapore (08/2022), Canada (08/2022), Australia (11/2022), UAE (01/2023), Kuwait (05/2023), Israel (06/2023), Japan (09/2023), and Saudi Arabia (01/2024) under the brand name KORSUVA injection. For the three months ended March 31, 2023, we recorded royalty revenue of approximately $125,000, which represented our royalties on net sales of Kapruvia.

During the fourth quarter of 2023, we 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, pursuant to which HCR will receive current and future royalty and milestone payments for Kapruvia and KORSUVA (ex-U.S. only) up to certain capped amounts in exchange for certain payments made to us. As a result, there was no royalty revenue recorded for the three months ended March 31, 2024. However, we recorded other revenue of approximately $623,000, of which approximately $290,000 related to CSL Vifor royalties to be paid to HCR under this agreement (see “Royalty Purchase and Sale Agreement” below).

We have out-licensed to Maruishi and its sub-licensee Kissei the commercialization of KORSUVA injection 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.

During the fourth quarter of 2023, we entered into the HCR Agreement where we sold our future royalties and milestones for KORSUVA in Japan to HCR. For the three months ended March 31, 2024, we recorded other revenue of approximately $623,000, of which approximately $333,000 related to Maruishi royalties to be paid to HCR under this agreement (see “Royalty Purchase and Sale Agreement” below). There was no other revenue recorded for the three months ended March 31, 2023 as the HCR Agreement was not entered into until the fourth quarter of 2023.

As a result of our sales of the royalties and milestones for KORSUVA/Kapruvia, we expect no meaningful revenue contribution from KORSUVA/Kapruvia royalties and milestones in the foreseeable future.

KORSUVA Injection U.S. Commercialization

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, large dialysis organizations, or LDOs, came on-line driving a significant quarter-to-quarter increase in order volume from the wholesaler. This stocking at the clinic level, particularly from Fresenius Medical Care, or FMC, resulted in significant subsequent quarterly revenue fluctuations. In the third quarter of 2023, FMC decided to reallocate all remaining clinic level inventory within its network of clinics resulting in limited revenues in the fourth quarter of 2023 and in the first quarter of 2024.

KORSUVA Injection and Kapruvia Revenue and Other Metrics

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

- Collaborative revenue from our share of the profit generated by KORSUVA injection sales in the United States. For the three months ended March 31, 2024 and 2023, we recorded collaborative revenue of $0.8 million and $2.8 million, respectively.

- Commercial supply revenue from our sales of commercial product to CSL Vifor, which is subsequently sold to wholesalers. For the three months ended March 31, 2024 and 2023, we recorded commercial supply revenue of $0.6 million and $3.2 million, respectively.

- Royalty revenue in conjunction with the launch of Kapruvia. For the three months ended March 31, 2023, we recorded royalty revenue of approximately $125,000, which represented royalty payments earned by us. We

recorded no royalty revenue in connection with Kapruvia for the three months ended March 31, 2024 as a result of entering the HCR Agreement in the fourth quarter of 2023.

During the fourth quarter of 2023, we entered into the HCR Agreement where we sold our current and future royalties and milestone payments for Kapruvia and KORSUVA injection to HCR. For the three months ended March 31, 2024, we recorded other revenue of approximately $623,000, of which approximately $290,000 related to CSL Vifor royalties and approximately $333,000 related to Maruishi royalties to be paid to HCR under this agreement (see “Royalty Purchase and Sale Agreement” below).

We are also eligible for sales-based or regulatory milestone payments, which could be earned in the future in accordance with certain licensing agreements and would be subject to the HCR Agreement for ex-U.S. milestone payments. For the three months ended March 31, 2024 and 2023, we did not record any sales-based or regulatory milestone revenue.

Additional metrics that we have reported in the past:

- Net sales of KORSUVA injection in the United States. This amount is the net sales amount recorded by CSL Vifor to reflect shipments of KORSUVA injection vials from CSL Vifor to wholesalers. For the three months ended March 31, 2024 and 2023, CSL Vifor recorded net sales of KORSUVA injection in the United States of approximately $1.8 million and $5.7 million, respectively.

- Shipments of KORSUVA injection vials from wholesalers in the United States to the dialysis clinics. 111,720 and 45,720 KORSUVA injection vials were shipped from wholesalers to the dialysis clinics for the three months ended March 31, 2024 and 2023, respectively. Of the vials shipped to the FMC dialysis centers for the three months ended March 31, 2024, a portion was reallocated product by FMC within its network of clinics.

Royalty Purchase and Sale Agreement

During the fourth quarter of 2023, we, through our wholly-owned subsidiary Cara Royalty Sub LLC, or Cara Royalty Sub, entered into the HCR Agreement, pursuant to which Cara Royalty Sub sold to HCR certain of its rights to receive future royalties and milestone payments, or the Royalties, due and payable to Cara Royalty Sub (as our assignee) under our agreements with Maruishi and CSL Vifor, collectively the Covered License Agreements, in exchange for up to $40.0 million. We have retained all of our rights, 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, Cara received an initial payment of $17.5 million less certain transaction costs in November 2023. In December 2023, we received an additional $20.0 million less certain advisory fees, upon satisfying the milestone event for pricing of Kapruvia® (difelikefalin) in Germany being approved above a certain threshold amount per dose. The terms of the HCR Agreement also provide for an additional $2.5 million milestone payment to Cara 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 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 not achieved on or prior to December 31, 2029. In the event of a change of control, Cara Royalty Sub will pay to HCR an amount equal to 2.8 times the aggregate amount of payments made by HCR less the total net amounts paid by Cara Royalty Sub to HCR as of the effective date of control. In certain situations, Cara Royalty Sub would not be obligated to pay the change of control payment to HCR. After the HCR Agreement expires, all rights to receive the Royalties return to Cara Royalty Sub. During the three months ended March 31, 2024, approximately $0.7 million was repaid to HCR under the HCR Agreement.

Collaboration and License Agreements

Agreements with CSL Vifor

We are party to two separate license agreements with CSL Vifor. In October 2020, we granted CSL Vifor 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.

We received 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 represented a premium over a pre-determined average closing price of our common stock. The U.S. regulatory approval of KORSUVA injection in August 2021 triggered an additional $50.0 million equity purchase by CSL Vifor in October 2021, in which we sold an aggregate of 3,282,391 shares of our common stock at a price of $15.23 per share, which represented a 20% premium to the 30-day trailing average price of our common stock. In addition, pursuant to this agreement, we are eligible to receive payments of up to $240.0 million upon the achievement of certain sales-based milestones. However, based on the limited commercial success of KORSUVA injection, we do not expect to achieve these sales-based milestones.

Pursuant to the agreement for commercialization of KORSUVA in the United States, we are generally entitled to 60% of the net profits from sales of KORSUVA 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 a separate agreement), subject to potential temporary adjustment in future years based on certain conditions. Under this agreement, 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 cost of goods sold, or COGS, are deducted from net sales in calculating the net profits that are subject to the profit-sharing arrangement under the agreement.

Under a separate agreement with CSL Vifor, in May 2018, we granted CSL Vifor 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). Under the agreement, CSL Vifor also has the right to promote KORSUVA injection in the United States in the dialysis clinics of Fresenius Medical Care North America, or FMCNA, under a profit-sharing arrangement.

Upon entry into this agreement, 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.

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 CSL Vifor. 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 this agreement) based on net FMCNA clinic sales) 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. During the fourth quarter of 2023, we entered into the HCR Agreement pursuant to which we sold our future royalties and milestone payments under this agreement to HCR (see "Royalty Purchase and Sale Agreement" above).

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 indication of chronic 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.

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). In January 2021, we met the milestone criteria, as set forth in the Maruishi Agreement, for Maruishi's first initiation of a Phase 3 trial for uremic pruritus in Japan. As a result, we received the $2.0 million milestone payment ($1.9 million after contractual foreign currency exchange adjustments) in May 2021.

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. In November 2023, we entered into an active pharmaceutical ingredient, or API, supply agreement with Maruishi for difelikefalin.

To date, 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. During the fourth quarter of 2023, we entered into the HCR Agreement pursuant to which we sold our future royalties and milestone payments under the Maruishi Agreement to HCR (see "Royalty Purchase and Sale Agreement" above).

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). To date, 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.

The CKDP Agreement continues until CKDP no longer has any obligation to pay us royalties on any product. Either we or CKDP may terminate the CKDP Agreement for the other party's breach of the CKDP Agreement or bankruptcy. CKDP may terminate the CKDP Agreement if any of the licensed patent rights is invalid, unenforceable, is narrowed in scope or is deemed unpatentable, except as a result of a challenge by CKDP, or a third party commercializes a product containing a compound identical to difelikefalin without infringing any of the licensed patent rights in South Korea. We may terminate the CKDP Agreement if CKDP challenges the licensed patent rights or if a third party in South Korea owns an issued patent that claims difelikefalin and CKDP's sale of products would infringe that patent. In addition, in connection with the CKDP Agreement, CKDP made a $0.4 million equity investment in our company.

Manufacturing and License Agreements

Polypeptide Laboratories S.A., or 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 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 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.

Enteris Biopharma, Inc., or Enteris

In August 2019, we entered into a non-exclusive license agreement with Enteris Biopharma, Inc. (Enteris), or the Enteris License Agreement. Pursuant to the Enteris License Agreement, Enteris granted to 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. Until the second anniversary of the entry into the Enteris License Agreement, we had the right, but not the obligation, to terminate our obligation to pay any royalties under the Royalty Buyout. We did not exercise our Royalty Buyout right and such right expired in August 2021. During the three months ended March 31, 2024 and 2023, no milestone payments or royalties were paid to Enteris by us in relation to the Enteris License Agreement.

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

Either party may terminate the Enteris License Agreement upon written notice if the other party has failed to remedy a material breach within 60 days (or 30 days in the case of a material breach of a payment obligation). Enteris may terminate the Enteris License Agreement upon 30 days' written notice to us if we or any of our affiliates formally challenge the validity of any licensed patent rights or assists a third party in doing so. We may terminate the Enteris License Agreement for any reason or no reason (a) prior to receipt of first regulatory approval for a licensed product in the United States for any indication upon 30 days' prior written notice to Enteris or (b) on or after receipt of first regulatory approval for a licensed product in the United States for any indication upon 60 days' prior written notice to Enteris.

Patheon UK Limited, or 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.

Either party may terminate the MSA or a Product Agreement upon written notice if the other party (1) has failed to remedy a material breach within a specified time or (2) is declared insolvent or bankrupt, voluntarily files a petition of bankruptcy or assigns such agreement for the benefit of creditors. We may terminate a Product Agreement (a) upon 90 days' prior written notice if any governmental agency takes any action that prevents us from selling the relevant product in the relevant territory, (b) upon six months' prior written notice if we do not intend to order manufacturing services due to a product's discontinuance in the market, or (c) upon 90 days' prior written notice if we determine that the manufacture or supply of a product likely infringes third-party rights. Patheon may terminate the MSA or a Product Agreement (i) upon six months' prior written notice if we assign such agreement to an assignee that is unacceptable to Patheon for certain reasons, or (ii) upon 30 days' prior written notice if, after the first year of commercial sales, we forecast zero volume for 12 months.

The MSA contains, among other provisions, customary representations and warranties by the parties, a grant to Patheon of certain limited license rights to our intellectual property in connection with Patheon's performance of the services under the MSA, certain indemnification rights in favor of both parties, limitations of liability and customary confidentiality provisions.

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.

In December 2023, we entered into an agreement with Patheon to reimburse Patheon approximately $1.7 million for forecasted manufacturing commitments that are no longer needed due to the reduced demand expectations of KORSUVA in the United States. As of March 31, 2024, $0.2 million of the $1.7 million remained within accounts payable and accrued expenses on our Condensed Consolidated Balance Sheet. In connection with the agreement with Patheon, we agreed to schedule additional manufacturing commitments in 2024.

Components of Operating Results

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

Revenue

To date, we have generated 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) the receipt of upfront license fees and milestone payments; (4) royalty revenue in conjunction with sales of Kapruvia in Europe through September 30, 2023; and (5) clinical compound sales from certain license agreements. We are eligible to receive sales-based milestones in the future in accordance with certain licensing agreements.

Beginning in the fourth quarter of 2023, the revenue received under our agreements with CSL Vifor and Maruishi for royalty and sales-based milestone payments received in conjunction with ex-U.S. sales of KORSUVA/Kapruvia were recorded as other revenue and considered non-cash until we have fulfilled our obligations under HCR Agreement (see “Royalty Purchase and Sale Agreement” above).

To date, we have earned a total of $138.3 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 (which ceased upon entry into the HCR Agreement during the fourth quarter of 2023).

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, 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 two years. On October 27, 2023, CMS published the final CY 2024 rule, which finalized the post-TDAPA add-on payment 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 the total trailing 12-months expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment will be applied to all ESRD PPS payments and paid for 3 years, adjusted annually. The add-on payments for KORSUVA injection commenced on April 1, 2024. The anticipated unfavorable CMS reimbursement codified in the final CY 2024 rule has resulted in a lack of sequential revenues growth for KORSUVA injection since its launch. As a result, we expect no meaningful revenue contribution from KORSUVA injection post its TDAPA expiration.

In the third quarter of 2023, FMC decided to reallocate all remaining clinic level inventory within its network of clinics resulting in limited revenues in the fourth quarter of 2023 and in the first quarter of 2024. During the three months ended March 31, 2024, there was approximately $1.8 million of net sales by CSL Vifor.

As of March 31, 2024, Vifor International owned 7,396,770, or 13.5%, of our common stock. CSL Vifor and its affiliates are all considered related parties as of March 31, 2024 and December 31, 2023 (see Note 18 of Notes to Condensed Consolidated Financial Statements, *Related Party Transactions*, in this Quarterly Report on Form 10-Q).

Cost of Goods Sold (COGS)

COGS includes costs related to sales of our commercial product, KORSUVA injection, to CSL Vifor. Costs related to the sales of KORSUVA injection are generally recognized upon receipt of shipment by CSL Vifor. Our COGS for KORSUVA injection include the cost of producing commercial product that correspond with commercial supply revenue, such as third-party supply and overhead costs, as well as certain period costs related to freight, packaging,

stability, and quality testing. The related COGS for CSL Vifor associated with the net profit share arrangement as well as the marketing and distribution fee for the applicable period reduces our profit share revenue for the period.

For the three months ended March 31, 2024 and 2023, we recorded commercial supply revenue of $0.6 million and $3.2 million, respectively, with associated COGS of $0.6 million for the 2024 period and $2.6 million for the 2023 period. 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 oral 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 vendors and 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 decrease in the future as we focus our development efforts on the clinical trials for NP. However, it is difficult to determine with certainty the duration and completion costs of our current studies in NP or future nonclinical and clinical studies of our current or any future 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 oral difelikefalin or any future product candidates.

The duration, costs and timing of clinical trials and development of our product candidate 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 our product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. In the future, we will determine which, if any, other programs to pursue and how much to fund each program in response to the scientific and clinical success of our product candidate, as well as an assessment of our 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 decrease in the future as a result of our workforce reduction in January 2024. G&A expenses include costs related to 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 12 of Notes to Condensed Consolidated Financial Statements, C*ollaboration and Licensing Arrangements*, in this Quarterly Report on Form 10-Q).

Restructuring

On January 22, 2024, we announced a workforce reduction of up to 50% of our employees in order to reduce our operating expenses and focus our efforts on development of oral difelikefalin in chronic pruritus associated with NP. Restructuring expenses consist of pre-tax severance and employee-related costs for those involuntary terminations associated with the strategic prioritization of NP and the related workforce reduction (see Note 17 of Notes to Condensed Consolidated Financial Statements, C*ommitments and Contingencies – Restructuring Action*, 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.

Non-cash Interest Expense on Liability Related to Sales of Future Royalties and Milestones

Non-cash interest expense on liability related to sales of future royalties and milestone payments, which are received in conjunction with ex-U.S. sales of KORSUVA/Kapruvia under our agreements with CSL Vifor and Maruishi, consists of imputed interest on the carrying value of the liability and the amortization of the related issuance costs resulting from the HCR Agreement (see "Royalty Purchase and Sale Agreement" above). This non-cash interest expense is recognized separately on the Condensed Consolidated Statement of Comprehensive Loss for the three months ended March 31, 2024.

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 March 31, 2024; however, we will continue to evaluate the effect on the tax provision each reporting period.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

Revenue

	Three Months Ended March 31,		
	2024	2023	% change
	Dollar amounts in thousands		
Collaborative revenue	$ 788	$ 2,750	-71%
Commercial supply revenue	640	3,191	-80%
Royalty revenue	—	125	-100%
Clinical compound revenue	84	99	-16%
Other revenue	623	—	N/A
Total revenue	$ 2,135	$ 6,165	-65%

Collaborative Revenue

We recognized collaborative revenue of $0.8 million and $2.8 million for the three months ended March 31, 2024 and 2023, respectively. This change in collaborative revenue was related to our share of the profit from CSL Vifor's sales of KORSUVA injection to third parties in the United States, which commercially launched in April 2022 (see Notes 12 and 13 of Notes to Condensed Consolidated 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 $0.6 million and $3.2 million for the three months ended March 31, 2024 and 2023, respectively. This change in commercial supply revenue was related to our sales of KORSUVA injection to CSL Vifor, which commercially launched in April 2022.

Royalty revenue

We recognized royalty revenue of approximately $125,000 for the three months ended March 31, 2023, which was related to our royalties on the net sales of Kapruvia in Europe prior to October 1, 2023. Beginning on October 1, 2023, royalty revenue will no longer be recognized until we have fulfilled our obligations under the HCR Agreement (see "Royalty Purchase and Sale Agreement" above). As a result, there was no royalty revenue for the three months ended March 31, 2024.

Clinical compound revenue

We recognized clinical compound revenue of approximately $84,000 and $99,000 for the three months ended March 31, 2024 and 2023, respectively, which were related to sales of clinical compound to Maruishi.

Other revenue

We recognized non-cash revenue of approximately $623,000 for the three months ended March 31, 2024, which represent royalty payments earned in conjunction with ex-U.S. sales of KORSUVA/Kapruvia under our agreements with CSL Vifor and Maruishi, which were sold to HCR under the HCR Agreement. There was no non-cash revenue recognized for the three months ended March 31, 2023.

Cost of Goods Sold (COGS)

	Three Months Ended March 31,		
	2024	2023	% change
	Dollar amounts in thousands		
Cost of Goods Sold	$ 620	$ 2,590	-76%

During the three months ended March 31, 2024 and 2023, we recorded COGS of $0.6 million and $2.6 million, respectively, which was related to our commercial supply revenue for KORSUVA injection sales to CSL Vifor.

Research and Development Expense

	Three Months Ended March 31,		
	2024	2023	% change
	Dollar amounts in thousands		
Direct clinical trial costs	$ 15,655	$ 13,749	14%
Consultant services in support of clinical trials	579	1,071	-46%
Stock-based compensation	759	1,659	-54%
Depreciation and amortization	12	29	-59%
Other R&D operating expenses	4,959	7,826	-37%
Total R&D expense	$ 21,964	$ 24,334	-10%

For the three months ended March 31, 2024 compared to the three months ended March 31, 2023, the $1.9 million increase in direct clinical trial costs was primarily due to increases related to the oral difelikefalin NP program, partially offset by the discontinuations of the oral difelikefalin program in atopic dermatitis due to the clinical trial results in December 2023 and the oral difelikefalin program in advanced chronic kidney disease due to the prioritization of the NP program. The decrease in stock compensation expense is primarily related to the reduction in workforce and the resulting reversal of stock compensation expense for unvested stock options and restricted stock units that were forfeited during the three months ended March 31, 2024, partially offset by performance-based restricted stock units that were achieved during the three months ended March 31, 2024. The decrease in other R&D operating expenses for the three months

ended March 31, 2024 compared to the three months ended March 31, 2023 was primarily related to decreases in payroll and related costs, travel costs and other related conference costs.

The following table summarizes our R&D expenses by program for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,		
	2024	2023	% change
	Dollar amounts in thousands		
External research and development expenses:			
Oral difelikefalin – Pruritus	16,216	14,806	10%
Internal research and development expenses	5,748	9,528	-40%
Total research and development expenses	$ 21,964	$ 24,334	-10%

General and Administrative Expenses

	Three Months Ended March 31,		
	2024	2023	% change
	Dollar amounts in thousands		
Professional fees and public/investor relations	$ 1,157	$ 1,644	-30%
Stock-based compensation	2,586	1,694	53%
Depreciation and amortization	30	29	3%
Other G&A operating expenses	3,043	3,524	-14%
Total G&A expense	$ 6,816	$ 6,891	-1%

For the three months ended March 31, 2024 compared to the three months ended March 31, 2023, the decrease in professional fees and public/investor relations was primarily due to decreases in legal costs. The increase in stock-based compensation expense was primarily related to performance-based restricted stock units that were achieved during the three months ended March 31, 2024, partially offset by the reduction in workforce and the resulting reversal of stock compensation expense for unvested stock options that were forfeited during the three months ended March 31, 2024. The decrease in other G&A operating expenses for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was primarily related to decreases in payroll and related costs, travel costs and other related conference costs.

Restructuring Expenses

	Three Months Ended March 31,		
	2024	2023	% change
	Dollar amounts in thousands		
Restructuring expenses	$ 2,401	$ —	N/A

For the three months ended March 31, 2024, restructuring expenses were $2.4 million which were related to our strategic prioritization of NP and the associated workforce reduction during the three months ended March 31, 2024. There were no restructuring expenses recorded during the three months ended March 31, 2023.

Other Income, Net

	Three Months Ended March 31,		
	2024	2023	% change
	Dollar amounts in thousands		
Other income, net	$ 952	$ 985	-3%

For the three months ended March 31, 2024 compared to the three months ended March 31, 2023, the decrease in other income, net was primarily due to a decrease in interest income resulting from a lower balance in our portfolio of investments in 2024 as compared to 2023, partially offset by a higher yield on our portfolio of investments in 2024 as compared to 2023, and an increase in accretion income from our available-for-sale marketable securities.

Non-cash Interest Expense on Liability Related to the Sales of Future Royalties and Milestones

	Three Months Ended March 31,		
	2024	2023	% change
	Dollar amounts in thousands		
Non-cash interest expense on liability related to sales of future royalties and milestones	$ 1,982	$ —	N/A

We recognized $2.0 million of non-cash interest expense on the liability related to sales of future royalties and milestones for the three months ended March 31, 2024, which represented imputed interest on the carrying value of the liability to HCR in the first quarter of 2024 and the amortization of the related issuance costs associated with the HCR Agreement. There was no non-cash interest expense on liability recognized during the three months ended March 31, 2023 as the HCR Agreement was entered into in the fourth quarter of 2023 (see “Royalty Purchase and Sale Agreement” above).

Benefit from Income Taxes

We have not exchanged our R&D tax credit for cash for the three months ended March 31, 2024, and were not eligible to exchange our R&D tax credit for cash for the three months ended March 31, 2023, therefore there was no benefit from income taxes for each of the three months ended March 31, 2024 and 2023. As of March 31, 2024, we recorded $0.7 million within income tax receivable which related to the 2020 R&D credit.

We recognized a full valuation allowance against deferred tax assets at March 31, 2024 and December 31, 2023. 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 the three months ended March 31, 2024 and 2023.

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, third-party clinical R&D services, clinical costs related to the oral difelikefalin program, and compensation and related expenses.

As of March 31, 2024, we have no commitments for capital expenditures in either the short-term or long-term. The following discussion summarizes our current and long-term material cash requirements as of March 31, 2024, which we expect to fund primarily with current unrestricted cash and cash equivalents and available-for-sale marketable securities:

	Material Cash Requirements *(amounts in thousands)*						
	Total	**2024**	**2025**	**2026**	**2027**	**2028**	**Thereafter**
Operating lease obligation[1]	$ 14,371	$ 108	$ 1,298	$ 1,330	$ 1,363	$ 1,398	$ 8,874
Manufacturing purchase obligations[2]	1,789	1,789	—	—	—	—	—
Other obligations[3]	1,500	—	—	—	—	—	1,500
Total	$ 17,660	$ 1,897	$ 1,298	$ 1,330	$ 1,363	$ 1,398	$ 10,374

(1) Operating lease obligations in 2024 and beyond relate to our new Stamford operating lease entered into in May 2023 for our new principal office, for which rent payments are expected to begin in late 2024. See Note 17 of Notes to Condensed Consolidated 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, 2024. In December 2023, we entered into an agreement with Patheon to reimburse Patheon approximately $1.7 million for forecasted manufacturing commitments that were no longer needed due to the reduced demand expectations of KORSUVA in the United States. As of March 31, 2024, $0.2 million of the $1.7 million remained within accounts payable and accrued expenses on our Condensed Consolidated Balance Sheet. In the event the purchase capacity reservation is not met in 2024, it will rollover into 2025. We expect a portion of this capacity reservation will be reimbursed in accordance with the supply agreement with CSL Vifor. See Note 17 of Notes to Condensed Consolidated 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 new lease for office space in Stamford, Connecticut. After the first and second anniversaries of the rent commencement date, the face amount of the letter of credit can be reduced by $500,000 each period if we are not in default of our lease obligations. See Note 6 of Notes to Condensed Consolidated Financial Statements, *Restricted Cash*, in this Quarterly Report on Form 10-Q for details about our letter of credit for our new lease for our principal office in Stamford, Connecticut.

Based on the Enteris License Agreement that we entered into in August 2019, we are obligated to pay (1) milestone payments upon the achievement of certain development, regulatory and commercial milestones and (2) low-single digit royalty percentages on net sales of licensed products, subject to reductions in specified circumstances. As these milestone payments may or may not be achieved, and royalties may or may not be owed depending on our future commercial success, there were no future potential payments that were considered cash requirements in the table above as of March 31, 2024. We did not make any milestone payments to Enteris during the three months ended March 31, 2024 and 2023. See Note 17 of Notes to Condensed Consolidated Financial Statements, *Commitments and Contingencies*, in this Quarterly Report on Form 10-Q for details about our Enteris License Agreement.

During the fourth quarter of 2023, we, through our wholly-owned subsidiary Cara Royalty Sub, entered into the HCR Agreement with HCR pursuant to which Cara Royalty Sub sold to HCR certain of its rights to the Royalties, due and payable to Cara Royalty Sub (as our assignee) under our agreements with CSL Vifor and Maruishi, in exchange for up to $40.0 million. We have retained all of our rights, title and interest in, to and under the Covered License Agreements that relate to any non-intravenous formulation of difelikefalin. These future payments to HCR were not included in the table above since the amounts and timing of royalty and milestone payments received under the agreements with CSL Vifor and Maruishi could change in the future as they are subject to CSL Vifor's and Maruishi's commercialization efforts (see "Royalty Purchase and Sale Agreement" above).

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 $30.7 million and $26.7 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $715.4 million. We expect to continue to incur significant expenses and operating and net losses in the foreseeable future, as we develop and seek marketing approval for oral difelikefalin in NP. Our financial results may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and the future sales of KORSUVA.

We anticipate that our expenses will be focused on:

- the continued development of oral difelikefalin for chronic pruritus associated with NP;
- the potential regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establishing a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any other products for which we may obtain regulatory approval; and
- maintaining, expanding, and protecting our global intellectual property portfolio.

The successful development of our product candidate 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 complete the development of oral difelikefalin in NP. 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 candidate;
- 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 global health crises, introducing additional uncertainty.

Our product candidate is still in clinical development and since the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product

candidate 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 global health crises, geopolitical tensions, such as the ongoing conflicts between Russia and Ukraine, conflict in the Middle East, and increasing tensions between China and Taiwan, and government actions implemented as a result of the foregoing, fluctuations in inflation, rising interest rates, uncertainty and liquidity concerns in the broader financial services industry, and a potential recession in the United States. If we are not able to do so, we could be required to postpone, scale back or eliminate some, or all, of these objectives. To the extent that we raise additional capital through the future sale of equity or convertible debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Sources of Liquidity

Since our inception to date, we have raised an aggregate of $943.8 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 in 2023; (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) $258.8 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 $29.8 million; (5) net proceeds of $98.0 million from the purchase of our common stock in relation to the license agreements with CSL Vifor; and (6) net proceeds of $36.5 million from the sale of future ex-U.S. royalties and milestones to HCR under our agreements with CSL Vifor and Maruishi (see Note 12 of Notes to Condensed Consolidated Financial Statements, *Collaboration and Licensing Agreements*, in this Quarterly Report on Form 10-Q).

During the fourth quarter of 2023, we, through our wholly-owned subsidiary Cara Royalty Sub, entered into the HCR Agreement with HCR pursuant to which Cara Royalty Sub sold to HCR certain of its rights to receive the Royalties, due and payable to Cara Royalty Sub (as our assignee) under the Covered License Agreements, in exchange for up to $40.0 million. We have retained all of our rights, 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, Cara Royalty Sub received an initial payment of $17.5 million less certain transaction costs in November 2023. In December 2023, we received an additional $20.0 million, less certain advisory fees, upon satisfying the milestone event for pricing for Kapruvia® (difelikefalin) in Germany being approved above a certain threshold amount per dose. The terms of the HCR Agreement also provide for an additional $2.5 million milestone payment to Cara 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, or Jefferies, 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 pursuant to the Shelf Registration Statement. Jefferies is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. The common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. No shares were sold under the Sales Agreement during the three months ended March 31, 2024 and 2023.

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 our agreement with CSL Vifor for the commercialization of KORSUVA injection, we are eligible to receive commercial milestone payments in the aggregate of up to $240.0 million from CSL Vifor upon the achievement of certain sales-based milestones. In October 2021, we received a $50.0 million milestone payment from CSL Vifor in exchange for the issuance of 3,282,391 shares of our common stock to CSL Vifor as a result of the regulatory approval of KORSUVA injection in August 2021. To date, we have received $50.0 million of regulatory milestones from CSL Vifor under this agreement.

Under a separate agreement with CSL Vifor, 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 of difelikefalin injection in the licensed territories. To date, we have received $30.0 million of regulatory milestones from CSL Vifor. During the fourth quarter of 2023, we entered into the HCR Agreement where we sold our future royalties and milestone payments under this agreement to HCR (see “Royalty Purchase and Sale Agreement” above).

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. 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. To date, we have received $6.5 million (before contractual foreign currency exchange adjustments) for clinical development and regulatory milestones from Maruishi. During the fourth quarter of 2023, we entered into the HCR Agreement where we sold our future royalties and milestone payments to HCR (see “Royalty Purchase and Sale Agreement” above).

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. To date, $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 two years. 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 the total trailing 12-months 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 commenced on April 1, 2024. The unfavorable CMS reimbursement codified in the final CY2024

rule has resulted in a lack of sequential revenues growth for KORSUVA injection since its launch. As a result, we expect no meaningful revenue contribution from KORSUVA injection post its TDAPA expiration.

Our ability to earn these milestone and royalty payments and their timing is dependent upon successful commercialization of KORSUVA injection/Kapruvia, and successful future repayments made to HCR using CSL Vifor and Maruishi milestones and royalties under the HCR Agreement. However, our receipt of any further such amounts is uncertain at this time and we may never receive any more of these amounts.

Outlook

As a result of our strategic prioritization and reduction in workforce, we expect that our current unrestricted cash and cash equivalents and available-for-sale marketable securities will be sufficient to fund our currently anticipated operating plan into 2026. Our anticipated operating expenses include contractually committed costs as well as non-contractually committed clinical trial costs for trials that may be delayed or not initiated and other non-committed controllable costs. Because the process of testing product candidates in clinical trials is costly and the timing of progress in these trials is uncertain, it is possible that the assumptions upon which we have based this estimate may prove to be wrong, and we could use our capital resources sooner than we presently expect.

Cash Flows

The following is a summary of the net cash flows provided by (used in) our operating, investing and financing activities for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
	Dollar amounts in thousands	
Net cash used in operating activities	$ (30,453)	$ (34,618)
Net cash provided by investing activities	25,951	17,708
Net cash (used in) provided by financing activities	(685)	560
Net decrease in cash, cash equivalents and restricted cash	$ (5,187)	$ (16,350)

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2024 consisted primarily of a net loss of $30.7 million and a $4.9 million cash outflow from net changes in operating assets and liabilities, partially offset by a $5.1 million cash inflow from net non-cash charges. The change in operating assets and liabilities primarily consisted of a decrease of $10.2 million in accounts payable and accrued expenses due to operating payments made during the period, partially offset by a decrease in prepaid expenses of $2.4 million, primarily related to a decrease in prepaid clinical costs, an increase of $1.7 million for lease incentives reimbursed to us, and a decrease in accounts receivable, net – related party of $1.0 million. Net non-cash charges primarily consisted of stock-based compensation expense of $3.3 million and the noncash interest expense related to the HCR Agreement of $2.0 million.

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

Net cash provided by investing activities

Net cash provided by investing activities was $26.0 million for the three months ended March 31, 2024, which primarily included cash inflows of $59.0 million from maturities of available-for-sale marketable securities, partially offset by cash outflows of $32.2 million for the purchases of available-for-sale marketable securities and $0.8 million for the purchases of property and equipment.

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

Net cash (used in) provided by financing activities

Net cash used in financing activities for the three months ended March 31, 2024 consisted of payments made to HCR under the royalty purchase and sale agreement of approximately $685,000.

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

Recent Accounting Pronouncements

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

Critical Accounting Estimates

The preparation of our condensed consolidated 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 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 financial statements prospectively from the date of the change in estimate. Note 2 of Notes to Consolidated Financial Statements, *Summary of Significant Accounting Policies* , in our Annual Report describes the significant accounting policies and methods used in the preparation of our condensed consolidated 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.

Accounting Pronouncements Recently Adopted; Recent Accounting Pronouncements Not Yet Adopted

We do not expect that any recently issued accounting pronouncements will have a material effect on our condensed consolidated financial statements. Refer to Note 2 of Notes to Condensed Consolidated Financial Statements within this Quarterly Report on Form 10-Q, as well as Note 2 of Notes to Consolidated Financial Statements*, Summary of Significant Accounting Policies* in our Annual Report for a full description of accounting pronouncements recently adopted, and issued but not yet adopted, if applicable.

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

Interest Rate Risk

Historically, we invested substantially all 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 Consolidated Financial Statements, *Available-for-Sale Marketable Securities*, in this Quarterly Report on Form 10-Q for details about our available-for-sale marketable securities.

As of March 31, 2024, we had invested $22.8 million of our cash reserves in such marketable securities. Those marketable securities included $22.8 million of investment grade debt instruments with a yield of approximately 3.83% and maturities through November 2024. As of December 31, 2023, we had invested $49.0 million of our cash reserves in such marketable securities. Those marketable securities included $49.0 million of investment grade debt instruments with a yield of approximately 4.41% and maturities through November 2024.

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

Duration is a sensitivity measure that can be used to approximate the change in the fair value of a security that will result from a change in interest rates. Applying the duration model, a hypothetical 100 basis point, or 1%, increase in interest rates as of March 31, 2024 and December 31, 2023, would have resulted in immaterial decreases in the fair values of our portfolio of marketable securities at those dates.

Credit Quality Risk

Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. As of March 31, 2024 and December 31, 2023, the aggregate unrealized losses on our available-for-sale marketable securities were $0.2 million and $0.3 million, respectively. For each of the three months ended March 31, 2024 and 2023, we did not record any charges to credit loss expense for our available-for-sale securities. Refer to Note 3 of Notes to Condensed Consolidated Financial Statements, *Available-for-Sale Marketable Securities*, in this Quarterly Report on Form 10-Q.

As of March 31, 2024 and December 31, 2023, we had accounts receivable, net - related party from CSL Vifor of $1.7 million and $2.8 million, respectively, primarily for our share of the profit generated by KORSUVA injection sales and commercial supply revenues, and payments for ex-U.S. royalties from CSL Vifor. We also had $0.3 million and $0.4 million recorded within other receivables for Japan royalties/milestones owed to us from Maruishi which was included within other receivables as of March 31, 2024 and December 31, 2023, respectively. 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 March 31, 2024 and December 31, 2023.

Item 4. ***Controls and Procedures*.**

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of March 31, 2024. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2024, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls and Procedures

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

PART II

OTHER INFORMATION

Item 1. ***Legal Proceedings***

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

Item 1A. ***Risk Factors***

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and trading price of our securities. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors described in Part I, Item 1A. “Risk Factors” of our Annual Report. We may disclose changes to risk factors or disclose additional factors from time to time in our future filings with the SEC. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. 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, 2023.

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: May 13, 2024

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

Date: May 13, 2024

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: May 13, 2024

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: May 13, 2024

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 March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Christopher Posner, Chief Executive Officer of the Company, and Ryan Maynard, 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: May 13, 2024

/s/ RYAN MAYNARD
Name: Ryan Maynard
Title: Chief Financial Officer
(Principal Financial Officer)
Date: May 13, 2024

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cara Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.