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, 2021

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

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	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, 2021, the Registrant had 27,355,454 common shares, $0.0001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements 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. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the completion of activities required for the resubmission of the FUROSCIX® new drug application, or NDA, with West's proprietary on-body infusor on our current projected timelines and subsequent review and potential approval by the U.S. Food and Drug Administration, or FDA, including any delays in submission or approval related to COVID-19;
- the likelihood of approval by the FDA of our regulatory filings for FUROSCIX using our next generation delivery device;
- the timing or likelihood of other regulatory filings and approvals;
- the outcome of any bridging studies, clinical trials or human factors studies that may be required by the FDA for approval of any of our product candidates;
- the commercialization of FUROSCIX, if approved, including launch preparation, ability to interact with physicians, patient access to FUROSCIX or manufacturing and supply chain matters;
- the pricing, reimbursement or pharmacoeconomic benefit of FUROSCIX or any other of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of FUROSCIX or any other of our product candidates for which we receive marketing approval;
- the initiation, timing, progress and results of our research and development programs, including future preclinical and clinical studies;
- our ability to advance any other product candidates into, and successfully complete, clinical studies and obtain regulatory approval for them;
- our ability to identify additional product candidates;
- the implementation of our strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering FUROSCIX or any other of our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to manufacture, or the ability of third parties to deliver, sufficient quantities of components and drug product for commercialization of FUROSCIX or any other of our product candidates, including any delays related to COVID-19;
- our ability to maintain and establish collaborations;
- our financial performance;
- developments relating to our competitors and our industry, including the impact of government regulation; and
- other risks and uncertainties, including those listed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020.

In some cases, forward-looking statements can be identified by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Item 1A, "Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission on March 23, 2021, 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 on Form 10-Q.

SCPHARMACEUTICALS INC.

INDEX

PART I — FINANCIAL INFORMATION

SCPHARMACEUTICALS INC.

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

	December 31, 2020	September 30, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 71,819	$ 79,323
Short-term investments	33,276	5,515
Prepaid expenses	2,610	1,621
Other current assets	121	11
Total current assets	107,826	86,470
Restricted cash	182	182
Property and equipment, net	93	77
Right-of-use lease assets - operating, net	815	513
Deposits and other assets	132	289
Total assets	$ 109,048	$ 87,531
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,666	$ 447
Accrued expenses	4,787	3,484
Term loan, short-term	2,408	9,777
Lease obligation - operating, short-term	460	497
Total current liabilities	9,321	14,205
Term loan, long-term	16,858	9,777
Lease obligation - operating, long-term	480	99
Other liabilities	219	340
Total liabilities	26,878	24,421
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, 2021; 27,325,959 and 27,355,454 shares issued and outstanding as of December 31, 2020 and September 30, 2021, respectively	3	3
Additional paid-in capital	243,830	245,487
Accumulated deficit	(161,664)	(182,380)
Accumulated other comprehensive gain	1	-
Total stockholders' equity	82,170	63,110
Total liabilities and stockholders' equity	$ 109,048	$ 87,531

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,	
	2020	2021	2020	2021
Operating expenses:				
Research and development	$ 5,119	$ 3,694	$ 14,404	$ 11,509
General and administrative	3,319	2,211	8,359	7,593
Total operating expenses	8,438	5,905	22,763	19,102
Loss from operations	(8,438)	(5,905)	(22,763)	(19,102)
Other income (expense)	19	10	(13)	298
Interest income	36	10	281	42
Interest expense	(655)	(667)	(1,930)	(1,954)
Net loss	$ (9,038)	$ (6,552)	$ (24,425)	$ (20,716)
Net loss per share — basic and diluted	$ (0.33)	$ (0.24)	$ (1.03)	$ (0.76)
Weighted average common shares outstanding — basic and diluted	27,319,465	27,355,454	23,644,580	27,349,279
Other comprehensive loss:				
Unrealized gain on short-term investments	$ 8	$ -	$ 8	$ -
Comprehensive loss	$ (9,030)	$ (6,552)	$ (24,417)	$ (20,716)

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, 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
At December 31, 2019	19,418,955	$ 2	$ 180,818	$ (129,455)	$ —	$ 51,365
Net loss	—	—	—	(7,092)	—	(7,092)
Issuance of common stock under at-the-market offering net of commissions and issuance costs (Note 9)	1,502,892	—	10,253	—	—	10,253
Issuance of common stock upon exercise of stock options	30,143	—	154	—	—	154
Vesting of restricted stock	29,890	—	(84)	—	—	(84)
Stock-based compensation	—	—	508	—	—	508
At March 31, 2020	20,981,880	2	191,649	(136,547)	—	55,104
Net loss	—	—	—	(8,295)	—	(8,295)
Common stock offering, net of commissions and issuance costs (Note 9)	6,220,589	1	50,147	—	—	50,148
Issuance of common stock upon exercise of stock options	85,528	—	561	—	—	561
Vesting of restricted stock	—	—	(80)	—	—	(80)
Stock-based compensation	—	—	621	—	—	621
At June 30, 2020	27,287,997	3	242,898	(144,842)	—	98,059
Net loss	—	—	—	(9,038)	—	(9,038)
Issuance costs	—	—	40	—	—	40
Issuance of common stock upon exercise of stock options	500	—	2	—	—	2
Vesting of restricted stock	31,962	—	—	—	—	—
Stock-based compensation	—	—	744	—	—	744
Unrealized gain on short-term investments	—	—	—	—	8	8
At September 30, 2020	27,320,459	$ 3	$ 243,684	$ (153,880)	$ 8	$ 89,815

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,	
	2020	2021
Cash flows from operating activities		
Net loss	$ (24,425)	$ (20,716)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	25	26
Amortization expense - right-of-use leased assets - operating	270	301
Accretion of discount on investments	45	120
Stock-based compensation	1,873	1,729
Non-cash interest expense	380	410
Fair value adjustment to derivative liability	30	-
Changes in operating assets and liabilities		
Prepaid expenses and other assets	1,671	941
Accounts payable, accrued expenses and other liabilities	1,618	(2,864)
Net cash used in operating activities	(18,513)	(20,053)
Cash flows from investing activities		
Purchases of property and equipment	-	(10)
Maturities of short-term investments	-	36,650
Purchases of short-term investments	(70,161)	(9,011)
Net cash (used in) provided by investing activities	(70,161)	27,629
Cash flows from financing activities		
Proceeds from common stock offering, net	50,187	-
Proceeds from at-the-market offering, net	10,388	-
Proceeds from the exercise of vested stock options	717	9
Payment of term loan exit fee	(800)	-
Settlements of restricted stock units for tax withholding obligations	(164)	(81)
Net cash provided by (used in) financing activities	60,328	(72)
Net (decrease) increase in cash, cash equivalents and restricted cash	(28,346)	7,504
Cash, cash equivalents and restricted cash at beginning of period	72,806	72,001
Cash, cash equivalents and restricted cash at end of period	$ 44,460	$ 79,505
Supplemental cash flow information		
Interest paid	$ 1,471	$ 1,550
Taxes paid	$ 144	$ 166
Supplemental non-cash information		
Transfer of issuance costs from other noncurrent assets to equity	$ 135	$ -

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, 2020 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 23, 2021. The Company has determined that it operates in one segment.

The accompanying condensed consolidated balance sheet as of September 30, 2021, the condensed consolidated statements of operations and comprehensive loss and stockholders' equity for the three and nine months ended September 30, 2020 and 2021 and condensed consolidated statements of cash flows for the nine months ended September 30, 2020 and 2021 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, 2021 are not necessarily indicative of the results expected for the full year ending December 31, 2021.

Liquidity

As of September 30, 2021, the Company had an accumulated deficit of approximately $182.4 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, 2021, the Company had cash, cash equivalents, restricted cash, and short-term investments of $85.0 million. The Company believes that its existing cash, cash equivalents, restricted cash and short-term investments 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.

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, 2021, 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, 2020	September 30, 2021
Cash and cash equivalents	$ 71,819	$ 79,323
Restricted cash	182	182
Cash, cash equivalents and restricted cash	$ 72,001	$ 79,505

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 corporate debt 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, 2021, the Company had no such accruals.

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,	
	2020	2021	2020	2021
Net loss	$ (9,038)	$ (6,552)	$ (24,425)	$ (20,716)
Weighted-average shares used in computing net loss per share	27,319,465	27,355,454	23,644,580	27,349,279
Net loss per share, basic and diluted	$ (0.33)	$ (0.24)	$ (1.03)	$ (0.76)

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,	
	2020	2021	2020	2021
Stock options to purchase common stock	2,183,217	2,677,743	2,183,217	2,677,743
Unvested restricted stock units	80,450	42,250	80,450	42,250
Total	2,263,667	2,719,993	2,263,667	2,719,993

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

	At September 30, 2021			
Investments - Current:	Cost Basis	Accumulated Unrealized Gains	Accumulated Unrealized Losses	Fair Value
Corporate debt securities	$ 4,498	$ -	$ -	$ 4,498
Commercial paper	1,017	-	-	1,017
Total	$ 5,515	$ -	$ -	$ 5,515

The amortized cost and fair value of the Company's available-for-sale investments, by contract maturity, as of September 30, 2021 consisted of the following (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$ 5,515	$ 5,515
Total	$ 5,515	$ 5,515

5. Property and Equipment

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

	ESTIMATED USEFUL LIFE	December 31, 2020	September 30, 2021
Office equipment	5 years	$ 10	$ 10
Office furniture	7 years	116	126
Computer equipment	3 years	8	8
Leasehold improvements	Life of lease	95	95
		229	239
Less: Accumulated depreciation		(136)	(162)
Property and equipment, net		$ 93	$ 77

Depreciation expense for the three months ended September 30, 2020 and September 30, 2021 was $8,000 and $10,000, respectively.

Depreciation expense for the nine months ended September 30, 2020 and September 30, 2021 was $25,000 and $26,000, respectively.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2020	September 30, 2021
Contract research and development	$ 2,274	$ 1,954
Employee compensation and related costs	1,978	930
Consulting and professional service fees	364	311
Interest	88	170
Financing related costs	43	60
Deposit liability	-	20
State taxes	40	17
Other	-	22
Total accrued expenses	$ 4,787	$ 3,484

7. Fair Value of Financial Instruments

The 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, 2020			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 70,797	$ 68,798	$ 1,999	$ —
Total cash equivalents	70,797	68,798	1,999	—
United States Treasury securities	8,213	8,213	—	—
Corporate debt securities	11,973	—	11,973	—
Commercial paper	13,090	—	13,090	—
Investments	33,276	8,213	25,063	—
Total	$ 104,073	$ 77,011	$ 27,062	$ —

	As of September 30, 2021			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 76,946	$ 76,946	$ —	$ —
Total cash equivalents	76,946	76,946	—	—
Corporate debt securities	1,017	—	1,017	—
Commercial paper	4,498	—	4,498	—
Investments	5,515	—	5,515	—
Total	$ 82,461	$ 76,946	$ 5,515	$ —

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. The 2017 Loan Agreement had a maturity date of May 1, 2021. Debt issuance costs for the 2017 Loan Agreement were to be amortized to interest expense over the remaining term of the 2017 Loan Agreement using the effective-interest method.

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 restructured four-year term loan facility allows for an expansion of the 2017 Loan Agreement. Some of the proceeds from the 2019 Loan Agreement were used to pay off the 2017 Loan Agreement including the final fee of $325,000. The 2019 Loan Agreement extends the term of the credit facility until September 17, 2023. The payoff of the 2017 Loan Agreement was treated as a modification of the debt. Debt issuance costs for the 2019 Loan Agreement, including unamortized issuance costs for the 2017 Loan Agreement, will 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 is the higher of (i) LIBOR plus 7.95% or (ii) 10.18% and there is an interest-only period until September 30, 2021. The rate at September 30, 2021 was 10.18%. Pursuant to the 2019 Loan Agreement, the

Company provided a first priority security interest in substantially all of the Company's assets, including intellectual property, subject to certain exceptions.

The Company entered into an Exit Agreement in connection with the 2019 Loan Agreement which provides 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 concluded that the exit payment obligation met the definition of a derivative that was required to be accounted for as a separate unit of accounting. The Company recorded the issuance-date fair value of the derivative liability of $763,000 as a debt discount and as a derivative liability in the Company's balance sheet. The derivative liability is re-measured at each balance sheet date and any changes in estimated fair value is recorded as other income (expense). 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. Prior to its public offering in 2020, the Company recorded $30,000 in non-cash expense as a fair value adjustment to the derivative liability.

As of September 30, 2021, unpaid borrowings under the 2019 Loan Agreement totaled $20.0 million. 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. For the three and nine months ended September 30, 2020, the Company recorded $94,000 and $260,000, respectively, related to the amortization of debt discount associated with the 2019 Loan Agreement.

The 2019 Loan Agreement allows 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 is due upon the earlier to occur of the maturity date or prepayment of such borrowings. 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. For the three and nine months ended September 30, 2020, the Company recorded $40,000 and $120,000, 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 will be increased by 5% and the balance under the loan may become immediately due and payable at the option of the lenders.

The 2019 Loan Agreement includes 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, 2021
Face value	$ 20,000
Less: discount	(446)
Total	$ 19,554
Less: current portion	(9,777)
Long-term portion	$ 9,777

As of September 30, 2021, future principal payments due under the 2019 Loan Agreement are as follows (in thousands):

Year ended:	
December 31, 2021	$ 2,500
December 31, 2022	10,000
December 31, 2023	7,500
Total	$ 20,000

9. Stockholders' Equity

2019 At-the-Market Issuance Sales Agreement

On August 23, 2019, the Company entered into an Open Market Sale Agreement℠ ("2019 ATM Agreement"), with Jefferies LLC ("Jefferies") with respect to an at-the-market offering program (the "2019 ATM Program") under which the Company could offer and sell shares of its common stock (the "2019 ATM Shares"), having an aggregate offering price of up to $15.0 million through

Jefferies as its sales agent. The offering and sale of 2019 ATM Shares were made pursuant to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC on February 11, 2019 (the "Registration Statement").

The Company agreed to pay Jefferies a commission equal to 3.0% of the gross sales proceeds of such 2019 ATM Shares. The Company incurred $189,000 of legal, accounting and other costs to establish and activate the 2019 ATM program.

During 2020, the Company sold a total of 1,502,892 2019 ATM Shares under the 2019 ATM Agreement, in the open market, at a weighted average gross selling price of $7.13 per share for net proceeds of $10.4 million, which completed the program. The Company charged $135,000 in costs related to establishing and activating the program against additional paid in capital upon issuance of shares during 2020.

2021 At-the-Market Issuance Sales Agreement

On March 23, 2021, the Company entered into an Open Market Sale Agreement (the "2021 ATM Agreement") with Cowen and Company, LLC ("Cowen") with respect to an at-the-market offering program (the "2021 ATM 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, 2021, the Company had received no proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

Sale of Common Stock

In May 2020, the Company completed an underwritten public offering of 5,780,347 shares of its common stock (the "2020 Offering Shares"), pursuant to the Registration Statement. The 2020 Offering Shares were sold at an offering price of $8.65 per share, resulting in net proceeds of $46.6 million, after deducting underwriting discounts, commissions and offering expenses. In addition, the underwriters of the offering were granted the option for a period of 30 days to purchase up to an additional 867,052 shares of common stock at $8.65 per share. In June 2020, the underwriters exercised their option and purchased an additional 440,242 shares of common stock at $8.65 per share, resulting in additional net proceeds to the Company of $3.6 million, after deducting underwriting discounts, commissions and offering expenses.

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 upon the completion of the Company's initial public offering and no further options were granted under the 2014 Stock Plan. At September 30, 2021, there were 600,688 options outstanding under the 2014 Stock Plan.

As of September 30, 2021, there were 5,051,920 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan, including 359,651 options that have been forfeited from the 2014 Stock Plan.

At September 30, 2021, there were 2,902,811 options available for issuance under the 2017 Stock Plan, 2,077,055 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,	
	2020	2021
Risk-free interest rate	0.41% - 1.71%	0.50% - 0.88%
Expected dividend yield	0%	0%
Expected life	5.5-6.6 years	5.5-6.7 years
Expected volatility	72%-75%	72%-74%
Weighted-average grant date fair value	$ 4.06	$ 4.25

The following table summarizes information about stock option activity during the nine months ended September 30, 2021 (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, 2020	2,224,913	$ 6.26		
Granted	911,506	6.68		
Exercised	(2,501)	3.81		
Forfeited	(456,175)	6.64		
Outstanding, September 30, 2021	2,677,743	$ 6.34	7.72	$ 2,821
Vested and exercisable, September 30, 2021	1,293,635	$ 5.97	6.39	$ 2,265
Vested and expected to vest, September 30, 2021	2,190,833	$ 6.27	7.43	$ 2,643

Of the options granted during the nine months ended September 30, 2021, 112,050 were performance-based options. Vesting of these performance-based options is contingent on the occurrence of certain regulatory and commercial milestones. The Company is recognizing the expense straight-line over the expected performance achievement term.

The following table summarizes information about RSU activity during the nine months ended September 30, 2021:

	RSUs	AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE)
Outstanding, December 31, 2020	80,450	$ 3.25
Granted	—	—
Vested	(38,200)	3.25
Forfeited	—	—
RSUs outstanding at September 30, 2021	42,250	$ 3.25

The number of RSUs vested includes shares of common stock withheld on behalf of employees to satisfy the minimum statutory tax withholding requirements.

Unrecognized compensation expense related to unvested options as of September 30, 2021 was $3.1 million and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 2.4 years. Unrecognized compensation expense related to unvested RSUs as of September 30, 2021 was $31,000 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 year.

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, 2020 and 2021 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2021	2020	2021
Research and development	$ 213	$ 235	$ 534	$ 695
General and administrative	531	384	1,339	1,034
Total	$ 744	$ 619	$ 1,873	$ 1,729

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 2022 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, 2021 (in thousands):

Year ended:	
December 31, 2021	$ 133
December 31, 2022	496
Total minimum lease payments	629
Less imputed interest	(33)
Total	$ 596

	Nine Months Ended September 30,	
	2020	2021
Lease cost:		
Operating lease cost	$ 365	$ 365
Short-term lease cost	-	5
Sublease income	(38)	(39)
Total lease cost	$ 327	$ 331
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 391	$ 396
Operating cash flows from operating leases	$ (32)	$ (43)
Weighted-average remaining lease term - operating leases	2.2 years	1.2 years
Weighted-average discount rate - operating leases	10.1%	10.1%

In July 2021, the Company signed a lease agreement for a new office facility located in Salem, New Hampshire. The lease commenced on September 1, 2021 and has an initial term of 12 months with an optional extension term through August 2023. The lease is considered short-term and is being recognized on a straight-line basis over the initial term as the Company does not currently intend to exercise the option.

In February 2018, the Company signed a sublease agreement for its facility located in Lexington, Massachusetts. The lease commenced on April 1, 2018 and has an initial term of three years with an extension term through December 2022. In February 2020, the sublease was extended until December 31, 2022.

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.

Contingencies

The Company follows subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies.

Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be

estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed. Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed.

Due to the discontinuation of use of the sc2Wear Infusor, the Company has received notice of termination costs related to the program. The Company has accrued all costs for which it either believes it is contractually liable or for which the Company has negotiated settlement agreements in good faith. However, certain of the Company's vendors have claimed or billed for additional costs for which the Company believes it is not obligated. At this time, the Company estimates that additional termination costs, if any, will be immaterial to the Company's financial statements.

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 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, 2020 (the "Annual Report") filed with the Securities and Exchange Commission (the "SEC") on March 23, 2021. 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 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 advances the quality and convenience of care. Our lead product candidate, FUROSCIX, consists of our novel formulation of furosemide delivered via an on-body infusor and is under development for treatment of congestion in patients with heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization.

We resubmitted our new drug application, or NDA, for FUROSCIX, with the U.S. Food and Drug Administration, or FDA, on June 30, 2020. The resubmission was a response to a Complete Response Letter, or CRL, from the FDA with respect to our NDA submitted in August 2017, which indicated that, among other things, certain device modifications to our infusor were required. Based on our interactions with the FDA, which required device modifications necessary to advance FUROSCIX using its then current technology, we decided to transition to our next generation device. The resubmission incorporated our next generation device which is being developed through a partnership with West Pharmaceutical Services, Inc., or West, using its proprietary on-body infusor.

On July 23, 2020, the FDA accepted the resubmission of our NDA and we were given a Prescription Drug User Fee Act, or PDUFA, target action date of December 30, 2020; however, on December 3, 2020, we received a CRL from the FDA, in which, among other things, the FDA raised questions related to testing, labeling and features of the combination product unrelated to the drug constituent. The FDA also indicated that they needed to conduct pre-approval inspections at three of our third-party manufacturing facilities. No clinical deficiencies were noted. On January 28, 2021, we had a Type A meeting with the FDA to discuss the issues described in the CRL and steps required for the resubmission of the NDA for FUROSCIX. On June 2, 2021, we had a Type C meeting with the FDA regarding the requirements for resubmission of the FUROSCIX NDA. Based on guidance we received during the meeting and subsequently contained within the meeting minutes, we are conducting the required bench testing for the West proprietary on-body infusor. The FDA has not requested modifications to the device and all testing to date on devices manufactured on the planned commercial line has been successful, however, due to COVID-19 related global supply chain logistics we plan to resubmit our NDA in the first quarter of 2022. If the resubmission is approved, we still anticipate a commercial launch in the fourth quarter of 2022.

In May 2021, we completed enrollment in FREEDOM-HF, a prospective clinical trial evaluating overall and heart failure-related costs for subjects treated with FUROSCIX outside the hospital for 30 days post-discharge from the emergency department compared to patients receiving intravenous furosemide in the hospital setting. Based on the results from a planned, prespecified interim analysis conducted to confirm the final sample size, and following input from statisticians, principal investigators, payer advisors and Health Economics and Outcomes Research (HEOR) experts, enrollment was closed on May 17, 2021, prior to the enrollment target of 34 patients. This decision was made due to the statistically significant reduction observed in 30-day heart failure-related costs in patients who received FUROSCIX in the interim analysis. The final analysis included 24 subjects treated with FUROSCIX and 66 matched comparators based on seven variables associated with hospitalization. On July 13, 2021, we announced top-line results from FREEDOM-HF, demonstrating that average 30-day heart failure-related costs were reduced by $17,753 per study subject in the FUROSCIX arm compared to historically matched comparators ($p < 0.0001$). In September, we announced additional results from FREEDOM-HF, demonstrating that average 30-day total healthcare costs were reduced by $30,568 per study subject in the FUROSCIX arm compared to historically matched comparators ($p < 0.0001$). Since the price for FUROSCIX has not been established, the difference in costs does not include the cost of FUROSCIX. These results support our hypothesis that treating heart failure patients presenting to the emergency department with worsening congestion with FUROSCIX outside of the hospital setting has the potential to dramatically reduce the significant costs associated with hospital admissions and readmissions.

We conducted an analysis of additional secondary endpoints in FREEDOM-HF which provided additional insights into the clinical effectiveness of FUROSCIX. In this analysis, it was determined that patients who received FUROSCIX had a median reduction of

heart failure peptide biomarkers from study entry to first visit, and to last visit, of 42.3% and 28%, respectively ($p \leq 0.01$). In addition, patients who received FUROSCIX had a 12.8-point improvement in the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) Summary Score 30 days after study entry.

We continued enrollment in AT HOME-HF PILOT, a multicenter, randomized, open label, controlled study in heart failure patients with worsening signs and symptoms of congestion requiring augmentation in diuretic therapy outside of an acute care setting. The objective of this pilot study is to evaluate the effectiveness and safety of FUROSCIX versus continued medical therapy to inform a larger, pivotal clinical trial. We anticipate completing enrollment in the AT HOME-HF PILOT study in the first half of 2022.

We have funded our operations from inception through September 30, 2021 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. We do not have any products approved for sale and have not generated any revenue from product sales.

As of September 30, 2021, we had an accumulated deficit of $182.4 million. We expect to continue to incur net losses for the foreseeable future as we develop the infrastructure to commercialize our products, if approved, 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. 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 and 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 remained operational. The extent of the impact of the evolving COVID-19 pandemic on the timing of our ability to resubmit the FUROSCIX NDA, the FDA’s subsequent review of the FUROSCIX NDA or possible delays in enrolling patients to our upcoming or recently initiated 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, including the ability of the FDA to inspect facilities required for approval of our NDA, the impact to the business of our suppliers, service providers or customers, and other items identified under “Risk Factors” in our Annual Report on Form 10-K, 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, or 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 candidate 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:

- pursue regulatory approval of FUROSCIX incorporating the West proprietary on-body infusor;
- 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, or 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.

If we receive FDA approval for FUROSCIX incorporating West's proprietary on-body infusor, we anticipate that our G&A expenses will increase as we continue to build our corporate and commercial infrastructure to support the development and commercial launch of FUROSCIX in the United States.

Results of Operations

Comparison of Three Months Ended September 30, 2020 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2021 (in thousands):

	Three Months Ended September 30,		Increase
	2020	2021	(Decrease)
Operating expenses:			
Research and development	$ 5,119	$ 3,694	$ (1,425)
General and administrative	3,319	2,211	(1,108)
Total operating expenses	8,438	5,905	(2,533)
Loss from operations	(8,438)	(5,905)	(2,533)
Other income	19	10	(9)
Interest income	36	10	(26)
Interest expense	(655)	(667)	12
Net loss	$ (9,038)	$ (6,552)	$ (2,486)

Research and development expenses. R&D expenses were $3.7 million for the three months ended September 30, 2021, compared to $5.1 million for the three months ended September 30, 2020. The decrease of $1.4 million was primarily attributable to a decrease of $1.1 million in device development costs, a $0.4 million decrease in pharmaceutical development costs, and a $0.1 million decrease in clinical study costs. The decrease was partially offset by a $0.2 million increase in quality and regulatory consulting costs.

General and administrative expenses. G&A expenses were $2.2 million for the three months ended September 30, 2021, compared to $3.3 million for the three months ended September 30, 2020. The decrease of $1.1 million was primarily attributable to a $0.6 million decrease in employee related costs, including stock-based compensation and bonus, a $0.3 million decrease in commercial preparation costs and a $0.3 million decrease in legal costs. The decrease was partially offset by $0.1 million increase in director and officer's insurance.

Other income. Other income was $10,000 for the three months ended September 30, 2021, compared to $19,000 for the three months ended September 30, 2020. The decrease in income of $9,000 was primarily attributable to foreign exchange losses offset by income from a rental arrangement.

Interest income. Interest income was $10,000 for the three months ended September 30, 2021, compared to $36,000 for the three months ended September 30, 2020. The decrease of $26,000 was primarily attributable to lower interest rates on our financial instruments.

Interest expense. Interest expense was $0.7 million for the three months ended September 30, 2021 compared to $0.7 million for the three months ended September 30, 2020. Interest expense consists of interest on the $20.0 million term loan with SLR Investment Corp. (f/k/a Solar Capital Ltd.) and Silicon Valley Bank.

Comparison of Nine Months Ended September 30, 2020 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2021 (in thousands):

	Nine Months Ended September 30,		Increase
	2020	2021	(Decrease)
Operating expenses:			
Research and development	$ 14,404	$ 11,509	$ (2,895)
General and administrative	8,359	7,593	(766)
Total operating expenses	22,763	19,102	(3,661)
Loss from operations	(22,763)	(19,102)	(3,661)
Other (expense) income	(13)	298	311
Interest income	281	42	(239)
Interest expense	(1,930)	(1,954)	24
Net loss	$ (24,425)	$ (20,716)	$ (3,709)

Research and development expenses. R&D expenses were $11.5 million for the nine months ended September 30, 2021, compared to $14.4 million for the nine months ended September 30, 2020. The decrease of $2.9 million was primarily attributable to a decrease of $4.4 million in device development costs. The decrease was partially offset by a $0.5 million increase in employee-related costs, a $0.4 million increase in contract services for medical affairs, a $0.3 million increase in clinical study activity, $0.2 million increase in quality assurance professional services, and a $0.1 million increase in pharmaceutical development costs.

General and administrative expenses. G&A expenses were $7.6 million for the nine months ended September 30, 2021, compared to $8.4 million for the nine months ended September 30, 2020. The decrease of $0.8 million was primarily attributable to a $0.6 million decrease in legal costs, a $0.4 million decrease in commercial preparation costs, a $0.3 million decrease in employee-related costs, and a $0.2 million decrease in investor relation service costs. The decrease was partially offset by a $0.4 million increase in director and officer's insurance and a $0.3 million increase in consulting fees.

Other (expense) income. Other income was $0.3 million for the nine months ended September 30, 2021, compared to other expense of $13,000 for the nine months ended September 30, 2020. The increase in income of $0.3 million was primarily attributable to the recovery of fees associated with a post-employment matter.

Interest income. Interest income was $42,000 for the nine months ended September 30, 2021, compared to $0.3 million for the nine months ended September 30, 2020. The decrease of $0.2 million was primarily attributable to lower interest rates on our financial instruments.

Interest expense. Interest expense was $2.0 million for the nine months ended September 30, 2021 compared to $1.9 million for the nine months ended September 30, 2020. Interest expense consists of interest on the $20.0 million term loan with SLR Investment Corp. (f/k/a Solar Capital Ltd.) and Silicon Valley Bank.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through September 30, 2021 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. As of September 30, 2021, 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, 2021, we had cash, cash equivalents and restricted cash of $79.5 million and short-term investments of $5.5 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, 2021, we had received no proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

We expect to incur substantial additional expenditures in the near future to support our ongoing activities and our plans to obtain regulatory approval for FUROSCIX incorporating West's proprietary on-body infusor. 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 prepare for and, if approved, 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. Additionally, we will incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the time and expense required to resubmit the NDA for FUROSCIX;
- the potential FDA approval of FUROSCIX;
- the costs and expenses of establishing our U.S. sales and marketing infrastructure;
- the degree of success we experience in commercializing FUROSCIX, if approved;
- the revenue generated by sales of FUROSCIX, if approved, and other products that may be approved;
- the pricing and reimbursement of FUROSCIX, if approved, 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, if approved, 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:

(in thousands)	Nine Months Ended September 30, 2020	2021
Net cash (used in) provided by:		
Operating activities	$ (18,513)	$ (20,053)
Investing activities	(70,161)	27,629
Financing activities	60,328	(72)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (28,346)	$ 7,504

Net Cash Used in Operating Activities

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.

During the nine months ended September 30, 2020, net cash used in operating activities was $18.5 million, consisting primarily of a net loss of $24.4 million. This was offset by non-cash charges of $2.6 million and an increase in net operating liabilities of $3.3 million. 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, accretion of discount on investments and the fair value adjustment to the derivative liability.

Net Cash (Used in) Provided by Investing Activities

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

During the nine months ended September 30, 2020, net cash used in investing activities was $70.2 million, consisting of purchases of short-term investments.

Net Cash Provided by (Used in) Financing Activities

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.

During the nine months ended September 30, 2020, net cash provided by financing activities was $60.3 million, consisting primarily of net proceeds of $50.2 million from the public offering, net proceeds of $10.4 million from the 2019 at-the-market offering and stock option exercises. The proceeds were offset by the $0.8 million Exit Fee associated with the 2019 Loan Agreement and tax obligations on the settlement of restricted stock units.

OFF-BALANCE SHEET ARRANGEMENTS

We currently have no off-balance sheet arrangements.

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 on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 23, 2021.

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, or U.S. GAAP. 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 on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 23, 2021.

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, 2021, our aggregate outstanding indebtedness was $20.0 million, which bears interest at the rate at the higher of (i) LIBOR plus 7.95% or (ii) 10.18%. 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.

Item 4. 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. Based on that evaluation of our disclosure controls and procedures as of September 30, 2021, 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. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

There were no changes in our internal control over financial reporting during the nine months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Information regarding risk factors appears in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 23, 2021. There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K.

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
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.

† This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act, except to the extent specifically incorporated by reference into such filing.

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, 2021

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, 2021 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, 2021

/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, 2021, 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 Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to my knowledge:

1) the Report which this statement accompanies 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, 2021

/s/ John H. Tucker

John H. Tucker

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