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 June 30, 2023

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.)
2400 District Avenue, Suite 310 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 August 9, 2023, the Registrant had 35,857,045 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 label to include NYHA Class IV heart failure patients and timing thereof, 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, cash equivalents and short-term investments and our ability to raise additional capital to fund our operations, 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. 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, 2022, which was filed with the Securities and Exchange Commission on March 22, 2023, 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.

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

	December 31, 2022	June 30, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 71,061	$ 71,350
Short-term investments	47,125	31,527
Restricted cash	182	-
Accounts receivable	-	1,610
Inventory	1,230	5,832
Prepaid expenses	2,282	1,835
Deposits and other current assets	1,428	1,420
Total current assets	123,308	113,574
Property and equipment, net	54	45
Right-of-use lease assets - operating, net	566	363
Deposits and other assets	267	189
Total assets	$ 124,195	$ 114,171
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,518	$ 1,182
Accrued expenses	5,289	5,120
Lease obligation - operating, short-term	567	267
Other current liabilities	42	66
Total current liabilities	7,416	6,635
Term loan, long-term	36,794	37,741
Derivative liability	7,517	6,267
Lease obligation - operating, long-term	7	4
Other liabilities	28	97
Total liabilities	51,762	50,744
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 June 30, 2023; 34,257,916 and 35,849,482 shares issued and outstanding as of December 31, 2022 and June 30, 2023, respectively	3	4
Additional paid-in capital	298,934	315,329
Accumulated deficit	(226,536)	(251,900)
Accumulated other comprehensive income (loss)	32	(6)
Total stockholders' equity	72,433	63,427
Total liabilities and stockholders' equity	$ 124,195	$ 114,171

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 June 30,		Six Months Ended June 30,	
	2022	2023	2022	2023
Product revenues, net	$ -	$ 1,638	$ -	$ 3,701
Operating expenses:				
Cost of product revenues	-	354	-	959
Research and development	5,142	2,934	9,489	5,050
Selling, general and administrative	4,279	12,096	7,172	22,992
Total operating expenses	9,421	15,384	16,661	29,001
Loss from operations	(9,421)	(13,746)	(16,661)	(25,300)
Other income	64	239	78	1,229
Interest income	107	1,363	120	2,678
Interest expense	(447)	(2,010)	(965)	(3,971)
Net loss	$ (9,697)	$ (14,154)	$ (17,428)	$ (25,364)
Net loss per share — basic and diluted	$ (0.35)	$ (0.36)	$ (0.64)	$ (0.66)
Weighted average common shares outstanding — basic and diluted	27,378,507	38,692,624	27,373,459	38,249,255
Other comprehensive loss:				
Unrealized loss on short-term investments	$ (3)	$ (14)	$ (6)	$ (38)
Comprehensive loss	$ (9,700)	$ (14,168)	$ (17,434)	$ (25,402)

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

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

	COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED	OTHER COMPREHENSIVE	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	CAPITAL	DEFICIT	INCOME (LOSS)	EQUITY
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
Net loss	—	—	—	(14,154)	—	(14,154)
Issuance of common stock under at-the-market offering, net of issuance costs (Note 10)	33,333	—	332	—	—	332
Issuance of common stock upon exercise of stock options	18,000	—	101	—	—	101
Issuance of common stock through employee stock purchase plan	29,076	—	176	—	—	176
Stock-based compensation	—	—	1,179	—	—	1,179
Unrealized loss on short-term investments	—	—	—	—	(14)	(14)
At June 30, 2023	35,849,482	$ 4	$ 315,329	$ (251,900)	$ (6)	$ 63,427
At December 31, 2021	27,366,707	$ 3	$ 246,166	$ (189,698)	$ (1)	$ 56,470
Net loss	—	—	—	(7,731)	—	(7,731)
Issuance of common stock upon exercise of stock options	4,781	—	21	—	—	21
Stock-based compensation	—	—	636	—	—	636
Unrealized loss on short-term investments	—	—	—	—	(3)	(3)
At March 31, 2022	27,371,488	3	246,823	(197,429)	(4)	49,393
Net loss	—	—	—	(9,697)	—	(9,697)
Issuance of common stock through employee stock purchase plan	23,658	—	84	—	—	84
Stock-based compensation	—	—	680	—	—	680
Unrealized loss on short-term investments	—	—	—	—	(3)	(3)
At June 30, 2022	27,395,146	$ 3	$ 247,587	$ (207,126)	$ (7)	$ 40,457

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)

	Six Months Ended June 30,	
	2022	**2023**
Cash flows from operating activities		
Net loss	$ (17,428)	$ (25,364)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	18	12
Amortization expense - right-of-use leased assets - operating	212	202
Accretion on short-term investments	(24)	(871)
Stock-based compensation	1,316	2,159
Non-cash interest expense	218	1,017
Fair value adjustment to derivative liability	-	(1,250)
Changes in operating assets and liabilities		
Accounts receivable	-	(1,610)
Inventory	-	(4,602)
Prepaid expenses and other assets	809	456
Accounts payable, accrued expenses and other liabilities	335	(784)
Net cash used in operating activities	(14,544)	(30,635)
Cash flows from investing activities		
Purchases of property and equipment	(6)	(3)
Maturities of short-term investments	7,000	28,100
Purchases of short-term investments	(20,645)	(11,670)
Net cash (used in) provided by investing activities	(13,651)	16,427
Cash flows from financing activities		
Proceeds from at-the-market offering, net	-	14,038
Principal payments on term loan	(5,000)	-
Proceeds from employee stock purchase plan	84	176
Proceeds from the exercise of vested stock options	21	101
Net cash (used in) provided by financing activities	(4,895)	14,315
Net (decrease) increase in cash, cash equivalents and restricted cash	(33,090)	107
Cash, cash equivalents and restricted cash at beginning of period	74,450	71,243
Cash, cash equivalents and restricted cash at end of period	$ 41,360	$ 71,350
Supplemental cash flow information		
Interest paid	$ 794	$ 2,970
Taxes paid	$ 114	$ 156
Supplemental disclosure of non-cash activities		
Transfer of issuance costs from other noncurrent assets to equity	$ -	$ 79

The accompanying notes are an integral part of these 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, 2022 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 22, 2023. The Company has determined that it operates in one segment.

The accompanying condensed consolidated balance sheet as of June 30, 2023, the condensed consolidated statements of operations and comprehensive loss and stockholders' equity for the three and six months ended June 30, 2022 and 2023 and condensed consolidated statements of cash flows for the six months ended June 30, 2022 and 2023 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 and six months ended June 30, 2023 are not necessarily indicative of the results expected for the full year ending December 31, 2023.

Liquidity

As of June 30, 2023, the Company had an accumulated deficit of approximately $251.9 million. Management expects to continue to incur operating losses for the foreseeable future. The Company has financed its operations to date from proceeds from the sale of common stock, preferred stock and the incurrence of debt.

As of June 30, 2023, the Company had cash, cash equivalents, and short-term investments of $102.9 million. 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). The Company's existing cash, cash equivalents and short-term investments, including the available proceeds from the first tranche of the Oaktree Agreement, will be sufficient to meet its cash commitments for at least the next 12 months after the date that the interim condensed consolidated financial statements are issued. Additionally, the Company expects to have access to funds pursuant to an at-the-market offering program with Cowen and Company, LLC (Note 10), or could otherwise seek additional funding through a combination of public or private equity offerings if it believes additional resources are needed. Additional financing may not be available on a timely basis on terms acceptable to the Company, or at all.

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, Cash Equivalents and Restricted Cash

Cash, cash equivalents and restricted cash 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.

Cash, cash equivalents and restricted cash consists of the following (in thousands):

	December 31, 2022	June 30, 2023
Cash and cash equivalents	$ 71,061	$ 71,350
Restricted cash	182	-
Cash, cash equivalents and restricted cash	$ 71,243	$ 71,350

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. To date, expected credit losses have not been material.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and short-term investments. 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's short-term investments consist of United States Treasury securities, commercial paper and United States Government Agency securities. 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.

As the Company executes its commercial launch, the Company has a limited number of specialty pharmacy customers. As of June 30, 2023, one customer represents 99% of accounts receivable. For the three and six months ended June 30, 2023, one customer represents 99% and 94% of revenue, respectively.

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 (expense). 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 arrangement 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 to specialty pharmacies (“SPs”). The Company recognizes revenue from product sales at a point in time, typically upon receipt of product at the SPs, 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 requirement. 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 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. 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 June 30, 2023, 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 June 30,		Six Months Ended June 30,	
	2022	2023	2022	2023
Net loss	$ (9,697)	$ (14,154)	$ (17,428)	$ (25,364)
Weighted-average shares used in computing net loss per share	27,378,507	38,692,624	27,373,459	38,249,255
Net loss per share, basic and diluted	$ (0.35)	$ (0.36)	$ (0.64)	$ (0.66)

Basic and diluted weighted average shares of common stock outstanding for the three and six months ended June 30, 2023 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 June 30,		Six Months Ended June 30,	
	2022	2023	2022	2023
Stock options to purchase common stock	3,771,435	4,734,049	3,771,435	4,734,049
Warrants to purchase common stock	-	516,345	-	516,345
Unvested restricted stock units	42,250	341,408	42,250	341,408
Total	3,813,685	5,591,802	3,813,685	5,591,802

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, 2022 and June 30, 2023 consisted of the following (in thousands):

	At December 31, 2022			
Investments - Current:	Cost Basis	Accumulated Unrealized Gains	Accumulated Unrealized Losses	Fair Value
Commercial paper	$ 16,741	$ -	$ -	$ 16,741
United States Treasury securities	15,768	7	-	15,775
United States Government Agency securities	14,584	25	-	14,609
Total	$ 47,093	$ 32	$ -	$ 47,125

	At June 30, 2023			
Investments - Current:	Cost Basis	Accumulated Unrealized Gains	Accumulated Unrealized Losses	Fair Value
United States Government Agency securities	$ 14,886	$ -	$ (7)	$ 14,879
Commercial paper	10,771	1	-	10,772
United States Treasury securities	5,876	-	-	5,876
Total	$ 31,533	$ 1	$ (7)	$ 31,527

The amortized cost and fair value of the Company's available-for-sale investments, by contract maturity, as of June 30, 2023 consisted of the following (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$ 31,533	$ 31,527
Total	$ 31,533	$ 31,527

5. Inventory

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

	December 31, 2022	June 30, 2023
Raw materials	$ 1,201	$ 888
Work-in-process	29	4,249
Finished goods	-	695
	$ 1,230	$ 5,832

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. 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, 2022	June 30, 2023
Office equipment	5 years	$ 6	$ 9
Office furniture	7 years	126	126
Computer equipment	3 years	15	15
Leasehold improvements	Life of lease	95	95
		242	245
Less: Accumulated depreciation		(188)	(200)
Property and equipment, net		$ 54	$ 45

Depreciation expense for the three months ended June 30, 2022 and June 30, 2023 was $9,000 and $6,000, respectively.

Depreciation expense for the six months ended June 30, 2022 and 2023 was $18,000 and $12,000, respectively.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2022	June 30, 2023
Employee compensation and related costs	$ 2,754	$ 2,369
Accrued sales allowances and related costs	—	914
Consulting and professional service fees	603	856
Contract research and development	1,827	565
Accrued manufacturing costs	—	174
State taxes	49	157
Accrued royalty payable	—	43
Financing related costs	29	—
Interest	16	—
Other	11	42
Total accrued expenses	$ 5,289	$ 5,120

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, 2022			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 65,875	$ 65,875	$ —	$ —
Total cash equivalents	65,875	65,875	—	—
Commercial Paper	16,741	—	16,741	—
United States Treasury securities	15,775	15,775	—	—
United States Government Agency securities	14,609	—	14,609	—
Investments	47,125	15,775	31,350	—
Total	$ 113,000	$ 81,650	$ 31,350	$ —
Liabilities:				
Derivative liability	$ 7,517	$ —	$ —	$ 7,517
Total	$ 7,517	$ —	$ —	$ 7,517

	As of June 30, 2023			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 69,967	$ 69,967	$ —	$ —
Total cash equivalents	69,967	69,967	—	—
United States Government Agency securities	14,879	—	14,879	—
Commercial paper	10,772	—	10,772	—
United States Treasury securities	5,876	5,876	—	—
Investments	31,527	5,876	25,651	—
Total	$ 101,494	$ 75,843	$ 25,651	$ —
Liabilities:				
Derivative liability	$ 6,267	$ —	$ —	$ 6,267
Total	$ 6,267	$ —	$ —	$ 6,267

Changes in the fair value of the Company's Level 3 derivative liability for the six months ended June 30, 2023 are as follows (in thousands):

At December 31, 2022	$ 7,517
Change in fair value of derivative liability	(1,250)
At June 30, 2023	$ 6,267

9. Debt

The following table presents the carrying value of the Company's debt balance as of December 31, 2022 and June 30, 2023 (in thousands):

	December 31, 2022	June 30, 2023
Face value	$ 50,000	$ 50,000
Less: discount	(13,206)	(12,259)
Total	36,794	$ 37,741
Less: current portion	—	—
Long-term portion	$ 36,794	$ 37,741

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 expected 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 June 30, 2023. 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 June 30, 2023, the fair value of the embedded derivative liability was $6.3 million.

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 and six months ended June 30, 2023, the Company recorded $488,000 and $947,000 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 and six months

ended June 30, 2023, the Company recorded $36,000 and $70,000 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.

SLR Investment Corp. and Silicon Valley Bank Term Loan

In May 2017, the Company entered into a loan and security agreement (the "2017 Loan Agreement"), with SLR Investment Corp. (f/k/a Solar Capital Ltd.) and Silicon Valley Bank (together, the "Lenders"), for $10.0 million.

In September 2019, the Company replaced the 2017 Loan Agreement with a new $20.0 million term loan with the Lenders (the "2019 Loan Agreement"). The 2019 Loan Agreement extended the term of the credit facility until September 17, 2023. Debt issuance costs for the 2019 Loan Agreement, including unamortized issuance costs for the 2017 Loan Agreement, were to be amortized to interest expense over the remaining term of the 2019 Loan Agreement using the effective-interest method.

The interest rate under the 2019 Loan Agreement was the higher of (i) LIBOR plus 7.95% or (ii) 10.18% and there was an interest-only period until September 30, 2021. The rate at December 31, 2022 was 10.18%. Pursuant to the 2019 Loan Agreement, the Company provided a first priority security interest in substantially all of the Company's assets, including intellectual property, subject to certain exceptions.

The Company entered into an Exit Agreement in connection with the 2019 Loan Agreement which provided for an aggregate payment of 4% of the loan commitment, or $800,000, to the lenders upon the occurrence of an exit event (the "Exit Fee"). The Company paid the Exit Fee during 2020 in conjunction with the Company's public offering, which was deemed to be an exit event pursuant to the Exit Agreement.

The 2019 Loan Agreement allowed the Company to voluntarily prepay all (but not less than all) of the outstanding principal at any time. A prepayment premium of 3% or 1% through the one-year anniversary and the two-year anniversary, respectively, would be assessed on the outstanding principal. After the two-year anniversary, a 0.5% prepayment premium would be assessed on the outstanding principal. A final payment fee of $500,000 was due upon the earlier to occur of the maturity date or prepayment of such borrowings.

In connection with the Oaktree Agreement, the Company paid off all unpaid borrowings under the 2019 Loan Agreement on October 13, 2022, including the $500,000 final fee and a prepayment premium of $46,000. For the three and six months ended June 30, 2022, the Company recorded $74,000 and $155,000, respectively, related to the amortization of debt discount associated with the 2019 Loan Agreement. For the three and six months ended June 30, 2022, the Company recorded $29,000 and $63,000, respectively, related to the amortization of the final payment fee associated with the 2019 Loan Agreement.

In an event of default under the 2019 Loan Agreement, the interest rate would have been increased by 5% and the balance under the loan may have become immediately due and payable at the option of the lenders.

The 2019 Loan Agreement included restrictions on, among other things, the Company's ability to incur additional indebtedness, change the name or location of the Company's business, merge with or acquire other entities, pay dividends or make other distributions to holders of its capital stock, make certain investments, engage in transactions with affiliates, create liens, sell assets or pay subordinated debt.

As of June 30, 2023, future principal payments due under the Oaktree Agreement were as follows (in thousands):

Year ended:		
December 31, 2023	$	—
December 31, 2024		—
December 31, 2025		2,500
December 31, 2026		10,000
December 31, 2027		37,500
Total	$	50,000

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. As of December 31, 2022, the Company had sold a total of 181,553 2021 ATM Shares under the 2021 ATM Program at a weighted average gross selling price of $6.33 per share for net proceeds of $1.1 million. During the six months ended June 30, 2023, the Company sold 1,544,490 2021 ATM Shares under the 2021 ATM Agreement at a weighted average gross selling price of $9.32 per share for net proceeds of $14.0 million.

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 June 30, 2023, there were 598,411 options outstanding under the 2014 Stock Plan.

As of June 30, 2023, there were 7,457,463 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan, including 359,860 options that have been forfeited from the 2014 Stock Plan.

At June 30, 2023, there were 3,067,825 options available for issuance under the 2017 Stock Plan, 4,008,138 options outstanding and 341,408 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 June 30, 2023, there were 372,500 options available for issuance under the Inducement Plan, and 127,500 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:

	Six Months Ended June 30,	
	2022	2023
Risk-free interest rate	1.67% - 3.58%	3.40% - 4.17%
Expected dividend yield	0%	0%
Expected life	5.5-6.7 years	5.5-7.0 years
Expected volatility	70%-73%	77%-85%
Weighted-average grant date fair value	$ 2.97	$ 5.31

The following table summarizes information about stock option activity during the six months ended June 30, 2023 (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, 2022	4,008,177	$ 5.76		
Granted	843,972	7.45		
Exercised	(18,000)	5.66		
Forfeited	(100,100)	5.69		
Outstanding, June 30, 2023	4,734,049	$ 6.07	7.41	$ 20,286
Vested and exercisable, June 30, 2023	2,596,264	$ 5.90	6.19	$ 11,646
Vested and expected to vest, June 30, 2023	4,181,799	$ 6.06	7.21	$ 17,989

The following table summarizes information about RSU activity during the six months ended June 30, 2023:

	RSUs	AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE)
Outstanding, December 31, 2022	—	$ —
Granted	350,825	6.19
Forfeited	(9,417)	6.14
RSUs outstanding at June 30, 2023	341,408	$ 6.19

Unrecognized compensation expense related to unvested options as of June 30, 2023 was $6.1 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 2.4 years. Unrecognized compensation expense related to unvested RSUs as of June 30, 2023 was $1.2 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 3.5 years.

During the three months ended June 30, 2023, as part of a severance arrangement, the Company extended the exercise period to six months for 111,532 vested options, with a weighted exercise price of $6.25, and recorded incremental stock based compensation of $87,000.

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.

During the six months ended June 30, 2023, 29,076 shares of common stock were issued under the ESPP. As of June 30, 2023, there were 1,318,615 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 and six months ended June 30, 2022 and 2023 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2023	2022	2023
Research and development	$ 265	$ 365	$ 519	$ 705
General and administrative	415	814	797	1,454
Total	$ 680	$ 1,179	$ 1,316	$ 2,159

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 2025 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 June 30, 2023 (in thousands):

Year ended:	
December 31, 2023	$ 271
December 31, 2024	9
December 31, 2025	1
Total minimum lease payments	281
Less imputed interest	(10)
Total	$ 271

	Six Months Ended June 30,	
	2022	2023
Lease cost:		
Operating lease cost	$ 250	$ 226
Short-term lease cost	18	19
Sublease income	(26)	-
Total lease cost	$ 242	$ 245
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 264	$ 326
Operating cash flows from operating leases	$ (26)	$ (101)
Weighted-average remaining lease term - operating leases	1.4 years	0.5 years
Weighted-average discount rate - operating leases	10.1%	10.2%

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, 2022 (the "Annual Report") filed with the Securities and Exchange Commission (the "SEC") on March 22, 2023. 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® (furosemide injection), consists of our novel formulation of furosemide delivered via West Pharmaceutical Services, Inc.'s on-body infusor, which delivers an 80 mg dose. 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 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. We estimate that there is a $6.9 billion total market opportunity for FUROSCIX in the United States.

The commercial launch of FUROSCIX commenced in the first quarter of 2023. 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. As of June 30, 2023, there were approximately 1,500 total FUROSCIX prescriptions written by around 600 unique prescribers, and of these, approximately 800 FURSOCIX prescriptions had been filled and there were approximately 300 prescriptions payer cleared or pending. Additionally, there have been more than 1,100 FUROSCIX in-services completed launch through June 30, 2023.

In July 2023, we received favorable Type C meeting feedback from the FDA regarding a potential expansion of the FUROSCIX indication to include New York Heart Association (NYHA) Class IV heart failure patients. We plan to file for inclusion of NYHA Class IV patients by the end of 2023. In addition, we have begun Investigational New Drug enabling studies on a concentrated formulation of furosemide, for which we have issued patents, that could enable the possibility of dosing flexibility of subcutaneous furosemide.

We have funded our operations from inception through June 30, 2023 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. Our first product, FUROSCIX, was approved for sale in October 2022 and became commercially available in February 2023 and, therefore, we have not generated significant revenue from product sales as of June 30, 2023.

As of June 30, 2023, we had an accumulated deficit of $251.9 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 building 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.

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, and 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 June 30, 2022 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2023 (in thousands):

	Three Months Ended June 30,		Increase (Decrease)
	2022	2023	
Product revenues, net	$ -	$ 1,638	$ 1,638
Operating expenses:			
Cost of product revenues	-	354	354
Research and development	5,142	2,934	(2,208)
Selling, general and administrative	4,279	12,096	7,817
Total operating expenses	9,421	15,384	5,963
Loss from operations	(9,421)	(13,746)	4,325
Other income	64	239	175
Interest income	107	1,363	1,256
Interest expense	(447)	(2,010)	1,563
Net loss	$ (9,697)	$ (14,154)	$ 4,457

Product revenues. Product revenues were $1.6 million for the three months ended June 30, 2023, compared to no product revenues for the three months ended June 30, 2022. The increase of $1.6 million was due to the commercial launch of FUROSCIX in February 2023.

Cost of product revenues. Cost of product revenues were $0.4 million for the three months ended June 30, 2023, compared to no cost of product revenues for the three months ended June 30, 2022. The increase of $0.4 million was due to the commercial launch of FUROSCIX in February 2023.

Research and development expenses. R&D expenses were $2.9 million for the three months ended June 30, 2023, compared to $5.1 million for the three months ended June 30, 2022. The decrease of $2.2 million was primarily attributable to a $0.8 million decrease in clinical study and medical affairs costs, a $0.7 million decrease in pharmaceutical development costs, a $0.5 million decrease in employee-related costs, and a $0.1 million decrease in patent costs.

Selling, general and administrative expenses. SG&A expenses were $12.1 million for the three months ended June 30, 2023, compared to $4.3 million for the three months ended June 30, 2022. The increase of $7.8 million was primarily attributable to a $5.1 million increase in employee-related costs, a $2.2 million increase in commercial costs, a $0.3 million increase in legal and professional service costs, and a $0.1 million increase in state taxes.

Other income. Other income was $0.2 million for the three months ended June 30, 2023, compared to $64,000 for the three months ended June 30, 2022. The increase in income of $0.2 million was primarily attributable to the fair value adjustment to the derivative liability in the three months ended June 30, 2023.

Interest income. Interest income was $1.4 million for the three months ended June 30, 2023, compared to $0.1 million for the three months ended June 30, 2022. The increase of $1.3 million was primarily attributable to higher interest rates and balances on our financial instruments.

Interest expense. Interest expense was $2.0 million for the three months ended June 30, 2023 compared to $447,000 for the three months ended June 30, 2022. The increase of $1.6 million was due to higher term loan balances as a result of the Oaktree Agreement which commenced October 13, 2022.

Comparison of Six Months Ended June 30, 2022 and June 30, 2023

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2023 (in thousands):

	Six Months Ended June 30,		Increase (Decrease)
	2022	2023	
Product revenues, net	$ -	$ 3,701	$ 3,701
Operating expenses:			
Cost of product revenues	-	959	959
Research and development	9,489	5,050	(4,439)
Selling, general and administrative	7,172	22,992	15,820
Total operating expenses	16,661	29,001	12,340
Loss from operations	(16,661)	(25,300)	8,639
Other income	78	1,229	1,151
Interest income	120	2,678	2,558
Interest expense	(965)	(3,971)	3,006
Net loss	$ (17,428)	$ (25,364)	$ 7,936

Product revenues. Product revenues were $3.7 million for the six months ended June 30, 2023, compared to no product revenues for the six months ended June 30, 2022. The increase of $3.7 million was due to the commercial launch of FUROSCIX in February 2023.

Cost of product revenues. Cost of product revenues were $1.0 million for the six months ended June 30, 2023, compared to no cost of product revenues for the six months ended June 30, 2022. The increase of $1.0 million was due to the commercial launch of FUROSCIX in February 2023.

Research and development expenses. R&D expenses were $5.1 million for the six months ended June 30, 2023, compared to $9.5 million for the six months ended June 30, 2022. The decrease of $4.4 million was primarily attributable to a $1.9 million decrease in clinical study and medical affairs costs, a $0.9 million decrease in pharmaceutical development costs, a $0.8 million decrease in employee-related costs, a $0.4 million decrease in quality and regulatory costs, and a $0.3 million decrease in device development costs.

Selling, general and administrative expenses. SG&A expenses were $23.0 million for the six months ended June 30, 2023, compared to $7.2 million for the six months ended June 30, 2022. The increase of $15.8 million was primarily attributable to a $9.9 million increase in employee-related costs, a $4.8 million increase in commercial costs, a $0.7 million increase in legal and professional service costs, a $0.2 million increase in quality and regulatory costs, a $0.2 million increase in state taxes, and a $0.2 million increase in facility related costs.

Other income. Other income was $1.2 million for the six months ended June 30, 2023, compared to $78,000 for the six months ended June 30, 2022. The increase in income of $1.2 million was primarily attributable to the fair value adjustment to the derivative liability in the six months ended June 30, 2023.

Interest income. Interest income was $2.7 million for the six months ended June 30, 2023, compared to $0.1 million for the six months ended June 30, 2022. The increase of $2.6 million was primarily attributable to higher interest rates and balances on our financial instruments.

Interest expense. Interest expense was $4.0 million for the six months ended June 30, 2023 compared to $1.0 million for the six months ended June 30, 2022. The increase of $3.0 million was due to higher term loan balances as a result of the Oaktree Agreement which commenced October 13, 2022.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through June 30, 2023 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 June 30, 2023, 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 Oaktree Agreement 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 $15.1 million from the sale of common stock in our 2021 at-the-market offering. As of June 30, 2023, we had cash and cash equivalents of $71.4 million and short-term investments of $31.5 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 the 2021 ATM Agreement with 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. As of December 31, 2022, we had sold a total of 181,553 shares of common stock pursuant to the 2021 ATM Agreement for net proceeds of $1.1 million. During the six months ended June 30, 2023, we sold 1,544,490 shares of our common stock under the 2021 ATM Agreement at a weighted average gross selling price of $9.32 per share for net proceeds of $14.0 million. 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. 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 believe our existing cash, cash equivalents and short-term investments, including the available proceeds from the first tranche of the Oaktree Agreement, will be sufficient to fund our operations through at least the next 12 months from the date of this Quarterly Report. 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. In connection with such development plans and activities, if we determine that we need additional cash resources, we would seek to access such funds either pursuant to our 2021 ATM Agreement or through a combination of public or private equity offerings or debt financings. Additionally, we continue to incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the costs and expenses of expanding our U.S. sales and marketing infrastructure;
- 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, 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:

	Six Months Ended June 30,	
(in thousands)	2022	2023
Net cash (used in) provided by:		
Operating activities	$ (14,544)	$ (30,635)
Investing activities	(13,651)	16,427
Financing activities	(4,895)	14,315
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (33,090)	$ 107

Net Cash Used in Operating Activities

During the six months ended June 30, 2023, net cash used in operating activities was $30.6 million, consisting primarily of a net loss of $25.4 million and an increase in net operating assets of $6.5 million. This was offset by non-cash charges of $1.3 million. 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.

During the six months ended June 30, 2022, net cash used in operating activities was $14.5 million, consisting primarily of a net loss of $17.4 million. This was offset by an increase in net operating liabilities of $1.7 million and non-cash charges of $1.1 million. The increase in net operating liabilities is related to accounts payable for commercial activity, recruiting and pharmaceutical development, as well as amortization of prepaid assets. 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 2019 Loan Agreement and accretion of discount on investments.

Net Cash (Used in) Provided by Investing Activities

During the six months ended June 30, 2023, net cash provided by investing activities was $16.4 million, consisting primarily of maturities of short-term investments, net of purchases.

During the six months ended June 30, 2022, net cash used in investing activities was $13.7 million, consisting primarily of purchases of short-term investments, net of maturities.

Net Cash (Used in) Provided by Financing Activities

During the six months ended June 30, 2023, net cash provided by financing activities was $14.3 million, consisting of proceeds from the 2021 ATM Agreement, purchases pursuant to our 2017 Employee Stock Purchase Plan and stock option exercises.

During the six months ended June 30, 2022, net cash used in financing activities was $4.9 million, consisting primarily of principal term loan payments, offset by purchases pursuant to our 2017 Employee Stock Purchase Plan and stock option exercises.

CONTRACTUAL OBLIGATIONS

There were no material changes in our commitments under contractual obligations, as disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report.

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. Except as described below, there have been no material changes to that information disclosed in our Annual Report during the six months ended June 30, 2023.

During the six months ended June 30, 2023, we have updated our critical accounting policies to include accounts receivable and revenue recognition.

Accounts Receivable

Accounts receivable are recorded net of any estimated expected credit losses. Our 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. To date, expected credit losses have not been material. Additionally, there have not been material changes in these estimates or assumptions pertaining to credit losses over the reporting periods presented. In the future, if there are material changes in the underlying estimates and assumptions pertaining to credit losses, the financial statements could be materially impacted.

Revenue Recognition

We recognize revenue when our 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 we determine are within the scope of Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customer ("Topic 606"), we perform 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 we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied. We have identified one performance obligation, the delivery of FUROSCIX to our customers. We have not incurred any incremental costs associated with obtaining contracts with customers. Our 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. We launched sales of FUROSCIX in the first quarter of 2023 to specialty pharmacies ("SPs"). We recognize revenue from product sales at a point in time, typically upon receipt of product at the SPs, 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 our estimates. If actual results vary from its estimates, we adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. To date, consideration subject to a constraint on revenue recognition has not been significant. Additionally, there have not been material changes in these estimates or assumptions pertaining to constraints on revenue recognition over the reporting periods presented. In the future, if there are material changes in the underlying estimates and assumptions pertaining to constraints on revenue recognition, the financial statements could be materially impacted.

Sales Discounts: Sales discounts are agreed-upon discounts, from negotiated contracts, taken directly off our 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. Our 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, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-Payment Assistance: We offer co-payment assistance to commercially insured patients meeting certain eligibility requirement. 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. Our 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, we offer SPs 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. We do not allow product returns for product that has been dispensed to a patient. As we receive inventory reports from the SPs and have the ability to control the amount of product that is sold to the SPs, we are 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. In arriving at our estimate, we also consider historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

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 June 30, 2023, 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 short-term duration of our indebtedness, 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 on Form 10-Q, 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 June 30, 2023, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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 June 30, 2023 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, 2022 (the "Annual Report"), which was filed with the SEC on March 22, 2023. There have been no material changes from the risk factors previously disclosed in our Annual Report.

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

None.

Item 3. Defaults Upon Senior Securities

None**.**

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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).
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.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
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: August 10, 2023

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

Exhibit 31.1

Certifications

I, John H. Tucker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2023 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: August 10, 2023

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

Certifications

I, Rachael Nokes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2023 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: August 10, 2023

/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 June 30, 2023, 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. Section 1350, as adopted pursuant to Section 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: August 10, 2023

/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 June 30, 2023, 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. Section 1350, as adopted pursuant to Section 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: August 10, 2023

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