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 September 30, 2022

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 November 8, 2022, the Registrant had 27,434,083 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 and launch preparation of FUROSCIX, including the timing thereof, the timing or likelihood of regulatory filings and approvals, 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, restricted cash and short-term investments and our ability to raise additional capital to fund our operations, our future financial performance, the anticipated impact of the COVID-19 pandemic and 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, in particular, our lead 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 product candidates, if approved, depends upon attaining market acceptance by hospital networks, physicians, nurses, patients, third-party payers and the medical community.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell FUROSCIX, we may be unable to generate any 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, 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 product candidates.
- The ongoing and evolving COVID-19 pandemic may materially and adversely affect our business and our financial results, including the activities required for our intended commercial launch of FUROSCIX.
- 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 this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the Securities and Exchange Commission on March 22, 2022, 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, 2021	September 30, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 74,268	$ 41,289
Restricted cash	182	—
Short-term investments	1,010	3,897
Prepaid expenses	2,791	1,643
Other current assets	24	340
Total current assets	78,275	47,169
Restricted cash	—	182
Property and equipment, net	69	62
Right-of-use lease assets - operating, net	410	677
Deposits and other assets	283	310
Total assets	$ 79,037	$ 48,400
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 544	$ 996
Accrued expenses	3,995	5,178
Term loan, short-term	9,805	9,880
Lease obligation - operating, short-term	476	594
Other current liabilities	26	528
Total current liabilities	14,846	17,176
Term loan, long-term	7,354	—
Lease obligation - operating, long-term	—	114
Other liabilities	367	—
Total liabilities	22,567	17,290
Commitments and contingencies (Note 11)		
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 September 30, 2022; 27,366,707 and 27,402,121 shares issued and outstanding as of December 31, 2021 and September 30, 2022, respectively	3	3
Additional paid-in capital	246,166	248,395
Accumulated deficit	(189,698)	(217,288)
Accumulated other comprehensive loss	(1)	-
Total stockholders' equity	56,470	31,110
Total liabilities and stockholders' equity	$ 79,037	$ 48,400

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 September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Operating expenses:				
Research and development	$ 3,694	$ 3,718	$ 11,509	$ 13,207
General and administrative	2,211	6,277	7,593	13,448
Total operating expenses	5,905	9,995	19,102	26,655
Loss from operations	(5,905)	(9,995)	(19,102)	(26,655)
Other income (expense)	10	(22)	298	55
Interest income	10	232	42	353
Interest expense	(667)	(377)	(1,954)	(1,343)
Net loss	$ (6,552)	$ (10,162)	$ (20,716)	$ (27,590)
Net loss per share — basic and diluted	$ (0.24)	$ (0.37)	$ (0.76)	$ (1.01)
Weighted average common shares outstanding — basic and diluted	27,355,454	27,401,060	27,349,279	27,382,760
Other comprehensive loss:				
Unrealized gain on short-term investments	$ -	$ 7	$ -	$ 1
Comprehensive loss	$ (6,552)	$ (10,155)	$ (20,716)	$ (27,589)

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

SCPHARMACEUTICALS INC.

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

	COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED	OTHER COMPREHENSIVE	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	CAPITAL	DEFICIT	INCOME	EQUITY
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
Net loss	—	—	—	(10,162)	—	(10,162)
Issuance of common stock upon exercise of stock options	6,975	—	23	—	—	23
Stock-based compensation	—	—	785	—	—	785
Unrealized gain on short-term investments	—	—	—	—	7	7
At September 30, 2022	27,402,121	$ 3	$ 248,395	$ (217,288)	$ —	$ 31,110
At December 31, 2020	27,325,959	$ 3	$ 243,830	$ (161,664)	$ 1	$ 82,170
Net loss	—	—	—	(7,102)	—	(7,102)
Issuance of common stock upon exercise of stock options	2,500	—	9	—	—	9
Vesting of restricted stock	26,994	—	(81)	—	—	(81)
Stock-based compensation	—	—	521	—	—	521
Unrealized loss on short-term investments	—	—	—	—	(2)	(2)
At March 31, 2021	27,355,453	3	244,279	(168,766)	(1)	75,515
Net loss	—	—	—	(7,062)	—	(7,062)
Issuance of common stock upon exercise of stock options	1	—	—	—	—	—
Stock-based compensation	—	—	589	—	—	589
Unrealized gain on short-term investments	—	—	—	—	1	1
At June 30, 2021	27,355,454	3	244,868	(175,828)	—	69,043
Net loss	—	—	—	(6,552)	—	(6,552)
Stock-based compensation	—	—	619	—	—	619
At September 30, 2021	27,355,454	$ 3	$ 245,487	$ (182,380)	$ —	$ 63,110

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)

	Nine Months Ended September 30,	
	2021	2022
Cash flows from operating activities		
Net loss	$ (20,716)	$ (27,590)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	26	28
Amortization expense - right-of-use leased assets - operating	301	320
Accretion of discount (premium) on investments	120	(40)
Stock-based compensation	1,729	2,101
Non-cash interest expense	410	309
Changes in operating assets and liabilities		
Prepaid expenses and other assets	941	804
Accounts payable, accrued expenses and other liabilities	(2,864)	1,328
Net cash used in operating activities	(20,053)	(22,740)
Cash flows from investing activities		
Purchases of property and equipment	(10)	(21)
Maturities of short-term investments	36,650	17,800
Purchases of short-term investments	(9,011)	(20,646)
Net cash provided by (used in) investing activities	27,629	(2,867)
Cash flows from financing activities		
Principal payments on term loan	—	(7,500)
Proceeds from employee stock purchase plan	—	84
Proceeds from the exercise of vested stock options	9	44
Settlements of restricted stock units for tax withholding obligations	(81)	—
Net cash used in financing activities	(72)	(7,372)
Net increase (decrease) in cash, cash equivalents and restricted cash	7,504	(32,979)
Cash, cash equivalents and restricted cash at beginning of period	72,001	74,450
Cash, cash equivalents and restricted cash at end of period	$ 79,505	$ 41,471
Supplemental cash flow information		
Interest paid	$ 1,550	$ 1,099
Taxes paid	$ 166	$ 114

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, 2021 included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 22, 2022. The Company has determined that it operates in one segment.

The accompanying condensed consolidated balance sheet as of September 30, 2022, the condensed consolidated statements of operations and comprehensive loss and stockholders’ equity for the three and nine months ended September 30, 2021 and 2022 and condensed consolidated statements of cash flows for the nine months ended September 30, 2021 and 2022 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 nine months ended September 30, 2022 are not necessarily indicative of the results expected for the full year ending December 31, 2022.

Liquidity

As of September 30, 2022, the Company had an accumulated deficit of approximately $217.3 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 September 30, 2022, the Company had cash, cash equivalents, restricted cash, and short-term investments of $45.4 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 12). The Company's existing cash, cash equivalents, restricted cash and short-term investments, along with proceeds from 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 9), 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.

As of September 30, 2022, the Company classified $182,000 as restricted cash related to a letter of credit issued as a security deposit in connection with the Company's lease of its corporate office facilities (Note 11). Cash, cash equivalents and restricted cash consists of the following (in thousands):

	December 31, 2021	September 30, 2022
Cash and cash equivalents	$ 74,268	$ 41,289
Restricted cash	182	182
Cash, cash equivalents and restricted cash	$ 74,450	$ 41,471

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 and commercial paper. 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.

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.

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.

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 September 30, 2022, 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 ending 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. The Company already capitalizes its research and development expenses for income tax purposes as it is a start-up company, so there is no material impact forecasted for this change in legislation in 2022.

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 September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Net loss	$ (6,552)	$ (10,162)	$ (20,716)	$ (27,590)
Weighted-average shares used in computing net loss per share	27,355,454	27,401,060	27,349,279	27,382,760
Net loss per share, basic and diluted	$ (0.24)	$ (0.37)	$ (0.76)	$ (1.01)

The Company’s potentially dilutive securities, which include stock options 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 September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Stock options to purchase common stock	2,677,743	3,864,895	2,677,743	3,864,895
Unvested restricted stock units	42,250	42,250	42,250	42,250
Total	2,719,993	3,907,145	2,719,993	3,907,145

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, 2021 and September 30, 2022 consisted of the following (in thousands):

	At December 31, 2021			
Investments - Current:	**Cost Basis**	**Accumulated Unrealized Gains**	**Accumulated Unrealized Losses**	**Fair Value**
Corporate debt securities	$ 1,011	$ -	$ (1)	$ 1,010
Total	$ 1,011	$ -	$ (1)	$ 1,010

	At September 30, 2022			
Investments - Current:	**Cost Basis**	**Accumulated Unrealized Gains**	**Accumulated Unrealized Losses**	**Fair Value**
United States Treasury securities	$ 2,000	$ -	$ -	$ 2,000
Commercial paper	1,897	-	-	1,897
Total	$ 3,897	$ -	$ -	$ 3,897

The amortized cost and fair value of the Company's available-for-sale investments, by contract maturity, as of September 30, 2022 consisted of the following (in thousands):

	Amortized Cost	**Fair Value**
Due in one year or less	$ 3,897	$ 3,897
Total	$ 3,897	$ 3,897

5. Property and Equipment

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

	ESTIMATED USEFUL LIFE	**December 31, 2021**	**September 30, 2022**
Office equipment	5 years	$ 10	$ 6
Office furniture	7 years	126	126
Computer equipment	3 years	8	15
Leasehold improvements	Life of lease	95	95
		239	242
Less: Accumulated depreciation		(170)	(180)
Property and equipment, net		$ 69	$ 62

Depreciation expense for the three months ended September 30, 2021 and September 30, 2022 was $10,000 and $10,000, respectively.

Depreciation expense for the nine months ended September 30, 2021 and September 30, 2022 was $26,000 and $28,000, respectively.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2021	September 30, 2022
Employee compensation and related costs	$ 1,152	$ 2,137
Contract research and development	2,350	2,074
Consulting and professional service fees	265	591
Financing related costs	60	202
Interest	154	88
State taxes	5	—
Other	9	86
Total accrued expenses	$ 3,995	$ 5,178

7. Fair Value of Financial Instruments

FASB ASC Topic, *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, 2021			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 72,449	$ 72,449	$ —	$ —
Total cash equivalents	72,449	72,449	—	—
Corporate debt securities	1,010	—	1,010	—
Investments	1,010	—	1,010	—
Total	$ 73,459	$ 72,449	$ 1,010	$ —

	As of September 30, 2022			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 39,408	$ 39,408	$ —	$ —
Total cash equivalents	39,408	39,408	—	—
United States Treasury securities	2,000	2,000	—	—
Commercial paper	1,897	—	1,897	—
Investments	3,897	2,000	1,897	—
Total	$ 43,305	$ 41,408	$ 1,897	$ —

8. 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 September 30, 2022 was 10.58%. 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.

As of September 30, 2022, unpaid borrowings under the 2019 Loan Agreement totaled $10.0 million. For the three and nine months ended September 30, 2022, the Company recorded $66,000 and $221,000, respectively, related to the amortization of debt discount associated with the 2019 Loan Agreement. For the three and nine months ended September 30, 2021, the Company recorded $106,000 and $288,000, respectively, related to the amortization of debt discount associated with the 2019 Loan 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. For the three and nine months ended September 30, 2022, the Company recorded $25,000 and $88,000, respectively, related to the amortization of the final payment fee associated with the 2019 Loan Agreement. For the three and nine months ended September 30, 2021, the Company recorded $41,000 and $122,000, 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.

Total term loan and unamortized debt discount balances are as follows (in thousands):

	September 30, 2022
Face value	$ 10,000
Less: discount	(120)
Total	$ 9,880
Less: current portion	(9,880)
Long-term portion	$ —

As of September 30, 2022, future principal payments due under the 2019 Loan Agreement were as follows (in thousands):

Year ended:	
December 31, 2022	$ 2,500
December 31, 2023	7,500
Total	$ 10,000

In conjunction with the closing of the Oaktree Agreement (Note 12), the Company used a portion of the proceeds of the term loan to prepay all outstanding loans under the 2019 Loan Agreement, including the final payment fee, on the Closing Date.

9. Stockholders' Equity

2021 At-the-Market Issuance Sales Agreement

On March 23, 2021, the Company entered into a Sales 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 September 30, 2022, the Company had received no proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

10. 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 September 30, 2022, there were 598,619 options outstanding under the 2014 Stock Plan.

As of September 30, 2022, there were 6,136,901 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan, including 359,652 options that have been forfeited from the 2014 Stock Plan.

At September 30, 2022, there were 2,798,571 options available for issuance under the 2017 Stock Plan, 3,266,276 options outstanding and 42,250 RSUs outstanding. Awards granted under the 2017 Stock Plan have a term of ten years. Vesting of awards under the 2017 Stock 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:

	Nine Months Ended September 30,	
	2021	2022
Risk-free interest rate	0.50% - 0.88%	1.67% - 3.58%
Expected dividend yield	0%	0%
Expected life	5.5-6.7 years	5.5-6.7 years
Expected volatility	72%-74%	70%-76%
Weighted-average grant date fair value	$ 4.25	$ 3.02

The following table summarizes information about stock option activity during the nine months ended September 30, 2022 (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, 2021	2,662,752	$ 6.28		
Granted	1,305,094	4.69		
Exercised	(11,756)	3.71		
Forfeited	(91,195)	6.77		
Outstanding, September 30, 2022	3,864,895	$ 5.74	7.62	$ 5,044
Vested and exercisable, September 30, 2022	1,854,299	$ 6.20	6.18	$ 2,319
Vested and expected to vest, September 30, 2022	3,297,128	$ 5.81	7.38	$ 4,294

The following table summarizes information about RSU activity during the nine months ended September 30, 2022:

	RSUs	AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE)
Outstanding, December 31, 2021	42,250	$ 3.25
Granted	—	—
Vested	—	—
Forfeited	—	—
RSUs outstanding at September 30, 2022	42,250	$ 3.25

Unrecognized compensation expense related to unvested options as of September 30, 2022 was $4.1 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 2.5 years. Unrecognized compensation expense related to unvested RSUs as of September 30, 2022 was $1,000 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 1 month.

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 nine months ended September 30, 2022, 23,658 shares of common stock were issued under the ESPP. As of September 30, 2022, there were 1,164,971 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 nine months ended September 30, 2021 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Research and development	$ 235	$ 263	$ 695	$ 781
General and administrative	384	522	1,034	1,320
Total	$ 619	$ 785	$ 1,729	$ 2,101

11. 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.

Pursuant to the terms of its lease agreement for the Company's headquarters, the Company obtained a letter of credit in the amount of approximately $182,000 as security on the lease obligation. The letter of credit is listed as restricted cash on the Company's consolidated balance sheets.

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 September 30, 2022 (in thousands):

Year ended:	
December 31, 2022	$ 151
December 31, 2023	596
December 31, 2024	9
December 31, 2025	1
Total minimum lease payments	757
Less imputed interest	(49)
Total	$ 708

	Nine Months Ended September 30,	
	2021	2022
Lease cost:		
Operating lease cost	$ 365	$ 376
Short-term lease cost	5	28
Sublease income	(39)	(39)
Total lease cost	$ 331	$ 365
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 396	$ 400
Operating cash flows from operating leases	$ (43)	$ (34)
Weighted-average remaining lease term - operating leases	1.2 years	1.2 years
Weighted-average discount rate - operating leases	10.1%	10.1%

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.

12. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

FDA Approval of FUROSCIX

On October 10, 2022, the Company announced that the U.S. Food and Drug Administration (FDA) approved FUROSCIX® (furosemide injection), a proprietary formulation of furosemide delivered via West Pharmaceutical Services, Inc.'s on-body infusor for the treatment of congestion due to fluid overload in adults with New York Heart Association Class II/III chronic heart failure.

Oaktree Financing

On October 13, 2022, the Company entered into the Oaktree Agreement. The Oaktree Agreement establishes a $100.0 million term loan facility, consisting of (i) $50.0 million funded immediately, (ii) $25.0 million that the Company may borrow in up to two draws on or prior to September 30, 2024 and (iii) $25.0 million that the Company may borrow on or prior to December 31, 2024.

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, 2021 (the "Annual Report") filed with the Securities and Exchange Commission (the "SEC") on March 22, 2022. 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 lead product candidate, FUROSCIX® (furosemide injection), consists of our novel formulation of furosemide delivered via West Pharmaceutical Services, Inc.'s on-body infusor. 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 not indicated for emergency situations or in patients with acute pulmonary edema. The FUROSCIX infusor will deliver only an 80-mg dose. 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. We expect the commercial launch of FUROSCIX in the first quarter of 2023.

Heart failure affects 7.2 million adults in the United States who collectively experience 4 million heart failure events annually. An estimated 59% of hospital admissions for heart failure are directly attributable to volume overload. Approximately 80% of heart failure patients discharged from hospital schedule a follow-up appointment and 25-30% of patients are readmitted to hospital post-discharge within 30 days. Repeat hospitalization for heart failure has been associated with increased mortality, with first-time discharges having a median survival (50% mortality) of 2.4 years, decreasing to 0.6 years following a fourth hospitalization. Our proprietary formulation of furosemide administered subcutaneously via an on-body infusor, which we refer to together as FUROSCIX, is intended to help alleviate the signs and symptoms associated with congestion due to fluid retention in heart failure patients, such as fatigue and shortness of breath. FUROSCIX is designed to offer alternative outpatient intervention for heart failure patients who display reduced responsiveness to oral diuretics in non-emergency situations and do not require hospitalization.

We believe FUROSCIX will allow heart failure patients to receive IV-strength diuresis outside the high-cost hospital setting. At a price of $822 per dose, we estimate the average cost of treatment with FUROSCIX for each heart failure exacerbation (comprising four doses of FUROSCIX) to be approximately $3,300. Prevention of hospital admission and reduced readmission rates would result in reducing the estimated 15 million days patients with heart failure spend in the hospital each year. By decreasing the number of admissions and readmissions to hospitals, we believe we can drive significant cost savings to payers and hospitals.

On September 30, 2022 we announced data from two poster presentations in connection with the Heart Failure Society of America's 2022 Annual Scientific Meeting. The first poster described the results of the AT HOME-HF study, a Phase 2, multicenter, pilot study where 51 subjects presenting to a heart failure clinic with worsening congestion requiring augmented diuresis were randomized (2:1) to receive FUROSCIX or enhanced oral diuretics. The objective of this pilot study was to evaluate prospective endpoints that could inform the design and sample size of a clinical trial that could be used to seek expansion of the indication for FUROSCIX to include a reduction of hospitalizations for heart failure or inclusion in treatment guidelines. Subjects in the AT HOME-HF study who received FUROSCIX demonstrated augmented decongestion compared with patients receiving enhanced oral diuretics as demonstrated by:

- Improved diuresis as measured by a greater reduction in body weight from baseline at study day 3 (2.8 kg vs 0.8 kg, p=0.035);
- Improvement from baseline in mean 5-point dyspnea score at day 3 (-0.5 vs. 0.1, p=0.019);
- Greater number of patients with markedly or moderately better shortness of breath based on 7-point dyspnea at day 3 (44% vs 6%, p=0.006);

- Clinically relevant improvement from baseline in quality of life as measured by Kansas City Cardiomyopathy questionnaire – 12 (KCCQ-12) summary score at study days 7 and 30 of 8.9 points and 9.3 points, respectively; and
- An increase of 55.8 meters in the average six-minute walk distance at day 30 (36.7 vs -19.1 meters, p=.012).

The win-ratio for the hierarchical endpoint of cardiovascular death, heart failure hospitalization, urgent ED/clinic visit for heart failure and the percentage change in NT-proBNP from baseline at day seven was 1.11 (95% Confidence Interval: 0.48-2.50) favoring the FUROSCIX group.

During the 30-day study period, subjects in the FUROSCIX group spent an average of 23.2 days heart failure event free compared to 14.3 in subjects receiving enhanced oral diuretics.

In the FUROSCIX group, 14.7% of subjects had a serum potassium level that was less than 3.5 mEq/L during the 30-day study and was managed effectively with oral potassium supplements.

The results of the AT HOME-HF study showed that subjects receiving subcutaneous FUROSCIX demonstrated augmented decongestion, as evidenced by a greater reduction in body weight, better dyspnea scores, greater exercise capacity and improvement of health-related quality of life compared with patients receiving enhanced oral diuretics, or standard treatment in a phase 2, pilot study. The favorable results in the AT HOME-HF study support conducting an adequately powered study.

The second poster presented described a study examining patients with brief hospitalizations related to acute decompensated heart failure (“ADHF”). This study investigated the volume, length of stay (“LOS”) and patient characteristics of patients hospitalized for ADHF in the US using the multicenter National Inpatient Sample (“NIS”) representing approximately 20% of US acute care hospitals. Of the approximately 5 million discharges with any heart failure diagnosis code, 1.2 million patients had heart failure as the principal diagnosis code and approximately 43% of such patients had a LOS of less than three days (“SLOS”) with the average LOS being 2.2 days. Compared to patients with LOS greater than three days, SLOS patients were less likely to require mechanical ventilation (2.8% vs 0.7%), dialysis (2.9% vs 0.4%) and undergo diagnostic procedures (70.4% vs 48.4%). SLOS patients were more likely to have a routine discharge to home (61.8% vs 39.7%). Based on these results, we concluded that an alternative outpatient heart failure management may allow many patients to avoid the need for short hospitalizations with its potential complications and healthcare costs.

Oaktree Financing

On October 13, 2022 (the "Closing Date"), we 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 (in such capacity, the “Agent”). The Oaktree Agreement establishes a $100.0 million term loan facility, consisting of (i) $50.0 million (the “Tranche A Loan”) funded immediately, (ii) $25.0 million (the “Tranche B Loan”) that we may borrow in up to two draws on or prior to September 30, 2024 and (iii) $25.0 million (the “Tranche C Loan” and, together with the Tranche A Loan and the Tranche B Loan, collectively, the “Term Loan”) that we may borrow on or prior to December 31, 2024; provided, in the case of the Tranche B Loan and the Tranche C Loan, that we have achieved certain net sales revenue milestone targets described in the Oaktree Agreement. The Term Loan has a maturity date of October 13, 2027 (the “Maturity Date”). We used a portion of the proceeds of the Term Loan to prepay all outstanding loans under our existing credit facility with SLR Investment Corp. and Silicon Valley Bank and intend to use the remainder of the proceeds to support our commercialization efforts for FUROSCIX and other working capital and general corporate purposes, including the payment of fees and expenses associated with the Oaktree Agreement.

Borrowings under the Term Loan will bear interest at a rate per annum equal to three-month term Secured Overnight Financing Rate ("SOFR") (subject to a 1.00% floor and a 3.00% cap), plus an applicable margin of 8.75%, payable monthly in arrears. From and after achieving $100.0 million in trailing 12-month net sales of FUROSCIX, the applicable margin shall be reduced from 8.75% to 8.25% through the Maturity Date. For the first two years, we may elect to pay up to 3.00% of interest in-kind. We are also permitted to make quarterly interest-only payments on the Term Loan through December 31, 2025. Beginning on March 31, 2026, we will be required to make quarterly payments of interest, plus repay 5.00% of the outstanding principal of the Term Loan in quarterly installments until maturity (subject to certain exceptions).

The Oaktree Agreement contains customary representations, warranties and affirmative and negative covenants, including financial covenants requiring us to (i) maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least $15.0 million at all times commencing from 30 days after the Closing Date and increasing to $20.0 million of cash and cash equivalents in such controlled accounts after we borrow the Tranche B Loan and (ii) meet minimum quarterly net sales revenue targets described in the Oaktree Agreement.

In connection with the Oaktree Agreement, we issued the Lenders warrants to purchase an aggregate of 516,345 shares of our common stock at an exercise price of $5.40 per share. The warrants are immediately exercisable, and the exercise period will expire 7 years from the date of issuance.

We have funded our operations from inception through September 30, 2022 primarily through the sale of shares of our common stock and, prior to that, through the private placement of our preferred stock and the incurrence of debt. Our first product, FUROSCIX, was approved for sale in October 2022 and therefore, we have not generated any revenue from product sales.

As of September 30, 2022, we had an accumulated deficit of $217.3 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. We will need additional funding to pay expenses related to our operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition.

IMPACT OF COVID-19

A new strain of novel coronavirus which causes a severe respiratory disease (“COVID-19”) was identified in 2019, and subsequently declared a pandemic by the World Health Organization, affecting the populations of the United States as well as the rest of the world. In response to the pandemic, we transitioned our workforce to work from home in March 2020. In July 2020, we opened our offices for limited access to employees integrating all recommendations for workplace safety, including appropriate protocols to ensure social-distancing. In May 2022, we expanded the opening of our offices to accommodate a hybrid work environment for our employees with access to our facilities five days a week. The health of our employees remains a top priority and we are continuing to monitor the impact of COVID-19, including the pace of vaccinations, the emergence of new and more contagious strains of the virus and government regulations.

To date, the third parties that perform our manufacturing, assembly, packaging and testing of our products have experienced delays relating to supply chain logistics but have generally remained operational. The extent of the impact of the evolving COVID-19 pandemic on the ability to timely enroll patients in our upcoming clinical trials and our operational and financial performance will depend on future developments, including the duration, severity and spread of the pandemic, related restrictions on travel and transportation, the impact of new strains of the virus, the effectiveness and availability of vaccines and other actions that may be taken by governmental authorities. Such developments may also impact our commercialization efforts of FUROSCIX, the business of our suppliers, service providers or customers, and other items identified under “Risk Factors” in this Quarterly Report and in our Annual Report, all of which are uncertain and cannot be predicted. An extended period of global supply chain and economic disruption may continue to impact us and could materially affect our business, results of operations, access to sources of liquidity and financial condition.

COMPONENTS OF OUR RESULTS OF OPERATIONS

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 lead 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.

General and Administrative Expenses

General and administrative ("G&A") expenses consist of employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense for personnel in executive, finance, commercial, human resources, facility operations and administrative functions. Other G&A expenses include pre-approval 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.

With the approval of FUROSCIX, we anticipate that our G&A expenses will increase as we continue to build our corporate and commercial infrastructure to support the commercialization activities of FUROSCIX in the United States.

Results of Operations

Comparison of Three Months Ended September 30, 2021 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2022 (in thousands):

	Three Months Ended September 30,		Increase
	2021	2022	(Decrease)
Operating expenses:			
Research and development	$ 3,694	$ 3,718	$ 24
General and administrative	2,211	6,277	4,066
Total operating expenses	5,905	9,995	4,090
Loss from operations	(5,905)	(9,995)	4,090
Other income (expense)	10	(22)	(32)
Interest income	10	232	222
Interest expense	(667)	(377)	(290)
Net loss	$ (6,552)	$ (10,162)	$ 3,610

Research and development expenses. R&D expenses were $3.7 million for the three months ended September 30, 2022, compared to $3.7 million for the three months ended September 30, 2021.

General and administrative expenses. G&A expenses were $6.3 million for the three months ended September 30, 2022, compared to $2.2 million for the three months ended September 30, 2021. The increase of $4.1 million was primarily attributable to a $2.7 million increase in employee-related costs, a $1.3 million increase in commercial preparation costs, and a $0.1 million increase in legal and public company costs.

Other income (expense). Other expense was $22,000 for the three months ended September 30, 2022, compared to other income of $10,000 for the three months ended September 30, 2021. The decrease in income of $32,000 was primarily attributable to income from a rental arrangement in the three months ended September 30, 2021 and foreign exchange losses in the three months ended September 30, 2022.

Interest income. Interest income was $232,000 for the three months ended September 30, 2022, compared to $10,000 for the three months ended September 30, 2021. The increase of $222,000 was primarily attributable to higher interest rates on our financial instruments.

Interest expense. Interest expense was $377,000 for the three months ended September 30, 2022 compared to $667,000 for the three months ended September 30, 2021. The decrease of $290,000 was due to lower term loan balances as a result of principal payments payable pursuant to our $20.0 million term loan with SLR Investment Corp. (f/k/a Solar Capital Ltd.) and Silicon Valley Bank, entered into in September 2019 (the "2019 Loan Agreement"), which commenced October 1, 2021.

Comparison of Nine Months Ended September 30, 2021 and September 30, 2022

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2022 (in thousands):

	Nine Months Ended September 30,		Increase (Decrease)
	2021	2022	
Operating expenses:			
Research and development	$ 11,509	$ 13,207	$ 1,698
General and administrative	7,593	13,448	5,855
Total operating expenses	19,102	26,655	7,553
Loss from operations	(19,102)	(26,655)	7,553
Other income	298	55	(243)
Interest income	42	353	311
Interest expense	(1,954)	(1,343)	(611)
Net loss	$ (20,716)	$ (27,590)	$ 6,874

Research and development expenses. R&D expenses were $13.2 million for the nine months ended September 30, 2022, compared to $11.5 million for the nine months ended September 30, 2021. The increase of $1.7 million was primarily attributable to a $1.8 million increase in pharmaceutical development and supplies, a $0.9 million increase in employee-related costs, and a $0.2 million increase in patent related costs. The increase was offset by a $0.6 million decrease in clinical study costs, a $0.3 million decrease in regulatory consulting costs, a $0.2 million decrease in medical affairs consulting costs, and a $0.1 million decrease in device development costs.

General and administrative expenses. G&A expenses were $13.4 million for the nine months ended September 30, 2022, compared to $7.6 million for the nine months ended September 30, 2021. The increase of $5.9 million was primarily attributable to a $4.1 million increase in employee-related costs, a $1.9 million increase in commercial preparation costs, and a $0.1 million increase in public company costs. The increase was offset by a $0.2 million decrease in professional service costs.

Other income. Other income was $55,000 for the nine months ended September 30, 2022, compared to $298,000 for the nine months ended September 30, 2021. The decrease in income of $243,000 was primarily attributable to the recovery of fees associated with a post-employment matter in the nine months ended September 30, 2021 and foreign exchange losses in the nine months ended September 30, 2022.

Interest income. Interest income was $353,000 for the nine months ended September 30, 2022, compared to $42,000 for the nine months ended September 30, 2021. The increase of $311,000 was primarily attributable to higher interest rates on our financial instruments.

Interest expense. Interest expense was $1.3 million for the nine months ended September 30, 2022 compared to $2.0 million for the nine months ended September 30, 2021. The decrease of $0.6 million was due to lower term loan balances as a result of principal payments payable pursuant to our 2019 Loan Agreement, which commenced October 1, 2021.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through September 30, 2022 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 September 30, 2022, we had received net cash proceeds of $92.7 million from our initial public offering, $56.7 million from sales of our preferred stock, $18.8 million from borrowings under our term loan, $13.5 million from sales of convertible notes, $50.2 million from our public offering in 2020 and $14.4 million from the sale of common stock in our 2019 at-the-market offering. As of September 30, 2022, we had cash, cash equivalents and restricted cash of $41.5 million and short-term investments of $3.9 million.

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 September 30, 2022, we had received no proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

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.

We expect to incur substantial additional expenditures in the near future to support our ongoing activities and our plans to execute on the launch of FUROSCIX. We believe our existing unrestricted cash is 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 commence U.S. commercialization of FUROSCIX, including the development of a 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 establishing 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;
- the impact of COVID-19 on our operations; 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.

CASH FLOWS

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

	Nine Months Ended September 30,	
(in thousands)	**2021**	**2022**
Net cash (used in) provided by:		
Operating activities	$ (20,053)	$ (22,740)
Investing activities	27,629	(2,867)
Financing activities	(72)	(7,372)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 7,504	$ (32,979)

Net Cash Used in Operating Activities

During the nine months ended September 30, 2022, net cash used in operating activities was $22.7 million, consisting primarily of a net loss of $27.6 million. This was offset by an increase in net operating liabilities of $2.1 million and non-cash charges of $2.7 million. The increase in net operating liabilities is related to accounts payable and accrued expenses for commercial activity, legal,

employee-related costs, and pharmaceutical development and supplies, 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 premium on investments.

During the nine months ended September 30, 2021, net cash used in operating activities was $20.1 million, consisting primarily of a net loss of $20.7 million and an increase in net operating assets of $1.9 million. This was offset by non-cash charges of $2.6 million, which 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. The increase in net operating assets is related to accrued expenses for employee-related and device development costs.

Net Cash Provided by (Used in) Investing Activities

During the nine months ended September 30, 2022, net cash used in investing activities was $2.9 million, consisting primarily of purchases of short-term investments, net of maturities.

During the nine months ended September 30, 2021, net cash provided by investing activities was $27.6 million, consisting primarily of maturities of short-term investments, net of purchases.

Net Cash Used in Financing Activities

During the nine months ended September 30, 2022, net cash used in financing activities was $7.4 million, consisting primarily of principal term loan payments, offset by purchases pursuant to our 2017 Employee Stock Purchase Plan and stock option exercises.

During the nine months ended September 30, 2021, net cash used in financing activities was $72,000, consisting primarily of tax obligations on the settlement of restricted stock units, offset by 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. During the nine months ended September 30, 2022, there were no material changes to our critical accounting policies and estimates from those discussed in our Annual Report.

JOBS ACT ACCOUNTING ELECTION

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to avail ourselves of this extended transition period and, as a result, we adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. This election is irrevocable.

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 September 30, 2022, our aggregate outstanding indebtedness was $10.0 million, which bore interest at the rate of the higher of (i) LIBOR plus 7.95% or (ii) 10.18%. This debt was repaid on October 13, 2022 in connection with our entry into the Oaktree Agreement. For additional information surrounding the Oaktree Agreement, see Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Oaktree Financing of this Quarterly Report on Form 10-Q. Interest on indebtedness assumed subsequent to quarter end bears interest at a rate per annum equal to three-month term SOFR (subject to a 1.00% floor and a 3.00% cap), plus an applicable margin of 8.75%. Due to the short-term duration and variable rate 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 September 30, 2022, 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 September 30, 2022 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. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors described in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2021 (the "Annual Report"), which was filed with the SEC on March 22, 2022. Except as discussed below, there have been no material changes from the risk factors previously disclosed in our Annual Report.

If we fail to produce FUROSCIX in the volumes that we require on a timely basis, we may face delays in our commercialization efforts.

We do not currently own or operate manufacturing facilities for the production of any of our product candidates, including FUROSCIX. We currently depend on third parties to manufacture our product candidates, including the drug formulation and device components for FUROSCIX, and expect to continue to rely on such third parties to produce the final commercial product. Any future curtailment in the availability of materials could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Pharmaceutical companies often encounter difficulties in production, particularly in scaling up production, of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. Recently, a third party supplier informed us of a potential quality issue relating to one component part of the on-body infusor. As of the date of this Quarterly Report on Form 10-Q, we are engaging with our third party supplier in an additional quality review on this component. We currently believe we will have a sufficient number of completed on-body infusors to support a commercial launch in the first quarter of 2023. However, these projections could change based on further developments. Any such delays in the manufacturing of finished drug product or device components could delay our commercial supply, which could delay, prevent or limit our ability to generate revenue and continue our business. Moreover, if we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to market our product candidate would be jeopardized.

Manufacturers of combination products need to comply with both pharmaceutical current good manufacturing practice requirements, or cGMPs, and medical device Quality System Regulations, or QSRs, enforced by the FDA through its facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP and QSR requirements and with other FDA and foreign regulatory requirements. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any of our product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize such product candidate, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in the commercialization of our product candidates, entail higher costs or even prevent us from effectively commercializing our product candidates.

Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for supply of the active pharmaceutical ingredients, or API, in our product candidates, and our furosemide formulation, as well as the device components

of our drug-device combination product candidates. Our current strategy is to outsource all manufacturing of our product candidates and products to third parties.

We currently engage third-party manufacturers to manufacture FUROSCIX and related supplies and packaging. For example, we have engaged a third-party manufacturer for the manufacture of the furosemide formulation used in FUROSCIX and we have engaged a third party designer and manufacturer, West, to develop and manufacture the on-body infusor for FUROSCIX. There is no guarantee that we can maintain our relationships with these manufacturers and we may incur added costs and delays in identifying and qualifying any replacements for such manufacturers. There is no assurance that we will be able to timely secure further needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to commercialize FUROSCIX. There may be difficulties and delays in scaling up to commercial quantities of FUROSCIX and the costs of manufacturing could be prohibitive. Beyond FUROSCIX, third parties also manufacture the materials that we require for the development of our other product candidates, and our reliance on these manufacturers for these activities carries similar risks as our reliance on third-party manufacturers in connection with FUROSCIX.

Reliance on third-party manufacturers entails additional risks, including:

- reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us.

Recently, a third party supplier informed us of a potential quality issue relating to one component part of the on-body infusor. As of the date of this Quarterly Report on Form 10-Q, we are engaging with our third party supplier in an additional quality review on this component. We currently believe we will have a sufficient number of completed on-body infusors to support a commercial launch in the first quarter of 2023. However, these projections could change based on further developments. If we do not maintain our key manufacturing relationships or if our third-party manufactures fail to comply with applicable regulations, we may need to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

If any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our product supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our lead product candidate, FUROSCIX, is a drug-device combination product that will be regulated under the drug regulations of the FDA based on its primary mode of action as a drug. Third-party manufacturers may not be able to comply with the regulatory requirements, known as cGMP, applicable to drug-device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the QSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and QSRs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could cause significant delays in our operating timelines and would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with applicable cGMPs and QSRs. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP or QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

The terms of our credit facility place restrictions on our operating and financial flexibility, and we may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

In October 2022, we entered into a credit agreement and guarantee, or the Credit Agreement, with, among others, the lenders from time to time party thereto, or the Lenders, and Oaktree Fund Administration, LLC, in its capacity as administrative agent for the Lenders. The Credit Agreement establishes a $100.0 million term loan facility, consisting of (i) $50.0 million, or the Tranche A Loan, funded at closing, (ii) $25.0 million, or the Tranche B Loan, that we may borrow in up to two draws on or prior to September 30, 2024, and (iii) $25.0 million, or the Tranche C Loan, that we may borrow on or prior to December 31, 2024; provided, in the case of the Tranche B Loan and the Tranche C Loan, that we have achieved certain net sales revenue milestone targets described in the Credit Agreement. We used a portion of the proceeds from the Tranche A Loan to prepay all outstanding loans under our prior loan and security agreement with SLR Investment Corp. (f/k/a Solar Capital Ltd.) and Silicon Valley Bank. All obligations under our secured credit facility are secured by substantially all of our existing property and assets (including our intellectual property assets), subject to certain exceptions. This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity.

The Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including financial covenants requiring us to (i) maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of Oaktree of at least $15.0 million at all times commencing from November 13, 2022 and increasing to $20.0 million of cash and cash equivalents in such controlled accounts after we borrow the Tranche B Loan, and (ii) meet minimum quarterly net sales revenue targets described in the Credit Agreement. In addition, the Credit Agreement contains customary events of default that entitle Oaktree to accelerate our indebtedness under the Credit Agreement to become immediately due and payable. Under the Credit Agreement, an event of default will occur if, among other things, we fail to make payments under the Credit Agreement (subject to specified periods), we or our subsidiaries breach any of the covenants under the Credit Agreement (subject to specified cure periods with respect to certain breaches), a material adverse change occurs, we, our subsidiaries or our respective assets become subject to certain legal proceedings, such as bankruptcy proceedings, we and/or our subsidiaries are unable to pay our debts as they become due or default on contracts with third parties which would permit the holder of indebtedness in excess of a certain threshold to accelerate the maturity of such indebtedness or that could cause a material adverse change.

Failure to satisfy our current and future debt obligations, including covenants to take or avoid specific actions, under our secured credit facility could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under our secured credit facility as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness while still pursuing our current business strategy. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

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).
10.1	Credit Agreement and Guaranty, dated October 13, 2022, by and among scPharmaceuticals Inc., the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Oaktree Fund Administration, LLC, as administrative agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on October 14, 2022).
31.1*	Certification of Principal Executive Officer and 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 and 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: November 9, 2022

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

Exhibit 31.1

Certification

I, John H. Tucker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2022 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. I am 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. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2022

/s/ John H. Tucker

John H. Tucker

President and Chief Executive Officer
(Principal Executive Officer and 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 September 30, 2022, 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 and 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: November 9, 2022

/s/ John H. Tucker

John H. Tucker

President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)