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, 2019

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 01803
(Address of principal executive office) (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 11, 2019, the Registrant had 18,633,530 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 timing or likelihood of approval by the U.S. Food and Drug Administration, or FDA, of our regulatory filings for FUROSCIX® using our next generation delivery device;
- the timing or likelihood of other regulatory filings and approvals, including any approval to market and sell subcutaneous ceftriaxone;
- 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, marketing and manufacturing of FUROSCIX or any other of our product candidates, if approved;
- the pricing and reimbursement 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 subcutaneous ceftriaxone and 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;
- 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, 2018.

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, 2018. 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.

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PART I — FINANCIAL INFORMATION

SCPHARMACEUTICALS INC.

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

	December 31, 2018	September 30, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 89,478	$ 83,562
Prepaid expenses	1,757	894
VAT receivable	479	303
Other current assets	179	128
Total current assets	91,893	84,887
Restricted cash	182	182
Property and equipment, net	164	136
Right-of-use lease assets - operating, net	1,506	1,264
Deposits and other assets	10	197
Total assets	$ 93,755	$ 86,666
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 587	$ 542
Accrued expenses	2,922	7,169
Term loan, short term	2,811	—
Lease obligation - operating, short term	353	393
Total current liabilities	6,673	8,104
Term loan, long term	6,826	18,842
Lease obligation - operating, long term	1,353	1,052
Derivative liability	—	766
Other liabilities	159	16
Total liabilities	15,011	28,780
Commitments and contingencies (Note 10)		
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, 2019; 18,569,289 and 18,629,730 shares issued and outstanding as of December 31, 2018 and September 30, 2019, respectively	2	2
Additional paid-in capital	175,201	176,524
Accumulated deficit	(96,459)	(118,640)
Total stockholders' equity	78,744	57,886
Total liabilities and stockholders' equity	$ 93,755	$ 86,666

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,	
	2018	2019	2018	2019
Operating expenses:				
Research and development	$ 3,896	$ 4,293	$ 12,799	$ 16,314
General and administrative	1,945	1,996	11,645	6,158
Total operating expenses	5,841	6,289	24,444	22,472
Loss from operations	(5,841)	(6,289)	(24,444)	(22,472)
Other (expense) income	(5)	83	(58)	61
Interest income	445	397	1,221	1,350
Interest expense	(360)	(398)	(1,062)	(1,121)
Net loss and comprehensive loss	$ (5,761)	$ (6,207)	$ (24,343)	$ (22,182)
Net loss per share — basic and diluted	$ (0.31)	$ (0.33)	$ (1.31)	$ (1.19)
Weighted average common shares outstanding — basic and diluted	18,569,289	18,584,327	18,551,690	18,580,192

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 CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT			
At December 31, 2018	18,569,289	$ 2	$ 175,201	$ (96,459)	$ 78,744
Net loss	—	—	—	(8,719)	(8,719)
Issuance of common stock upon exercise of stock options	11,141	—	18	—	18
Stock-based compensation	—	—	355	—	355
At March 31, 2019	18,580,430	2	175,574	(105,178)	70,398
Net loss	—	—	—	(7,255)	(7,255)
Stock-based compensation	—	—	326	—	326
At June 30, 2019	18,580,430	2	175,900	(112,433)	63,469
Net loss	—	—	—	(6,207)	(6,207)
Issuance of common stock under at-the-market offering, net of issuance costs (Note 9)	40,300	—	256	—	256
Issuance of common stock upon exercise of stock options	9,000	—	35	—	35
Stock-based compensation	—	—	333	—	333
At September 30, 2019	18,629,730	$ 2	$ 176,524	$ (118,640)	$ 57,886
At December 31, 2017	18,534,240	$ 2	$ 173,011	$ (67,016)	$ 105,997
Net loss	—	—	—	(8,732)	(8,732)
Issuance of common stock upon exercise of stock options	7,606	—	56	—	56
Vesting of restricted stock	366	—	1	—	1
Stock-based compensation	—	—	622	—	622
At March 31, 2018	18,542,212	2	173,690	(75,748)	97,944
Net loss	—	—	—	(9,850)	(9,850)
Issuance of common stock upon exercise of stock options	26,955	—	2	—	2
Vesting of restricted stock	122	—	—	—	—
Stock-based compensation	—	—	497	—	497
At June 30, 2018	18,569,289	2	174,189	(85,598)	88,593
Net loss	—	—	—	(5,761)	(5,761)
Offering costs	—	—	(5)	—	(5)
Stock-based compensation	—	—	563	—	563
At September 30, 2018	18,569,289	$ 2	$ 174,747	$ (91,359)	$ 83,390

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,	
	2018	2019
Cash flows from operating activities		
Net loss	$ (24,343)	$ (22,182)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	29	29
Amortization expense - right-of-use leased assets - operating	218	241
Stock-based compensation	1,682	1,014
Non-cash interest expense	278	260
Fair value adjustment to derivative liability	—	3
Changes in operating assets and liabilities		
Prepaid expenses and other assets	51	1,088
Accounts payable, accrued expenses and other liabilities	(926)	3,940
Net cash used in operating activities	(23,011)	(15,607)
Cash flows from investing activities		
Purchases of property and equipment	(41)	—
Net cash used in investing activities	(41)	—
Cash flows from financing activities		
Costs related to initial public offering	(5)	—
Proceeds from at-the-market offering, net of commissions	—	259
At-the-market offering costs	—	(189)
Proceeds from term loan, net of costs	—	9,568
Proceeds from the exercise of vested stock options	58	53
Net cash provided by financing activities	53	9,691
Net decrease in cash, cash equivalents and restricted cash	(22,999)	(5,916)
Cash, cash equivalents and restricted cash at beginning of period	118,480	89,660
Cash, cash equivalents and restricted cash at end of period	$ 95,481	$ 83,744
Supplemental cash flow information		
Interest paid	$ 738	$ 925
Taxes paid	$ 283	$ 296
Supplemental non-cash information		
Acquisition of right-of-use leased assets - operating, net of disposal	$ 26	$ —
Issuance of derivative in connection with modification of term loan	$ —	$ 763
Transfer of issuance costs from other noncurrent assets to equity	$ —	$ 3

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 proprietary platform is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous, or IV, delivery. The Company's headquarters and primary place of business is Burlington, Massachusetts.

In January 2019, following a Type C meeting with the Food and Drug Administration, management implemented a restructuring plan to reduce operating costs and better align its workforce with the needs of its business. The Company recorded a charge of $1.4 million during the nine months ended September 30, 2019 related to the restructuring plan, which included severance, benefits and related costs. The Company recorded $966,000 and $426,000 in research and development expenses and general and administrative expenses related to the restructuring, respectively. The Company paid $1.3 million of these costs during the nine months ended September 30, 2019 and expects to pay $18,000 in the fourth quarter of 2019. The remainder of the restructuring charge consists of a non-cash charge of $70,000 related to the modification of stock options (Note 6). As of September 30, 2019, the Company had a balance of $18,000 in accrued expenses related to severance benefits, and related costs associated with the restructuring plan.

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, 2018 included in the Company's Annual Report on Form 10-K filed with the SEC on March 21, 2019. The Company has determined that it operates in one segment.

The accompanying condensed consolidated balance sheet as of September 30, 2019, the condensed consolidated statements of operations and comprehensive loss and stockholders' equity for the three and nine months ended September 30, 2018 and 2019 and condensed consolidated statements of cash flows for the nine months ended September 30, 2018 and 2019 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, 2019 are not necessarily indicative of the results expected for the full year ending December 31, 2019.

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, certificates of deposit 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, 2019, 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 10). Cash, cash equivalents and restricted cash consist of the following:

	December 31, 2018	September 30, 2019
Cash and cash equivalents	$ 89,478	$ 83,562
Restricted cash	182	182
Cash, cash equivalents and restricted cash	$ 89,660	$ 83,744

Derivative Liability

In September 2019, the Company entered into a new loan and security agreement with Solar Capital Ltd. and Silicon Valley Bank (the "2019 Loan Agreement") to refinance the Company's 2017 Loan Agreement (Note 8). In connection with the 2019 Loan Agreement, the Company also entered into an exit agreement with Solar Capital Ltd. and Silicon Valley Bank (the "Exit Agreement"). The Exit Agreement provides for a payment to the lenders in the amount of 4% of the loan commitment, or $800,000, upon the occurrence of an exit event, as defined in the Exit Agreement. The Company classifies the exit payment obligation as a liability on its balance sheet because it represents a contingent payment obligation that is not clearly and closely related to the host instrument and meets the definition of a derivative. The derivative liability was initially recorded at fair value upon execution of the 2019 Loan Agreement and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the derivative liability are recognized as a component of other income (expense), net in the statement of operations and comprehensive loss. Changes in the fair value of the derivative liability will continue to be recognized until an exit event occurs.

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, 2019, the Company had no such accruals.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) ("ASU 2018-13"). ASU 2018-13 modifies fair value disclosure requirements, specifically around level transfers and valuation of Level 3 assets and liabilities. ASU 2018-13 is effective for financial statements issued for annual and interim periods beginning after December 15, 2019 for all entities. Early adoption of all or part of ASU No. 2018-13 is permitted. The Company does not expect ASU 2018-13 to have a material impact on its financial statements.

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,	
	2018	2019	2018	2019
Net loss and comprehensive loss	$ (5,761)	$ (6,207)	$ (24,343)	$ (22,182)
Weighted-average shares used in computing net loss per share	18,569,289	18,584,327	18,551,690	18,580,192
Net loss per share, basic and diluted	$ (0.31)	$ (0.33)	$ (1.31)	$ (1.19)

The Company's potentially dilutive securities, which include stock options and unvested restricted stock, 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,	
	2018	2019	2018	2019
Stock options to purchase common stock	1,746,287	1,424,018	1,746,287	1,424,018
Unvested restricted stock	—	160,900	—	160,900
Total	1,746,287	1,584,918	1,746,287	1,584,918

4. Property and Equipment

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

	ESTIMATED USEFUL LIFE	December 31, 2018	September 30, 2019
Office equipment	5 years	$ 10	$ 10
Office furniture	7 years	116	116
Computer equipment	3 years	8	8
Leasehold improvements	Life of lease	95	95
		229	229
Less: Accumulated depreciation		(65)	(93)
Property and equipment, net		$ 164	$ 136

Depreciation expense for the three months ended September 30, 2018 and September 30, 2019 was $10,000 and $10,000, respectively.

Depreciation expense for the nine months ended September 30, 2018 and September 30, 2019 was $29,000 and $29,000, respectively.

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

	ESTIMATED USEFUL LIFE	December 31, 2018	September 30, 2019
Right-of-use lease assets - operating	Lease term	$ 2,024	$ 2,024
Less: Accumulated amortization		(518)	(760)
Right-of-use lease assets - operating, net		$ 1,506	$ 1,264

Amortization expense for the three months ended September 30, 2018 and September 30, 2019 was $74,000 and $82,000, respectively.

Amortization expense for the nine months ended September 30, 2018 and September 30, 2019 was $218,000 and $241,000, respectively.

5. Accrued Expenses

Accrued expenses consist of (in thousands):

	December 31, 2018	September 30, 2019
Contract research and development	$ 1,492	$ 4,146
Unrecoverable component costs	—	1,668
Employee compensation and related costs	727	923
Consulting and professional service fees	356	338
State taxes	165	36
Severance costs	133	18
Other	49	40
Total accrued expenses	$ 2,922	$ 7,169

6. 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, 2019, there were 830,962 options outstanding under the 2014 Plan.

As of September 30, 2019, there were 3,166,868 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan, including 252,707 options that have been forfeited from the 2014 Plan.

At September 30, 2019, there were 2,412,912 options available for issuance under the 2017 Stock Plan, 593,056 options outstanding and 160,900 restricted stock units outstanding. Awards granted under the 2017 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,	
	2018	2019
Risk-free interest rate	2.42%-2.86%	1.61%-2.51%
Expected dividend yield	0%	0%
Expected life	5.5-7.0 years	5.5-6.1 years
Expected volatility	76%-86%	72%-74%
Weighted-average grant date fair value	$ 7.57	$ 2.17

The following table summarizes information about stock option activity during the nine months ended September 30, 2019 (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, 2018	1,588,306	$ 6.75		
Granted	145,022	3.34		
Exercised	(20,141)	2.62		
Forfeited	(289,169)	8.54		
Outstanding, September 30, 2019	1,424,018	$ 6.09	7.84	$ 1,842
Vested and exercisable, September 30, 2019	854,952	$ 6.20	7.45	$ 1,024
Vested and expected to vest, September 30, 2019	1,308,083	$ 6.15	7.76	$ 1,661

The following table summarizes information about RSU activity during the nine months ended September 30, 2019:

	RSUs	AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE)
Outstanding, December 31, 2018	—	$ —
Granted	160,900	1.43
Vested	—	—
Forfeited	—	—
RSUs outstanding at September 30, 2019	160,900	$ 1.43

Unrecognized compensation expense related to unvested options as of September 30, 2019 was $1.8 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 1.9 years. Unrecognized compensation expense related to unvested RSUs as of September 30, 2019 was $116,000 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 1.3 years.

During the nine months ended September 30, 2019, as part of the restructuring plan (Note 1), the Company extended the exercise period to one year for 55,677 vested options and for two years for 85,432 vested options of those affected, with a weighted average exercise price of $8.41, and recorded incremental stock-based compensation expense of $70,000.

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, 2018 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2019	2018	2019
Research and development	$ 154	$ 75	$ 394	$ 215
General and administrative	409	258	1,288	799
Total	$ 563	$ 333	$ 1,682	$ 1,014

7. Fair Value of Financial Instruments

The Financial Accounting Standards Board (“FASB”) Accounting Standard Codification (“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, value added tax, or VAT, receivable and deposits approximate their fair values due to their short-term nature. The carrying value of the Company’s loan payable was 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 table summarizes the Company’s assets and liabilities as of September 30, 2019 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):

	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 62,549	$ 62,549	$ —	$ —
Total	$ 62,549	$ 62,549	$ —	$ —
Liabilities:				
Derivative liability	$ 766	$ —	$ —	$ 766
Total	$ 766	$ —	$ —	$ 766

The fair value of the derivative liability recognized in connection with the Company’s 2019 Loan Agreement (Note 8) was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using the probability-weighted expected return method (“PWERM”), which considered as inputs the timing and probability of occurrence of an exit event, the amount of the payment, and the risk-free discount rate reflecting the expected risk profile for each of the potential settlement scenarios.

8. Term Loan

In May 2017, the Company entered into a loan and security agreement (the “2017 Loan Agreement”), with Solar Capital Ltd. and Silicon Valley Bank 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.

The interest rate under the 2017 Loan Agreement was LIBOR plus 8.45%. The initial interest-only period was until November 30, 2018, followed by a 30-month principal and interest period. The First Amendment to the Loan and Security Agreement, entered into in November 2018, extended the interest-only period through May 2019. The Third Amendment to the Loan and Security Agreement, entered into in May 2019, extended the interest-only period through August 2019, with the ability to further extend the interest only period to November 2019. Pursuant to the 2017 Loan Agreement, the Company provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property, owned by the Company.

For the three and nine months ended September 30, 2019, the Company recorded $53,000 and $169,000, respectively, related to the amortization of debt discount associated with the 2017 Loan Agreement. For the three and nine months ended September 30, 2018 the Company recorded $68,000 and $212,000, respectively, related to the amortization of debt discount associated with the 2017 Loan Agreement.

The 2017 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 1% would be assessed on the outstanding principal. A final payment fee of $250,000 was due upon the earlier to occur of the maturity date or prepayment of such borrowings. The final payment fee was increased to $325,000 in the First Amendment to the 2017 Loan Agreement. For the three and nine months ended September 30, 2019, the Company recorded $23,000 and $80,000, respectively, related to the amortization of the final payment fee associated with the 2017 Loan Agreement. For the three and nine months ended September 30, 2018, the Company recorded $22,000 and $66,000, respectively, related to the amortization of the final payment fee associated with the 2017 Loan Agreement.

In September 2019, the Company paid off the outstanding balance of the 2017 Loan Agreement, including accrued interest, and entered into the 2019 Loan Agreement for $20.0 million. The payoff was treated as a modification of the debt. The 2019 Loan Agreement has a maturity date of September 17, 2023. Debt issuance costs for the 2019 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, 2019 was 10.18%. Pursuant to the 2019 Loan Agreement, the Company provided a first priority security interest in all existing and after-acquired assets owned by the Company, including all intellectual property and subject to certain exceptions.

The Company entered into the 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 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.

As of September 30, 2019, unpaid borrowings under the 2019 Loan Agreement totaled $20.0 million. For the three and nine months ended September 30, 2019, the Company recorded $5,000 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, 2019, the Company recorded $6,000 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, 2019
Face value	$ 20,000
Less: discount	(1,158)
Total	$ 18,842
Less: current portion	—
Total	$ 18,842

As of September 30, 2019, 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

At-the-Market Issuance Sales Agreement

On August 23, 2019, the Company entered into an Open Market Sale AgreementSM ("ATM Agreement"), with Jefferies LLC ("Jefferies") with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value $0.0001 per share (the "ATM Shares"), having an aggregate offering price of up to $15.0 million through Jefferies as its sales agent. The offering and sale of ATM Shares by the Company under the ATM Agreement will be and is being made pursuant to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC on February 11, 2019.

Subject to the terms and conditions of the ATM Agreement, Jefferies will use its commercially reasonable efforts to sell the ATM Shares, based upon instructions from the Company, consistent with its normal trading and sales practices. The Company will pay Jefferies a commission equal to 3.0% of the gross sales proceeds of such ATM Shares.

During the three months ended September 30, 2019, the Company sold a total of 40,300 ATM Shares under the ATM Agreement, in the open market, at an average gross selling price of $6.63 per share for net proceeds of $259,000.

During the three months ended September 30, 2019, the Company incurred $189,000 of legal, accounting and other costs to establish and activate the ATM program. The Company charged $3,000 of these costs against additional paid in capital upon issuance of shares during the three months ended September 30,2019.

10. 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 ("CAM") 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, 2019 (in thousands):

Year ended:		
December 31, 2019	$	131
December 31, 2020		528
December 31, 2021		537
December 31, 2022		496
Total minimum lease payments		1,692
Less imputed interest		(247)
Total	$	1,445

	Nine Months Ended September 30,	
	2018	2019
Lease cost:		
Operating lease cost	$ 348	$ 368
Short-term lease cost	6	6
Sublease income	(26)	(38)
Total lease cost	$ 328	$ 336
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 302	$ 384
Operating cash flows from operating leases	$ 55	$ (21)
Weighted-average remaining lease term - operating leases	4.2 years	3.2 years
Weighted-average discount rate - operating leases	10.1%	10.1%

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.

Research and Development Agreements

As part of the Company's research and development efforts, the Company enters into research and development agreements with unrelated 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 the 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, 2018 (the "Annual Report") filed with the Securities and Exchange Commission on March 21, 2019. 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 reduces 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 worsening heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization.

We filed a new drug application, or NDA, for FUROSCIX, with the U.S. Food and Drug Administration, or FDA, in August 2017. On June 11, 2018, we received a Complete Response Letter, or CRL, from the FDA for our NDA, which indicated that, among other things, certain device modifications to our infusor were required. Based on the outcome of our interactions with the FDA, including clarification on an additional dose validation study and proposed device modifications necessary to advance FUROSCIX using the existing delivery technology, we have decided to discontinue use of the sc2Wear Infusor, and transition to our next generation device developed in partnership with West Pharmaceutical Services, Inc., or West, using its proprietary, wearable, SmartDose® drug delivery system. We held a Type C meeting with the FDA on June 18, 2019 and based on the results of that meeting we anticipate being able to resubmit the FUROSCIX NDA with the SmartDose drug delivery system by mid-year 2020.

We have funded our operations from inception through September 30, 2019 primarily through the sale of shares of our common stock in our initial public offering 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, 2019, we had an accumulated deficit of $118.6 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, continue research and development efforts, clinical trial activities, scale-up manufacturing, and seek regulatory approval for new product candidates and product enhancements. We will need additional funding to pay expenses relating 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 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; 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 SmartDose drug delivery system;
- 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 the next generation SmartDose drug delivery system, 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, 2018 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2019 (in thousands):

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2019	Increase (Decrease)
Operating expenses:			
Research and development	$ 3,896	$ 4,293	$ 397
General and administrative	1,945	1,996	51
Total operating expenses	5,841	6,289	448
Loss from operations	(5,841)	(6,289)	448
Other (expense) income	(5)	83	88
Interest income	445	397	(48)
Interest expense	(360)	(398)	38
Net loss	$ (5,761)	$ (6,207)	$ 446

Research and development expenses. R&D expenses were $4.3 million for the three months ended September 30, 2019, compared to $3.9 million for the three months ended September 30, 2018. The increase of $0.4 million was primarily attributable to a $0.9 million increase in pharmaceutical preparation costs and a $0.6 million increase in device development costs. The increase was partially offset by a $0.6 million decrease in employee-related costs, a $0.3 million decrease in supplies and contract services for clinical and medical affairs and a $0.2 million decrease in regulatory consulting.

General and administrative expenses. G&A expenses were $2.0 million for the three months ended September 30, 2019, compared to $1.9 million for the three months ended September 30, 2018. The increase of $0.1 million was primarily attributable to a $0.2 million increase in legal costs, a $0.1 million increase in costs related to commercial preparation, and a $0.1 million increase in public company related costs. The increase was partially offset by a $0.3 million decrease in employee-related costs.

Other (expense) income. Other income was $83,000 for the three months ended September 30, 2019, compared to expense of $5,000 for the three months ended September 30, 2018. The increase in income of $88,000 was primarily attributable to foreign exchange gains due to foreign currency fluctuations.

Interest income. Interest income was $397,000 for the three months ended September 30, 2019 compared to $445,000 for the three months ended September 30, 2018. The decrease of $48,000 was primarily attributable to lower money market fund holdings.

Interest expense. Interest expense increased $38,000 from the three months ended September 30, 2018 to $0.4 million for the three months ended September 30, 2019. This increase was attributable to increased rates and balances on the term loan with Solar Capital Ltd. and Silicon Valley Bank.

Comparison of Nine Months Ended September 30, 2018 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2019 (in thousands):

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Increase (Decrease)
Operating expenses:			
Research and development	$ 12,799	$ 16,314	$ 3,515
General and administrative	11,645	6,158	(5,487)
Total operating expenses	24,444	22,472	(1,972)
Loss from operations	(24,444)	(22,472)	(1,972)
Other (expense) income	(58)	61	119
Interest income	1,221	1,350	129
Interest expense	(1,062)	(1,121)	59
Net loss	$ (24,343)	$ (22,182)	$ (2,161)

Research and development expenses. R&D expenses were $16.3 million for the nine months ended September 30, 2019, compared to $12.8 million for the nine months ended September 30, 2018. The increase of $3.5 million was primarily attributable to a $4.0 million increase in device development costs, $1.7 million in unrecoverable component costs related to the sc2Wear Infusor, $0.8 million increase in severance costs, and a $0.7 million increase in pharmaceutical preparation costs. The increase was partially offset by a $1.9 million decrease in employee-related costs, a $1.6 million decrease in supplies and contract services for clinical and medical affairs, and a $0.2 million decrease in regulatory consulting.

General and administrative expenses. G&A expenses were $6.2 million for the nine months ended September 30, 2019, compared to $11.6 million for the nine months ended September 30, 2018. The decrease of $5.4 million was primarily attributable to a $3.1 million decrease in employee-related costs, a $2.2 million decrease in costs related to commercial preparation, and a decrease of $0.2 million in legal costs. The decrease was partially offset by an increase of $0.2 million in public company costs.

Other (expense) income. Other income was $61,000 for the nine months ended September 30, 2019, compared to expense of $58,000 for the nine months ended September 30, 2018. The increase in income of $119,000 was primarily attributable to foreign exchange gains due to activity denominated in foreign currency combined with foreign currency fluctuations.

Interest income. Interest income was $1.4 million for the nine months ended September 30, 2019, compared to $1.2 million for the nine months ended September 30, 2018. The increase of $129,000 was primarily attributable to higher returns due to money market fund holdings.

Interest expense. Interest expense increased $59,000 from the nine months ended September 30, 2018 to $1.1 million for the nine months ended September 30, 2019. This increase was attributable to increased rates on the $10.0 million loan entered into in May 2017 and the additional $10.0 million borrowed in the term loan modification with Solar Capital Ltd. and Silicon Valley Bank in September 2019.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through September 30, 2019 primarily through the sale of shares of our common stock in our initial public offering and, prior to that, through the private placement of our preferred stock and the incurrence of debt. As of September 30, 2019, we had received net cash proceeds of $92.7 million from our initial public offering, $56.7 million from sales of our preferred stock, $13.5 million in net proceeds from convertible notes payable and $259,000 from sales of our common stock under the ATM Agreement. Additionally, in September 2019 we entered into a new $20.0 million loan and security agreement with Solar Capital Ltd. and Silicon Valley Bank to refinance our prior $10.0 million 2017 Loan Agreement. As of September 30, 2019, we had cash and restricted cash of $83.7 million.

We expect to incur substantial additional expenditures in the near future to support ongoing activities and our plans to obtain regulatory approval for FUROSCIX incorporating the next generation SmartDose drug delivery system. 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 building of our commercial infrastructure, 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 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 refile an NDA for FUROSCIX incorporating the next generation SmartDose drug delivery system;
- 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; 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)	**2018**	**2019**
Net cash (used in) provided by:		
Operating activities	$ (23,011)	$ (15,607)
Investing activities	(41)	—
Financing activities	53	9,691
Net decrease in cash and restricted cash	$ (22,999)	$ (5,916)

Net Cash Used in Operating Activities

During the nine months ended September 30, 2019, net cash used in operating activities was $15.6 million, consisting primarily of a net loss of $22.2 million. This was offset by non-cash charges of $1.5 million and an increase in net operating liabilities of $5.0 million. The non-cash charges primarily consisted of depreciation, amortization related to our right of use leased assets, stock-based compensation expense and non-cash interest expense related to amortization of debt discount associated with the 2017 Loan Agreement. The increase in net operating liabilities related to accrued expenses for device and pharmaceutical development costs and materials as well as the amortization of prepaid insurance.

During the nine months ended September 30, 2018, net cash used in operating activities was $23.0 million, consisting primarily of a net loss of $24.3 million and a decrease in net operating liabilities of $0.9 million. This was offset by non-cash charges of $2.2 million. The decrease in net operating liabilities primarily consisted of prepayments for device and pharmaceutical development and clinical trials, offset by receipt of a refund for Value Added Tax. The non-cash charges primarily consisted of depreciation, amortization related to our right of use leased assets, stock-based compensation expense and non-cash interest expense related to amortization of debt discount associated with the 2017 Loan Agreement.

Net Cash Used in Investing Activities

There were no cash from investing activities during the nine months ended September 30, 2019.

During the nine months ended September 30, 2018, net cash used in investing activities consisted of purchases of property and equipment.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2019, net cash provided by financing activities was $9.7 million, consisting primarily of net proceeds from the 2019 Loan Agreement, net proceeds from sales made pursuant to the ATM Agreement, and stock option exercises.

During the nine months ended September 30, 2018, net cash provided by financing activities was $53,000, consisting primarily of stock option exercises.

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, 2018, filed with the SEC on March 21, 2019.

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, 2018, filed with the SEC on March 21, 2019.

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, 2019, our aggregate outstanding indebtedness was $20.0 million, which bears interest at the rate equal to 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 our 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, 2019, 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, 2019 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, 2018, which was filed with the SEC on March 21, 2019. 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
10.1	Loan and Security Agreement, dated September 17, 2019, by and among scPharmaceuticals Inc., Solar Capital Ltd. and Silicon Valley Bank.(1)
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*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

(1) Incorporated by reference to the Company's Form 8-K filed on April 10, 2019.

† This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 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 12, 2019

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, 2019 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)) 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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 12, 2019

/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, 2019, 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 12, 2019

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