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

Form 10-Q

☒ 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

For the transition period from _____ to

Commission file number: 001-38293

SCPHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	46-5184075
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
25 Mall Road, Suite 203 Burlington, Massachusetts (Address of principal executive office)	01803 (Zip Code)

Registrant's telephone number, including area code: (617) 517-0730

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	SCPH	The Nasdaq Global Select Market

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 ☒

As of May 13, 2024, the Registrant had 36,054,409 common shares, $0.0001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") contains express or implied forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact contained in this Quarterly Report are forward-looking statements, including, but not limited to, statements about the commercialization of FUROSCIX, including the timing and progress thereof, the timing or likelihood of regulatory filings and approvals, the potential expansion of the FUROSCIX indication to include New York Heart Association Class IV heart failure patients and timing thereof, the potential development of an auto-injector and related benefits and timing thereof, the potential expansion of the FUROSCIX indication to include treatment of edema in patients with chronic kidney disease, our plans to develop and commercialize our product candidates, the timing of our ongoing or planned clinical trials, the clinical utility of our product candidates, expectations surrounding manufacturing capabilities and supply chain matters, our commercialization capabilities and strategy, the sufficiency of our cash and cash equivalents and our ability to raise additional capital to fund our operations, our ability to remediate any material weakness, our future financial performance, the anticipated impact of general economic conditions on our business, and the plans and objectives of management for future operations, capital needs and capital expenditures, and our ability to continue as a going concern. In some cases, forward-looking statements can be identified by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology.

The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements on our management’s beliefs and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, you should not place undue reliance on forward-looking statements because they relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Important factors that may cause actual results to differ materially from current expectations include, among other things:

- We are heavily dependent on the success of our product candidates and our approved product, FUROSCIX® (furosemide injection). We have only one approved product and we cannot give any assurance that we will receive regulatory approval for any other product candidates, which is necessary before they can be commercialized.
- If we fail to produce FUROSCIX in the volumes that we require on a timely basis, we may face delays in our commercialization efforts.
- The commercial success of FUROSCIX and any other product candidates, if approved, depends upon attaining market acceptance by hospital networks, physicians, patients, third-party payers and the medical community.
- If we are unable to expand our sales and marketing capabilities or continue to enter into agreements with third parties to market and sell FUROSCIX, we may be unable to generate substantial revenue.
- We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future success.
- We have a history of significant operating losses and expect to incur significant and increasing losses for the foreseeable future; we may never achieve or maintain profitability.
- We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our success depends on our ability to manufacture, or the ability of third parties to deliver, sufficient quantities of supplies, components and drug product for commercialization of FUROSCIX or any of our product candidates, if approved, including our ability to monitor quality control issues related to the production of FUROSCIX and on-body infusors in the volumes that will be required on a timely basis.
- Our success depends on our ability to protect our intellectual property and proprietary technology, as well as the ability of our collaborators to protect their intellectual property and proprietary technology.
- If we fail to comply with our obligations under our existing and any future intellectual property license with third parties, we could lose license rights that are important to our business.
- We may be subject to product liability lawsuits related to our product candidates, if approved, which could divert our resources, result in substantial liabilities and reduce the commercial potential of our products and product candidates.
- Our failure to successfully identify, develop and market additional product candidates could impair our ability to grow.

•We depend heavily on our executive officers, directors and principal consultants and the loss of their services would materially harm our business.

•Other risks and uncertainties, including those listed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission on March 13, 2024, as well as in our subsequent filings with the Securities and Exchange Commission.

If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, then actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

SCPHARMACEUTICALS INC.

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PART I — FINANCIAL INFORMATION

SCPHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	December 31, 2023	March 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 46,814	$ 58,447
Short-term investments	29,199	-
Accounts receivable, net	4,489	5,772
Inventory, net	8,840	9,572
Prepaid expenses	2,436	2,198
Deposits and other current assets	1,160	536
Total current assets	92,938	76,525
Property and equipment, net	58	52
Right-of-use lease assets - operating, net	1,401	1,355
Deposits and other assets	82	522
Total assets	$ 94,479	$ 78,454
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,001	$ 2,706
Accrued expenses	8,901	9,206
Lease obligation - operating, short-term	176	184
Other current liabilities	56	222
Total current liabilities	13,134	12,318
Term loan, long-term	38,811	39,385
Derivative liability	3,857	733
Lease obligation - operating, long-term	1,282	1,233
Other liabilities	177	219
Total liabilities	57,261	53,888
Commitments and contingencies (Note 12)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding	-	-
Common stock, $0.0001 par value; 150,000,000 shares authorized as of March 31, 2024; 35,968,510 and 36,054,409 shares issued and outstanding as of December 31, 2023 and March 31, 2024, respectively	4	4
Additional paid-in capital	318,561	320,016
Accumulated deficit	(281,346)	(295,454)
Accumulated other comprehensive income	(1)	-
Total stockholders' equity	37,218	24,566
Total liabilities and stockholders' equity	$ 94,479	$ 78,454

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SCPHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2023	2024
Product revenues, net	$ 2,063	$ 6,102
Operating expenses:		
Cost of product revenues	605	1,785
Research and development	2,116	2,726
Selling, general and administrative	10,896	17,447
Total operating expenses	13,617	21,958
Loss from operations	(11,554)	(15,856)
Other income	990	2,972
Interest income	1,315	877
Interest expense	(1,961)	(2,101)
Net loss	$ (11,210)	$ (14,108)
Net loss per share — basic and diluted	$ (0.30)	$ (0.36)
Weighted average common shares outstanding — basic and diluted	37,800,960	38,952,131
Other comprehensive loss:		
Unrealized (loss) gain on short-term investments	$ (24)	$ 1
Comprehensive loss	$ (11,234)	$ (14,107)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SCPHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)
(Unaudited)

	COMMON STOCK SHARES	COMMON STOCK AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL STOCKHOLDERS' EQUITY
At December 31, 2023	35,968,510	$ 4	$ 318,561	$ (281,346)	$ (1)	$ 37,218
Net loss	—	—	—	(14,108)	—	(14,108)
Issuance of common stock upon exercise of stock options	32,754	—	181	—	—	181
Vesting of restricted stock	53,145	—	(166)	—	—	(166)
Stock-based compensation	—	—	1,440	—	—	1,440
Unrealized gain on short-term investments	—	—	—	—	1	1
At March 31, 2024	36,054,409	$ 4	$ 320,016	$ (295,454)	$ —	$ 24,566
At December 31, 2022	34,257,916	$ 3	$ 298,934	$ (226,536)	$ 32	$ 72,433
Net loss	—	—	—	(11,210)	—	(11,210)
Issuance of common stock under at-the-market offering, net of issuance costs (Note 10)	1,511,157	1	13,627	—	—	13,628
Stock-based compensation	—	—	980	—	—	980
Unrealized loss on short-term investments	—	—	—	—	(24)	(24)
At March 31, 2023	35,769,073	$ 4	$ 313,541	$ (237,746)	$ 8	$ 75,807

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SCPHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2023	2024
Cash flows from operating activities		
Net loss	$ (11,210)	$ (14,108)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	6	6
Amortization expense - right-of-use leased assets - operating	99	45
Accretion on short-term investments	(517)	(120)
Allowance for excess, damaged and obsolete inventory	-	25
Stock-based compensation	980	1,440
Non-cash interest expense	493	616
Fair value adjustment to derivative liability	(1,007)	(3,124)
Changes in operating assets and liabilities		
Accounts receivable	(3,004)	(1,283)
Inventory	(2,390)	(758)
Prepaid expenses and other assets	(261)	422
Accounts payable, accrued expenses and other liabilities	317	(862)
Net cash used in operating activities	(16,494)	(17,701)
Cash flows from investing activities		
Maturities of short-term investments	7,000	29,319
Net cash provided by investing activities	7,000	29,319
Cash flows from financing activities		
Proceeds from at-the-market offering, net	13,704	-
Proceeds from the exercise of vested stock options	-	181
Settlement of restricted stock units for tax withholding obligations	-	(166)
Net cash provided by financing activities	13,704	15
Net increase in cash and cash equivalents	4,210	11,633
Cash and cash equivalents at beginning of period	71,243	46,814
Cash and cash equivalents at end of period	$ 75,453	$ 58,447
Supplemental cash flow information		
Interest paid	$ 1,485	$ 1,469
Taxes paid	$ 69	$ 9
Supplemental disclosure of non-cash activities		
Transfer of issuance costs from other noncurrent assets to equity	$ 76	$ -

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SCPHARMACEUTICALS INC.

Notes to Unaudited Condensed Consolidated Financial Statements

1. Description of Business and Basis of Presentation

Description of Business

scPharmaceuticals LLC was formed as a limited liability company under the laws of the State of Delaware on February 19, 2013. On March 24, 2014, scPharmaceuticals LLC was converted to a Delaware corporation and changed its name to scPharmaceuticals Inc. (“the Company”). The Company is a pharmaceutical company focused on developing and commercializing products that have the potential to optimize the delivery of infused therapies, advance patient care and reduce healthcare costs. The Company’s strategy is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous (“IV”) delivery. The Company’s headquarters and primary place of business is Burlington, Massachusetts.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) for interim financial information and have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary, scPharmaceuticals Securities Corporation. Certain information and disclosures normally included in financial statements in accordance with U.S. GAAP have been condensed or omitted. Accordingly, these condensed consolidated financial statements should be read in conjunction with the Company’s audited financial statements and related notes for the year ended December 31, 2023 included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 13, 2024. The Company has determined that it operates in one segment.

The accompanying condensed consolidated balance sheet as of March 31, 2024, the condensed consolidated statements of operations and comprehensive loss and stockholders’ equity for the three months ended March 31, 2023 and 2024 and condensed consolidated statements of cash flows for the three months ended March 31, 2023 and 2024 are unaudited. The unaudited condensed consolidated financial statements have been prepared on a basis consistent with that used to prepare the Company’s audited annual financial statements and include, in the opinion of management, adjustments, consisting of normal recurring items, necessary for the fair statement of the condensed consolidated financial statements. The operating results for the three months ended March 31, 2024 are not necessarily indicative of the results expected for the full year ending December 31, 2024.

Liquidity and Going Concern

As of March 31, 2024, the Company had an accumulated deficit of approximately $295.5 million and cash and cash equivalents of $58.4 million. Management expects to continue to incur operating losses for the foreseeable future.

On October 13, 2022 (the “Closing Date”), the Company entered into a Credit Agreement and Guaranty (the "Oaktree Agreement") with, among others, the lenders from time to time party thereto (the "Lenders") and Oaktree Fund Administration, LLC, in its capacity as administrative agent for the Lenders (Note 9).

Historically, the Company has financed its operations to date from proceeds from the sale of common stock, preferred stock and the incurrence of debt. The Company plans to continue to fund its operations through cash and cash equivalents on hand, as well as through future equity offerings, including access to funds pursuant to an at-the-market offering program with Cowen and Company, LLC (Note 10), debt financings, including proceeds available from the Oaktree Agreement pursuant to reaching certain revenue milestones, and other third-party funding. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. Even if the Company raises additional capital, it may also be required to modify, delay or abandon some of its plans which could have a material adverse effect on the Company’s business, operating results and financial condition and the Company’s ability to achieve its intended business objectives. Any of these actions could materially harm the Company’s business, results of operations and future prospects.

Based on the Company’s current operating plan, there is substantial doubt about the Company’s ability to continue as a going concern for a period of one year following the date that these condensed consolidated financial statements are issued. The condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which

contemplates the realization of assets and settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates 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 expenses during the reported periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consists of bank deposits and money market accounts with financial institutions. Cash equivalents are carried at cost which approximates fair value due to their short-term nature and which the Company believes do not have a material exposure to credit risk. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. The Company's cash and cash equivalent accounts, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts.

Accounts Receivable

Accounts receivable are recorded net of any estimated expected credit losses. The Company's measurement of expected credit losses is based on relevant information about past events, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. The Company does not currently have a material credit loss allowance for uncollectible trade receivables.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company has adopted an investment policy that limits the amounts the Company may invest in any one type of investment and requires all investments held by the Company to hold a minimum rating, thereby reducing credit risk exposure.

Customer and Supplier Concentration

The Company has a limited number of specialty pharmacy customers and distributors. As of December 31, 2023 and March 31, 2024, three customers represented 99% and three customers represented 99% of accounts receivable, respectively. For the three months ended March 31, 2023 and March 31, 2024, one customer represented 92% and three customers represented 99% of revenue, respectively.

The Company depends on suppliers for raw materials, active pharmaceutical ingredients ("API"), and other components that are subject to stringent FDA requirements. Some of these materials may only be available from one or a limited number of sources. Establishing additional or replacement suppliers may take a substantial period of time, as suppliers must be approved by the FDA. If the Company is unable to secure, on a timely basis, sufficient quantities of the materials it depends on to manufacture its products, it could have a materially adverse effect on the Company's business, financial condition and results of operations.

Investments

The Company invests excess cash balances in available-for-sale debt securities. The Company determines the appropriate classification of these securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company reports available-for-sale investments at fair value at each balance sheet date and includes any unrealized gains and losses in accumulated other comprehensive income (loss), a component of stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in other income. If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate

the extent to which the decline is “other than temporary,” including the intention to sell and, if so, marks the investment to market through a charge to the Company’s consolidated statements of operations and comprehensive loss.

Inventory

Inventory is stated at the lower of cost and net realizable value and consists of raw materials, work-in-process and finished goods. The Company began capitalizing inventory costs following U.S. Food and Drug Administration ("FDA") approval of FUROSCIX on October 7, 2022. Inventory is sold on a first in, first out ("FIFO") basis. The Company periodically reviews inventory for expiry and obsolescence and writes it down accordingly, if necessary. Prior to FDA approval of FUROSCIX, the Company expensed all inventory-related costs, including that used for clinical development, to research and development ("R&D") costs in the period incurred.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use (“ROU”) lease assets, current portion of lease obligations, and long-term lease obligations on the Company’s balance sheets.

ROU lease assets represent the Company’s right to use an underlying asset for the lease term and lease obligations represent the Company’s obligation to make lease payments arising from the lease. Operating ROU lease assets and obligations are recognized at the commencement date based on the present value of lease payments over the lease term. As most of the Company’s leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The ROU lease asset excludes lease incentives. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Debt Issuance Costs

Debt issuance costs are amortized to interest expense using the effective interest rate method over the term of the debt. Debt issuance costs paid to the lender and third parties are reflected as a discount to the debt in the consolidated balance sheets.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customer (“Topic 606”), the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied. The Company has identified one performance obligation, the delivery of FUROSCIX to its customers. The Company has not incurred any incremental costs associated with obtaining contracts with customers. The Company’s revenues consist solely of the sale of FUROSCIX to customers in the United States.

Product Net Sales

FUROSCIX was approved by the FDA on October 7, 2022. The Company launched sales of FUROSCIX in the first quarter of 2023 and its customers consist of specialty pharmacies (“SPs”) and specialty distributors ("SDs"). The Company recognizes revenue from product sales at a point in time, typically upon receipt of product at the SPs and SDs, the date at which the rights, title, interest and risk of loss are transferred. Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration that result from (a) sales discounts, (b) rebates (c) co-pay assistance, and (d) product returns. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves for variable consideration are reflected as either as a reduction to the related account receivable or as an accrued liability, depending on how the consideration is settled. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration

ultimately received may differ from the Company's estimates. If actual results vary from its estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Sales Discounts: Sales discounts are agreed-upon discounts, from negotiated contracts, taken directly off the Company's sales invoices. Sales discounts are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowance for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit, TRICARE program and contractual rebates with commercial payers. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. The Company's estimates for expected utilization of rebates are based on utilization data received from the SPs since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued at the time of product sale to SPs based on estimated patient participation and average co-pay benefit to be paid per a claim. The Company's estimated amounts are compared to actual program participation and co-pay amounts paid using data provided by third-party administrators. If actual amounts differ from the original estimates the assumptions being applied are updated and adjustment for prior period accruals will be adjusted in the current period.

Product Returns: Consistent with industry practice, the Company offers SPs and SDs limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SPs and has the ability to control the amount of product that is sold to the SPs, it is able to make a reasonable estimate of future potential product returns based on this on-hand channel inventory data and sell-through data obtained from the SPs. Currently, sales to SDs are limited and there is no access to on-hand channel inventory or sell through data. As these arrangements mature, the Company will utilize any data that they can provide as part of this analysis. In arriving at its estimate, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

Research and Development Costs

Research and development costs are expensed as incurred. Nonrefundable advance payments, if any, for goods or services used in research and development are initially recorded as an asset and then recognized as an expense as the related goods are delivered or services are performed. Research and development expenses include contract services, consulting, salaries, materials and supplies and overhead.

Income Taxes

The Company accounts for income taxes in accordance with the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") 740, *Income Taxes.* Deferred tax assets and liabilities are recorded to reflect the impact of temporary differences between amounts of assets and liabilities for financial reporting purposes and such amounts as measured under enacted tax laws. A valuation allowance is required to offset any net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions. The tax benefits recorded are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is "more likely than not" to be realized following resolution of any uncertainty related to the tax benefit, assuming that the matter in question will be raised by the tax authorities. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense. At March 31, 2024, the Company had no such accruals.

As part of the Tax Cuts and Jobs Act of 2017 ("TCJA"), beginning with the Company's fiscal year ended December 31, 2022, the Company is required to capitalize research and development expenses, as defined under section 174 of the Internal Revenue Code of 1986, as amended. For expenses that are incurred for research and development in the United States, the amounts will be amortized over 5 years, and expenses that are incurred for research and experimentation outside the United States will be amortized over 15 years.

3. Net Loss per Share

Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share of common stock (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2023	2024
Net loss	$ (11,210)	$ (14,108)
Weighted-average shares used in computing net loss per share	37,800,960	38,952,131
Net loss per share, basic and diluted	$ (0.30)	$ (0.36)

Basic and diluted weighted average shares of common stock outstanding for the three months ended March 31, 2024 include the weighted average effect of outstanding pre-funded warrants for the purchase of shares of common stock for which the remaining unfunded exercise price is $0.001 per share.

The Company's potentially dilutive securities, which include unexercised stock options outstanding, unexercised warrants and unvested restricted stock units, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect.

	Three Months Ended March 31,	
	2023	2024
Stock options to purchase common stock	4,640,089	5,439,202
Warrants to purchase common stock	516,345	516,345
Unvested restricted stock units	333,125	721,809
Total	5,489,559	6,677,356

4. Investments

Cash in excess of the Company's immediate requirements is invested in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

A summary of the Company's available-for-sale classified investments as of December 31, 2023 the following (in thousands):

	At December 31, 2023			
Investments - Current:	**Cost Basis**	**Accumulated Unrealized Gains**	**Accumulated Unrealized Losses**	**Fair Value**
United States Treasury securities	$ 13,967	$ 2	$ -	$ 13,969
Commercial paper	$ 9,427	$ -	$ (2)	9,425
Corporate bonds	3,815	-	-	3,815
United States Government Agency securities	1,991	-	(1)	1,990
Total	$ 29,200	$ 2	$ (3)	$ 29,199

The Company did not have any investments as of March 31, 2024.

5. Inventory

The Company's inventory balance consists of the following (in thousands):

	December 31, 2023	March 31, 2024
Raw materials	$ 4,256	$ 4,139
Work-in-process	4,188	3,985
Finished goods	396	1,448
	$ 8,840	$ 9,572

Inventory is stated at the lower of cost and net realizable value and consists of raw materials, work-in-process and finished goods. The Company began capitalizing inventory costs following FDA approval of FUROSCIX in October 2022 and has not recorded any significant inventory write-downs since that time. At December 31, 2023 and March 31, 2024, the Company has an allowance for excess, damaged and obsolete inventory in the amount of $0 and $25,000, respectively. The Company currently uses a limited number of third-party contract manufacturing organizations ("CMOs") to produce its inventory.

6. Property and Equipment

Purchased property and equipment consist of the following (dollars in thousands):

	ESTIMATED USEFUL LIFE	December 31, 2023	March 31, 2024
Office equipment	5 years	$ 31	$ 31
Office furniture	7 years	64	64
Computer equipment	3 years	15	15
Leasehold improvements	Life of lease	9	9
		119	119
Less: Accumulated depreciation		(61)	(67)
Property and equipment, net		$ 58	$ 52

Depreciation expense for the three months ended March 31, 2023 and 2024 was $6,000 and $6,000, respectively.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2023	March 31, 2024
Employee compensation and related costs	$ 4,375	$ 2,723
Sales allowances and related costs	1,418	1,733
Contract research and development	1,202	1,696
Consulting and professional service fees	945	1,625
Manufacturing costs	434	822
Royalty	249	308
Financing costs	-	125
Inventory in transit	150	-
Other	128	174
Total accrued expenses	$ 8,901	$ 9,206

8. Fair Value of Financial Instruments

FASB ASC Topic 820, *Fair Value Measurements and Disclosures ("ASC 820"),* provides a fair value hierarchy, which classifies fair value measurements based on the inputs used in measuring fair value. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and observable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining

fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying values of the Company's cash and restricted cash, prepaid expenses and deposits approximate their fair values due to their short-term nature. The carrying value of the Company's loan payable is considered a reasonable estimate of fair value because the Company's interest rate is near current market rates for instruments with similar characteristics.

The following tables summarize the Company's assets that are measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	As of December 31, 2023			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 44,202	$ 44,202	$ —	$ —
Total cash equivalents	44,202	44,202	—	—
United States Treasury securities	13,969	13,969	-	—
Commercial paper	9,425	—	9,425	—
Corporate bonds	3,815	—	3,815	—
United States Government Agency securities	1,990	—	1,990	—
Investments	29,199	13,969	15,230	—
Total	$ 73,401	$ 58,171	$ 15,230	$ —
Liabilities:				
Derivative liability	$ 3,857	$ —	$ —	$ 3,857
Total	$ 3,857	$ —	$ —	$ 3,857

	As of March 31, 2024			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 57,054	$ 57,054	$ —	$ —
Total	57,054	57,054	—	—
Liabilities:				
Derivative liability	$ 733	$ —	$ —	$ 733
Total	$ 733	$ —	$ —	$ 733

Changes in the fair value of the Company's Level 3 derivative liability for the three months ended March 31, 2024 are as follows (in thousands):

At December 31, 2023	$ 3,857
Change in fair value of derivative liability	(3,124)
At March 31, 2024	$ 733

9. Debt

The following table presents the carrying value of the Company's debt balance as of December 31, 2023 and March 31, 2024 (in thousands):

	December 31, 2023	March 31, 2024
Face value	$ 50,000	$ 50,000
Less: discount	(11,189)	(10,615)
Total	38,811	39,385
Less: current portion	—	—
Long-term portion	$ 38,811	$ 39,385

Oaktree Agreement

On October 13, 2022 (“Closing Date”), the Company entered into a Credit Agreement and Guaranty (the “Oaktree Agreement”) with Oaktree Fund Administration, LLC as administrative agent, and the lenders party thereto (collectively “Oaktree”) to borrow up to $100.0 million in three tranches with a maturity date of October 13, 2027.

The first tranche of $50.0 million was drawn immediately, with $9.8 million of the proceeds used to repay in full the outstanding loan and fees under the 2019 Loan Agreement with SLR Investment Corp. and Silicon Valley Bank and $2.7 million in fees and expenses incurred in connection with the financing, leaving $37.5 million in available proceeds from the first tranche. The ability to draw the remaining $50.0 million is contingent upon reaching certain net sales revenue milestone targets prior to September 30, 2024 and December 31, 2024, respectively.

The term loan initially bears interest at the three-month term Secured Overnight Financing Rate (“SOFR”) plus an applicable margin of 8.75% (with a SOFR floor of 1.00% and a 3.00% cap). Once FUROSCIX achieves at least $100.0 million in trailing 12-month net sales, the applicable margin will step down to 8.25%. The Company is required to make quarterly interest-only payments until the third anniversary of the Closing Date, after which the Company is required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity.

In connection with entering into the Oaktree Agreement, the Company granted warrants to Oaktree to purchase up to an aggregate of 516,345 shares of the Company’s common stock at an exercise price of $5.40 per share. Upon inception, the Company evaluated the warrants and determined that they met all the requirements for equity classification under ASC Topic 815 *Derivatives and Hedging* ("ASC 815"). This transaction was accounted for as a detachable warrant at its fair value, using the relative fair value method, which is based on a number of unobservable inputs and is recorded as an increase to additional paid-in-capital on the consolidated statement of stockholder’s equity. The relative fair value of the warrants, $2.0 million, was reflected as a discount to the term loan and will be amortized over the life of the term loan using the effective interest method. The Company used the Black-Scholes option pricing model to determine the fair value of the warrants. Assumptions included the fair market value per share of common stock on the valuation date of $5.50, the exercise price per warrant equal to $5.40, the expected volatility of 77%, the risk-free interest rate of 4.11%, the contractual term of 7 years and the absence of a dividend. The warrants are immediately exercisable and the exercise period expires on October 13, 2029.

The Company identified a number of embedded derivatives that require bifurcation from the term loan and that were separately accounted for in the consolidated financial statements as one compound derivative liability. Certain of these embedded features include contingent interest rate reset upon event of default, contingent put options, including change in control and going concern provisions, and additional costs as a result of changes in law. These embedded features met the criteria requiring these to be bifurcated because they were not clearly and closely related to the host instrument in accordance with ASC 815-15 and the derivative liability is presented separately in the condensed consolidated balance sheet as of March 31, 2024. The fair value of the embedded derivative liabilities associated with the term loan was estimated using a hybrid between the discounted cash flow and Monte Carlo simulation methods. This involves significant Level 3 inputs and assumptions including an estimated probability and timing of a change in control. The Company re-evaluates this assessment each reporting period and any changes in estimated fair value is recorded as other income (expense). The initial recognition of the embedded derivative liability upon issuance of the Term Loan was $8.9 million. At March 31, 2024, the fair value of the embedded derivative liability was $733,000.

In connection with the issuance of the term loan, the Company recorded a debt discount of $13.6 million, inclusive of debt issuance costs, the derivative liability and the relative fair value of the warrants. The discount will be amortized over the life of the term loan using the effective interest method. For the three months ended March 31, 2023 and 2024, the Company recorded $459,000 and $574,000 related to the amortization of the debt discount associated with the Oaktree Agreement, respectively.

Prepayments of the term loan, in whole or in part, will be subject to a prepayment fee which declines each year until the fourth anniversary date of the Closing Date, after which no prepayment fee is required. The Company is also required to pay an exit fee

upon any payment or prepayment equal to 2.0% of the aggregate principal amount of the loans funded under the Oaktree Agreement. The Company recorded an additional debt discount of $1.0 million related to the exit fee. For the three months ended March 31, 2023 and 2024, the Company recorded $34,000 and $42,000 related to the amortization of the exit fee associated with the Oaktree Agreement, respectively.

The Oaktree Agreement contains customary representations, warranties and affirmative and negative covenants, including financial covenants requiring the Company to (i) maintain unrestricted cash of at least $15.0 million at all times, increasing to $20.0 million upon accessing the second tranche of the term loan and (ii) meet minimum quarterly net sales revenue targets.

In addition, the Oaktree Agreement contains customary events of default that could cause the Company's indebtedness to become immediately due and payable. The lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect as defined under the Oaktree Agreement. Upon the occurrence and for the duration of an event of default, an additional interest rate equal to 2.0% per annum could apply to all obligations owed under the Oaktree Agreement. Among other loan covenant requirements, the Oaktree Agreement also requires the Company to provide an audit opinion of its annual financial statements not subject to any "going concern" or like qualification or exception.

As of March 31, 2024, future principal payments due under the Oaktree Agreement were as follows (in thousands):

Year ended:		
December 31, 2024	$	—
December 31, 2025		2,500
December 31, 2026		10,000
December 31, 2027		37,500
Total minimum principal payments		50,000
Less unamortized discount		(10,615)
Carrying value of term loan	$	39,385

10. Stockholders' Equity

2021 At-the-Market Issuance Sales Agreement

On March 23, 2021, the Company entered into an Open Market Sale Agreement (the "2021 ATM Agreement") with Cowen and Company, LLC ("Cowen") with respect to an at-the-market offering program under which the Company could offer and sell shares of its common stock (the "2021 ATM Shares"), having an aggregate offering price of up to $50.0 million through Cowen as its sales agent. The Company agreed to pay Cowen a commission up to 3.0% of the gross sales proceeds of such 2021 ATM Shares. On March 13, 2024, the Company amended and restated the 2021 ATM Agreement and entered into a new $50.0 million Open Market Sales Agreement with Cowen (the "2024 ATM Agreement"). As of March 13, 2024, the Company had sold a total of 1,726,043 2021 ATM Shares under the 2021 ATM Program at a weighted average gross selling price of $9.01 per share for net proceeds of $15.2 million.

2024 At-the-Market Issuance Sales Agreement

Pursuant to the 2024 ATM Agreement, the Company could offer and sell shares of its common stock (the "2024 ATM Shares"), having an aggregate offering price of up to $50.0 million through Cowen as its sales agent (the "2024 ATM Program"). The offering and sale of the 2024 ATM Shares will be made pursuant to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC on March 22, 2024. There were no shares issued under the 2024 ATM Program as of March 31, 2024.

11. Stock-Based Compensation

Stock Options

The Company's 2017 Stock Option and Incentive Plan (the "2017 Stock Plan") became effective in November 2017, upon the closing of the Company's initial public offering and will expire in October 2027. Under the 2017 Stock Plan, the Company may

grant incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units (“RSUs”) and other stock-based awards. The Company’s 2014 Stock Incentive Plan (the “2014 Stock Plan”) was terminated in November 2017 effective upon the completion of the Company’s initial public offering and no further options will be granted under the 2014 Stock Plan. At March 31, 2024, there were 571,095 options outstanding under the 2014 Stock Plan.

As of March 31, 2024, there were 8,779,641 shares of the Company’s common stock authorized for issuance under the 2017 Stock Plan, including 366,823 options that have been forfeited from the 2014 Stock Plan.

At March 31, 2024, there were 3,298,122 options available for issuance under the 2017 Stock Plan, 4,693,655 options outstanding and 721,809 RSUs outstanding.

On February 1, 2023, the Board of Directors of the Company adopted the 2023 Employment Inducement Award Plan (the "Inducement Plan") and, subject to the adjustment provisions of the Inducement Plan, reserved 500,000 shares of the Company’s common stock for issuance pursuant to equity awards granted under the Inducement Plan. At March 31, 2024, there were 325,548 options available for issuance under the Inducement Plan, and 174,452 options outstanding.

Awards granted under the 2017 Stock Plan and the Inducement Plan have a term of ten years. Vesting of awards under the 2017 Stock Plan and Inducement Plan is determined by the board of directors, but is generally over one to four-year terms.

The fair value of options at date of grant was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2023	2024
Risk-free interest rate	3.40% - 4.17%	3.78% - 4.14%
Expected dividend yield	0%	0%
Expected life	5.6-7.0 years	5.7-6.7 years
Expected volatility	77%-85%	78%-79%
Weighted-average grant date fair value	$ 4.60	$ 4.06

The following table summarizes information about stock option activity during the three months ended March 31, 2024 (in thousands, except share and per share data):

	NUMBER OF SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM	AGGREGATE INTRINSIC VALUE
Outstanding, December 31, 2023	4,681,326	$ 6.09		
Granted	864,827	5.76		
Exercised	(8,411)	4.70		
Forfeited	(98,540)	6.81		
Outstanding, March 31, 2024	5,439,202	$ 6.03	7.23	$ 1,353
Vested and exercisable, March 31, 2024	3,108,416	$ 5.88	5.94	$ 1,158
Vested and expected to vest, March 31, 2024	4,911,795	$ 6.04	7.03	$ 1,312

24,343 options were exercised on December 29, 2023 and the shares settled on January 2, 2024. The share issuance has been recognized on the Company's Condensed Consolidated Statements of Stockholders' Equity for the quarter ending March 31, 2024.

The following table summarizes information about RSU activity during the three months ended March 31, 2024:

	RSUs	AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE)
RSUs outstanding, December 31, 2023	368,411	$ 6.03
Granted	442,407	4.09
Released	(79,108)	6.14
Forfeited	(9,901)	5.95
RSUs outstanding at March 31, 2024	721,809	$ 4.83

Unrecognized compensation expense related to unvested options as of March 31, 2024 was $6.6 million and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 2.7 years. Unrecognized compensation expense related to unvested RSUs as of March 31, 2024 was $2.2 million and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 3.3 years.

Employee Stock Purchase Plan

In October 2017, the board of directors approved the 2017 Employee Stock Purchase Plan (the "ESPP") which became effective in November 2017, upon the closing of the Company's IPO. As part of the ESPP, eligible employees may acquire an ownership interest in the Company by purchasing common stock, at a discount, through payroll deductions. Eligible employees who elected to participate were able to participate in the ESPP beginning September 1, 2021.

As of March 31, 2024, there were 1,462,566 shares of common stock available for issuance under the ESPP.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2024 (in thousands):

	Three Months Ended March 31, 2023	2024
Research and development	$ 340	$ 365
General and administrative	640	1,075
Total	$ 980	$ 1,440

12. Commitments and Contingencies

Operating Leases

The Company leases office facilities and equipment under long-term, non-cancelable operating lease agreements. The leases expire at various dates through 2029 and do not include renewal options.

Certain leases provide for increases in future minimum annual rental payments as defined in the lease agreements. The leases generally also include real estate taxes and common area maintenance charges in the annual rental payments.

Short-term leases are leases having a term of twelve months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases.

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities as of March 31, 2024 (in thousands):

Year ended:		
December 31, 2024	$	255
December 31, 2025		341
December 31, 2026		349
December 31, 2027		358
December 31, 2028		367
Thereafter		249
Total minimum lease payments		1,919
Less imputed interest		(502)
Total	$	1,417

	Three Months Ended March 31,	
	2023	2024
Lease cost:		
Operating lease cost	$ 112	$ 89
Short-term lease cost	9	10
Total lease cost	$ 121	$ 99
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 163	$ 84
Operating cash flows from operating leases	$ (50)	$ 4
Weighted-average remaining lease term - operating leases	0.7 years	5.4 years
Weighted-average discount rate - operating leases	10.1%	11.7%

Research and Development Agreements

As part of the Company's research and development efforts, the Company enters into research and development agreements with certain companies. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company. Some of these agreements also contain provisions which require the Company to make payments for exclusivity in the development of products in the area of loop diuretics.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report") and our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023 (the "Annual Report") filed with the Securities and Exchange Commission (the "SEC") on March 13, 2024. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those factors set forth in the "Risk Factors" section in our Annual Report and in this Quarterly Report, our actual results could differ materially from the results described in or implied by, the forward-looking statements contained in the following discussion and analysis.

OVERVIEW

We are a pharmaceutical company focused on developing and commercializing products that have the potential to optimize the delivery of infused therapies, advance patient care and reduce healthcare costs. Our strategy is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous, or IV, delivery. By moving delivery away from the high-cost healthcare settings typically required for IV administration, we believe our technology has the potential to reduce overall healthcare costs and advance the quality and convenience of care. Our approved product, FUROSCIX, consists of our novel formulation of furosemide delivered via West Pharmaceutical Services, Inc.'s, or West's, on-body infusor, which delivers an 80 mg/10 mL dose over 5 hours. On October 10, 2022, we announced that the U.S. Food and Drug Administration, or FDA, approved FUROSCIX for the treatment of congestion due to fluid overload in adults with New York Heart Association, or NYHA, Class II/III chronic heart failure. FUROSCIX is the first and only FDA-approved subcutaneous loop diuretic that delivers IV equivalent diuresis at home. IV equivalence was established in a clinical study in which FUROSCIX demonstrated 99.6% bioavailability (90% CI: 94.8%-104.8%) and 8-hour urine output of 2.7 L which was similar to subjects receiving intravenous furosemide. The commercial launch of FUROSCIX for congestion in patients with chronic heart failure commenced in the first quarter of 2023.

In the third quarter of 2023, we received positive feedback from the FDA on key long-term growth initiatives. The first was for the potential expansion of the FUROSCIX indication to include NYHA Class IV heart failure patients. Based on the feedback, we filed for NYHA Class IV indication expansion in early October. The second was Type C meeting feedback pertaining to the development of an 80mg/1mL auto-injector intended to provide an additional option to the on-body infusor for treatment of congestion due to fluid overload in eligible adult patients who do not require hospitalization. We believe that the development of an auto-injector, if successfully developed and approved, has the potential to significantly reduce manufacturing costs compared to the current on-body infusor and confer certain environmental advantages. We have submitted an investigational new drug application (IND), and initiated a pharmacokinetic/pharmacodynamic (PK/PD) study in April of 2024 and plan to submit a supplemental new drug application (sNDA) in the fourth quarter of 2024. Finally, we received feedback on the potential expansion of the FUROSCIX indication to include treatment of edema due to fluid overload in patients with chronic kidney disease (CKD). The agency confirmed that no additional clinical studies are needed to expand the indication to CKD, provided that we can demonstrate an adequate PK and pharmocodynamic bridge to the listed drug, furosemide injection, 10mg/mL. We submitted a sNDA in early May of 2024 seeking to expand the indication of FUROSCIX to include the treatment of edema due to fluid overload in adult patients with CKD. The anticipated Prescription Drug User Fee Act (PDUFA) date for edema in patients with CKD is the first quarter of 2025.

We estimate that there is a $12.5 billion total addressable market opportunity for FUROSCIX in the United States including both chronic heart failure and CKD. We believe FUROSCIX will allow eligible patients with chronic heart failure and, if approved, chronic kidney disease with worsening congestion due to fluid overload, to receive IV-strength diuresis outside the high-cost hospital setting. At a price of approximately $898 per dose, we estimate the average cost of treatment with FUROSCIX for each episode to be approximately $4,490, which can be significantly lower than the cost of a single hospitalization. Prevention of hospital admission and reduced readmission rates would result in reducing days patients spend in the hospital each year. By decreasing the number of admissions and readmissions to hospitals, we believe we can drive significant cost savings to payers and hospitals and improve patients' quality of life through outpatient management of their fluid overload.

We have secured positive coverage and a preferred formulary decision for FUROSCIX by a top five national commercial health plan, effective June 1, 2023, as well as national Medicaid coverage of FUROSCIX, effective July 1, 2023. In addition, in late October 2023, we reached an agreement with one of the largest closed integrated delivery networks (IDNs) in the United States, providing unrestricted access to FUROSCIX, without prior authorization, to over 8 million lives, at a fixed co-pay of $75 or less per prescription. As of November 1, 2023, FUROSCIX is on formulary as a preferred brand with one of the largest government retiree payer formularies, increasing the number of lives with preferred access to FUROSCIX by an additional 1.1 million lives. As of March 31, 2024, there have been approximately 47,000 total FUROSCIX doses written by around 2,200 unique prescribers, and of these, approximately 24,000 FUROSCIX doses had been filled and there were approximately 6,800 doses payer cleared or pending.

In the third quarter of 2023, we also announced the issuance of U.S. patents covering concentrated formulations of furosemide. We have completed initial solubility and stability studies on multiple formulations described in the patent properties, have identified potential product candidates, and commenced Investigational New Drug Application enabling studies.

We have funded our operations from inception through March 31, 2024 primarily through the sale of shares of our common stock and incurrence of debt and, prior to that, through the private placement of our preferred stock.

As of March 31, 2024, we had an accumulated deficit of $295.5 million. We expect to continue to incur net losses for the foreseeable future as we support the commercialization efforts of FUROSCIX in the United States, including expanding our sales and marketing organization, continuing research and development efforts, engaging in scale-up manufacturing and seeking regulatory approval for new product candidates and enhancements. Our financial results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of FUROSCIX, the scope and progress of our research and development efforts and timing of certain expenses.

Going Concern

As of March 31, 2024, we had an accumulated deficit of approximately $295.5 million and cash and cash equivalents of $58.4 million. Based on our existing cash and cash equivalents, we do not believe that we have sufficient cash on hand to support current operations and service our debt obligations for at least one year from the date of issuance of the condensed consolidated financial statements appearing in this Quarterly Report on Form 10-Q. This condition raises substantial doubt about the ability of the Company to continue as a going concern as of the filing date of this Quarterly Report and for one year from the issuance of the condensed consolidated financial statements. Historically, we have financed our operations to date from proceeds from the sale of common stock, preferred stock and the incurrence of debt. We plan to continue to fund our operations through cash and cash equivalents on hand, as well as through future equity offerings, including access to funds pursuant to an at-the-market offering program with Cowen and Company, LLC, debt financings, including proceeds available from the Oaktree Agreement pursuant to reaching certain revenue milestones, and other third-party funding. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Even if we raise additional capital, it may also be required to modify, delay or abandon some of its plans which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve its intended business objectives. Any of these actions could materially harm our business, results of operations and future prospects.

COMPONENTS OF OUR RESULTS OF OPERATIONS

Product Revenues

Product revenues, net, consist of net sales of FUROSCIX. We initiated shipments of FUROSCIX to customers in the United States, which include specialty pharmacies, in February 2023. We recognize revenue for product received by our customers net of allowances for customer discounts, service fees, estimated returns and rebates.

Cost of Product Revenues

Cost of product revenues include costs related to the manufacturing of FUROSCIX, including third party manufacturing costs, packaging and freight, in addition to royalty expenses. We began capitalizing inventory upon FDA approval of FUROSCIX. All costs related to inventory for FUROSCIX prior to FDA approval were expensed as incurred and therefore not included in cost of revenues.

Research and Development Expenses

Research and development ("R&D") expenses consist of the cost of engineering, clinical trials, regulatory and medical affairs and quality assurance associated with developing our proprietary technology and product candidates. R&D expenses consist primarily of:

- employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense;
- cost of outside consultants who assist with technology development, regulatory affairs, clinical trials and medical affairs, and quality assurance;
- cost of clinical trial activities performed by third parties;
- cost of pre-approval pharmaceutical batch manufacturing; and
- cost of facilities and supplies used for internal research and development and clinical activities.

We expense R&D costs as incurred. Given the emphasis to date on our approved product FUROSCIX, our R&D expenses have not been allocated on a program-specific basis. In the future, we expect R&D expenses to increase in absolute dollars as we continue to develop new products and enhance existing products and technologies. We anticipate that our expenses will increase significantly as we:

- continue to advance our pipeline programs beyond FUROSCIX;
- continue our current research and development activity;
- seek to identify additional research programs and additional product candidates;
- initiate preclinical testing and clinical trials for any product candidates we identify and develop, maintain, expand and protect our intellectual property portfolio; and
- hire additional research, clinical and scientific personnel.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses consist of employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense for personnel in executive, finance, commercial, field sales, human resources, facility operations and administrative functions. Other SG&A expenses include promotional activities, marketing, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and allocated facilities-related expenses.

We anticipate that our SG&A expenses will increase as we continue to expand our corporate and commercial infrastructure to support the commercialization activities of FUROSCIX in the United States.

Results of Operations

Comparison of Three Months Ended March 31, 2023 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2024 (in thousands):

	Three Months Ended March 31,		Increase
	2023	2024	(Decrease)
Product revenues, net	$ 2,063	$ 6,102	$ 4,039
Operating expenses:			
Cost of product revenues	605	1,785	1,180
Research and development	2,116	2,726	610
Selling, general and administrative	10,896	17,447	6,551
Total operating expenses	13,617	21,958	8,341
Loss from operations	(11,554)	(15,856)	4,302
Other income	990	2,972	1,982
Interest income	1,315	877	(438)
Interest expense	(1,961)	(2,101)	140
Net loss	$ (11,210)	$ (14,108)	$ 2,898

Product revenues. Product revenues were $6.1 million for the three months ended March 31, 2024, compared to $2.1 million for the three months ended March 31, 2023. The increase of $4.0 million was due to a full quarter of sales of FUROSCIX in 2024 versus a 5 week period in 2023, as well as an increase in demand of FUROSCIX further into the commercial launch.

Cost of product revenues. Cost of product revenues were $1.8 million for the three months ended March 31, 2024, compared to $0.6 million for the three months ended March 31, 2023. Similarly to product revenues, the increase of $1.2 million was due to a full quarter of sales of FUROSCIX in 2024 versus a 5 week period in 2023, as well as an increase in demand of FUROSCIX further into the commercial launch, and related manufacturing costs.

Research and development expenses. R&D expenses were $2.7 million for the three months ended March 31, 2024, compared to $2.1 million for the three months ended March 31, 2023. The increase of $0.6 million was primarily attributable to a $0.4 million

increase in device development costs, a $0.1 million increase in employee-related costs and a $0.1 million increase in clinical study costs.

Selling, general and administrative expenses. SG&A expenses were $17.4 million for the three months ended March 31, 2024, compared to $10.9 million for the three months ended March 31, 2023. The increase of $6.6 million was primarily attributable to a $3.9 million increase in employee-related costs, a $2.5 million increase in commercial costs and $0.3 million in patient support. The increase was partially offset by a $0.1 million decrease in directors and officers' insurance.

Other income. Other income was $3.0 million for the three months ended March 31, 2024, compared to $1.0 million for the three months ended March 31, 2023. The increase in income of $2.0 million was primarily attributable to the fair value adjustment to the derivative liability and foreign exchange gains in the three months ended March 31, 2024, offset by expired financing costs in the three months ended March 31, 2024.

Interest income. Interest income was $0.9 million for the three months ended March 31, 2024, compared to $1.3 million for the three months ended March 31, 2023. The decrease of $0.4 million was primarily attributable to lower balances on our financial instruments.

Interest expense. Interest expense was $2.1 million for the three months ended March 31, 2024 compared to $2.0 million for the three months ended March 31, 2023. The increase of $0.1 million was due to amortization of costs associated with the Oaktree Agreement (as defined below).

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through March 31, 2024 primarily through the sale of shares of our common stock, through the private placement of our preferred stock and the incurrence of debt. As of March 31, 2024, we had received net cash proceeds of $92.7 million from our initial public offering; $56.7 million from sales of our preferred stock; $48.6 million from borrowings under our previous term loan with SLR Investment Corp. and Silicon Valley Bank and our current term loan under the Credit Agreement and Guaranty (the “Oaktree Agreement”) with Oaktree Fund Administration, LLC as administrative agent, and the lenders party thereto (collectively “Oaktree”) to borrow up to $100.0 million in three tranches with a maturity date of October 13, 2027, in 2022, net; $13.5 million from sales of convertible notes; $50.2 million from our public offering of common stock in 2020; $46.6 million from our public offering of common stock in 2022; $14.4 million from the sale of common stock in our 2019 at-the-market offering; and $15.2 million from the sale of common stock in our 2021 at-the-market offering. As of March 31, 2024, we had cash and cash equivalents of $58.4 million. Our cash and cash equivalents are maintained at a number of financial institutions in amounts that may exceed federally insured limits.

On March 23, 2021, we entered into an Open Market Sales Agreement (the "2021 ATM Agreement") with Cowen and Company LLC ("Cowen") to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $50.0 million, through an at-the-market equity offering program under which Cowen will act as our sales agent. On March 13, 2024, we amended the 2021 ATM Agreement by issuing a the 2024 ATM Agreement. As of March 13, 2024, we had sold a total of 1,726,043 2021 ATM Shares under the 2021 ATM Program at a weighted average gross selling price of $9.01 per share for net proceeds of $15.2 million.

On March 13, 2024, we amended and restated the 2021 ATM Agreement where we entered into an Open Market Sales Agreement with Cowen with respect to an at-the-market offering program under which we could offer and sell the 2024 ATM Shares, having an aggregate offering price of up to $50.0 million through Cowen as its sales agent (the "2024 ATM Program"). The offering and sale of the 2024 ATM Shares will be made pursuant to the our shelf registration statement of Form S-3, which was declared effective by the SEC on March 22, 2024. There were no shares issued under the 2024 ATM Program as of March 31, 2024. Please see Note 10. Stockholders’ Equity to our condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information.

On October 13, 2022, we entered into the Oaktree Agreement which established a $100.0 million term loan facility, consisting of (i) $50.0 million funded immediately, (ii) $25.0 million that we may borrow in up to two draws on or prior to September 30, 2024 and (iii) $25.0 million that we may borrow on or prior to December 31, 2024. Our ability to draw the remaining $50.0 million is contingent upon reaching certain net sales revenue milestone targets prior to September 30, 2024 and December 31, 2024, respectively. Our contractual commitments under the Oaktree Agreement as of March 31, 2024 consist of an aggregate of $69.9 million in repayment obligations, inclusive of related interest amounts and final fee in the amount of $1.0 million. Please see Note 9. Debt to our condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information.

We expect to incur substantial additional expenditures in the near future to support our ongoing activities and commercialization of FUROSCIX. We expect our costs and expenses to increase in the future as we continue U.S. commercialization of FUROSCIX,

including the expansion of our direct sales force, and as we continue to make substantial expenditures on research and development, including to increase our manufacturing capacity and for conducting clinical trials of our product candidates. Additionally, we continue to incur additional costs as a result of operating as a public company. Based on our current operating plan, there is substantial doubt about our ability to continue as a going concern for a period of one year from the date of this Quarterly Report. We plan to continue to fund our operations through cash and cash equivalents on hand, as well as through future equity offerings, including access to funds pursuant to our at-the-market offering program with Cowen, debt financings, including proceeds available from the Oaktree Agreement pursuant to reaching certain revenue milestones, and other third-party funding. Our future capital requirements will depend on many factors, including without limitation:

- the costs and expenses of expanding our U.S. sales and marketing infrastructure;
- the costs and expenses related to the manufacturing of FUROSCIX and our agreements with third-party manufacturers;
- the degree of success we experience in commercializing FUROSCIX;
- the revenue generated by sales of FUROSCIX and of other product candidates that may be approved;
- the pricing and reimbursement of FUROSCIX and of other product candidates that may be approved;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our product candidates;
- the emergence of competing or complementary technological developments;
- the extent to which FUROSCIX is adopted by the healthcare community;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Additional financing may not be available on a timely basis on terms acceptable to us, or at all. We may raise funds in equity, royalty-based or debt financings or enter into additional credit facilities in order to access funds for our capital needs. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our Company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we raise additional funds through royalty-based financing arrangements, we will likely agree to relinquish rights to potentially valuable future revenue streams and may agree to covenants that restrict our operations or strategic flexibility. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment or expansion of sales and marketing capabilities or other activities necessary to commercialize our products. For example, the trading prices for our and other biopharmaceutical companies' securities have been highly volatile as a result of macroeconomic conditions and developments in our industry. As a result, we may face difficulties raising capital through sales of our securities and any such sales may be on unfavorable terms. Additionally, our ability to raise capital may be further impacted by global macroeconomic conditions including, for example, as a result of international political conflict and/or instability, including due to war or terrorism, supply chain issues and rising inflation and interest rates.

CASH FLOWS

The following table summarizes our sources and uses of cash for each of the periods presented:

	Three Months Ended March 31,	
(in thousands)	**2023**	**2024**
Net cash (used in) provided by:		
Operating activities	$ (16,494)	$ (17,701)
Investing activities	7,000	29,319
Financing activities	13,704	15
Net increase in cash and cash equivalents	$ 4,210	$ 11,633

Net Cash Used in Operating Activities

During the three months ended March 31, 2024, net cash used in operating activities was $17.7 million, consisting primarily of a net loss of $14.1 million, an increase in net operating assets of $2.5 million, and non-cash charges of $1.1 million. The increase in net operating assets is related to accounts receivable and inventory to support the ongoing commercial operations of FUROSCIX. The non-cash charges primarily consisted of depreciation, amortization related to our right-of-use leased assets, stock-based compensation expense, non-cash interest expense related to amortization of debt discount associated with the Oaktree Agreement, the fair value adjustment to the derivative liability and accretion of premium on investments.

During the three months ended March 31, 2023, net cash used in operating activities was $16.5 million, consisting primarily of a net loss of $11.2 million and an increase in net operating assets of $5.3 million. This was offset by non-cash charges of $54,000. The increase in net operating assets is related to accounts receivable and inventory to support the launch of FUROSCIX. The non-cash charges primarily consisted of depreciation, amortization related to our right-of-use leased assets, stock-based compensation expense, non-cash interest expense related to amortization of debt discount associated with the Oaktree Agreement, the fair value adjustment to the derivative liability and accretion of premium on investments.

Net Cash Provided by Investing Activities

During the three months ended March 31, 2024, net cash provided by investing activities was $29.3 million, consisting of maturities of short-term investments.

During the three months ended March 31, 2023, net cash provided by investing activities was $7.0 million, consisting of maturities of short-term investments.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2024, net cash provided by financing activities was $15,000 due to stock option exercises, offset by amounts paid to settle restricted stock unit tax withholding obligations.

During the three months ended March 31, 2023, net cash provided by financing activities was $13.7 million, consisting of proceeds from the 2021 ATM Agreement.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. Our critical accounting policies are more fully described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates" in our Annual Report. There have been no material changes to that information disclosed in our Annual Report during the three months ended March 31, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks related to changes in foreign currency exchange rates and interest rates.

We contract with vendors in foreign countries. As such, we have exposure to adverse changes in exchange rates of foreign currencies, principally the Swiss franc and the Euro, associated with our foreign transactions. We believe this exposure to be immaterial. We currently do not hedge against this exposure to fluctuations in exchange rates.

Our exposure to market risk also relates to interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of March 31, 2024, our aggregate outstanding indebtedness was $50.0 million, which bears interest per annum equal to three-month term SOFR (subject to a 1.00% floor and a 3.00% cap), plus applicable margin of 8.75%. Due to the cap on SOFR in our outstanding indebtedness and the current SOFR rate, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our debt instruments.

We do not believe that inflation has had a material effect on our business. However, if our costs, in particular costs related to manufacture and supply, were to become subject to significant inflationary pressures, it may adversely impact our business, operating results and financial condition.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation of our disclosure controls and procedures as of March 31, 2024, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were not effective at a reasonable assurance level due to the continued material weakness in our internal control over financial reporting as described below and in Item 9A, Controls and Procedures, in our Annual Report which was filed on March 13, 2024.

In light of the identified material weakness, we performed additional analysis and other procedures around the review of the calculation performed by our third-party valuation specialist.

Previously Reported Material Weakness in Internal Control over Financial Reporting

As previously disclosed in Item 9A, Controls and Procedures, on Form 10-K filed March 13, 2024, as of and for the year ended December 31, 2023, we identified a deficiency resulting in a material weakness further described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the preparation of our financial statements our Annual Report on Form 10-K, management identified a material weakness related to the controls, processes and procedures over the fair value accounting associated with the embedded derivative liability in connection with the Oaktree Agreement. Please see Note 9, Debt, to our condensed consolidated financial statements included elsewhere in this Quarterly Report for a description of the Oaktree Agreement. Specifically, the calculation performed by our third-party valuation specialist during the fourth quarter of fiscal 2023 as it relates to fair value accounting for the liability included errors resulting in an overstatement in the fair value of the liability. We made adjustments necessary to properly reflect the fair value of the derivative liability in the financial statements included in our Annual Report . There were no changes to previously released financial results as a result of this material weakness.

Remediation Plan

Management is actively working to remediate the identified material weakness and is committed to remediating the material weakness in a timely manner. Our remediation process is ongoing and includes the following steps, but is not limited to the following:

(a) additional quality control processes implemented by our third-party valuation specialist,

(b) detailed discussions around changes in assumptions used in the valuation and their effect on the valuation, and

(c) more thorough review of sample iterations used in determining the fair value of the derivative.

While the audit committee of our board of directors and senior management are closely monitoring the remediation efforts, until the remediation efforts discussed in this section, including any additional remediation efforts that our senior management identifies as necessary, are complete, tested and determined effective, we will not be able to conclude that the material weakness has been remediated. The material weakness will not be considered remediated until the controls are in place for a period of time and management concludes based on its evaluation that these controls are properly designed and operating effectively.

Changes in Internal Control over Financial Reporting

Other than the material weakness described above, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Information regarding risk factors appears in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2023 (the "Annual Report"), which was filed with the SEC on March 22, 2024. There have been no material changes from the risk factors previously disclosed in our Annual Report except as specified below.

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

As of March 31, 2024, we had an accumulated deficit of approximately $295.5 million and cash and cash equivalents of $58.4 million. Based on our existing cash and cash equivalents, we do not believe we have sufficient cash on hand to support current operations and service our debt obligations for at least one year from the date of issuance of the condensed consolidated financial statements appearing in this Quarterly Report on Form 10-Q. This condition raises substantial doubt about our ability to continue as a going concern for at least one year from the date that our financial statements for the period ended March 31, 2024 are issued. Historically, we have financed our operations to date from proceeds from the sale of common stock, preferred stock and the incurrence of debt. We plan to continue to fund our operations through cash and cash equivalents on hand, as well as through future equity offerings, including access to funds pursuant to an at-the-market offering program with Cowen and Company, LLC, debt financings, including proceeds available from the Oaktree Agreement pursuant to reaching certain revenue milestones, and other third-party funding. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Even if we raise additional capital, we may also be required to modify, delay or abandon some of its plans which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve its intended business objectives. Any of these actions could materially harm our business, results of operations and future prospects. There can be no assurance that we will be able to continue as a going concern and we may be forced to delay, reduce or discontinue our product development programs or commercialization efforts in order to preserve cash.

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

(a)Disclosure in lieu of reporting on a Current Report on Form 8-K.

None.

(b)Material changes to the procedures by which security holders may recommend nominees to the board of directors.

None.

(c)Insider Trading Arrangements and Policies.

During the three months ended March 31, 2024, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of scPharmaceuticals Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on November 21, 2017).
3.2	Amended and Restated By-laws of scPharmaceuticals Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on November 21, 2017).
3.3	Amendment No. 1 to the Amended and Restated By-laws of scPharmaceuticals Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on June 10, 2020).
3.4	Amendment No. 2 to the Amended and Restated By-laws of scPharmaceuticals Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on March 12, 2021).
4.1	Amended and Restated Investors' Rights Agreement among scPharmaceuticals Inc. and certain of its stockholders, dated December 22, 2016 (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on October 23, 2017).
4.2	Form of Warrant, dated October 13, 2022, issued by scPharmaceuticals Inc. to certain lenders, together with a schedule of warrant holders (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on October 14, 2022).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on November 23, 2022).
10.1	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.6 in the Registrant's Annual Report on Form 10-K (File No. 001-38293) filed on March 13, 2024.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, "Financial Statements" of this Quarterly Report on Form 10-Q.
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101*).

* Filed herewith.
** Furnished herewith.

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.

SCPHARMACEUTICALS INC.

Date: May 14, 2024

By: /s/ Rachael Nokes
Rachael Nokes
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, John H. Tucker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2024 of scPharmaceuticals 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 14, 2024

/s/ John H. Tucker
John H. Tucker
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Rachael Nokes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2024 of scPharmaceuticals 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 14, 2024

/s/ Rachael Nokes
Rachael Nokes
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION 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 scPharmaceuticals Inc. (the "Company") for the period ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John H. Tucker, President and Chief Executive Officer (Principal Executive Officer), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2024

/s/ John H. Tucker
John H. Tucker
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION 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 scPharmaceuticals Inc. (the "Company") for the period ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Rachael Nokes, Chief Financial Officer (Principal Financial Officer), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2024

/s/ Rachael Nokes
Rachael Nokes
Chief Financial Officer
(Principal Financial Officer)