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, 2018

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

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 13, 2018, the Registrant had 18,569,289 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 FDA of our new drug application for Furoscix, including our plans to resubmit an NDA for Furoscix;
- our efforts to address the deficiencies the FDA has identified in its Complete Response Letter, during our September 2018 Type A Post-Action Meeting or may identify in the future with respect to Furoscix, our plans to remediate any of these deficiencies and whether we will successfully execute any plans to remediate any of these;
- the patient populations for which Furoscix may be prescribed, if approved, and any statements that will be included in the label for Furoscix, if approved;
- the timing or likelihood of other regulatory filings and approvals, including any approval to market and sell subcutaneous ceftriaxone;
- 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, 2017 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 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 our Annual Report on Form 10-K for the year ended December 31, 2017 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 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 BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	December 31, 2017	September 30, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 118,298	$ 95,299
Prepaid expenses	823	981
VAT receivable	655	454
Other current assets	107	97
Total current assets	119,883	96,831
Restricted cash	182	182
Property and equipment, net	203	215
Right-of-use lease assets - operating (Type B), net	1,773	1,582
Deposits and other assets	7	9
Total assets	$ 122,048	$ 98,819
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,591	$ 1,667
Accrued expenses	3,063	2,212
Term loan, short term	314	3,210
Current portion of lease obligation - operating (Type B)	242	341
Other current liabilities	1	-
Total current liabilities	5,211	7,430
Term loan, long term	9,105	6,421
Long term lease obligation - operating (Type B)	1,683	1,448
Other liabilities	52	130
Total liabilities	16,051	15,429
Commitments and contingencies (Note 8)		
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, 2018; 18,534,240 and 18,569,289 shares issued and outstanding as of December 31, 2017 and September 30, 2018, respectively	2	2
Additional paid-in capital	173,011	174,748
Accumulated deficit	(67,016)	(91,360)
Total stockholders' equity	105,997	83,390
Total liabilities and stockholders' equity	$ 122,048	$ 98,819

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

SCPHARMACEUTICALS INC.

CONDENSED 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,	
	2017	2018	2017	2018
Operating expenses:				
Research and development	$ 3,585	$ 3,896	$ 10,615	$ 12,799
General and administrative	1,665	1,945	6,113	11,645
Total operating expenses	5,250	5,841	16,728	24,444
Loss from operations	(5,250)	(5,841)	(16,728)	(24,444)
Other income (expense)	15	(5)	82	(58)
Interest income	75	445	170	1,221
Interest expense	(329)	(360)	(461)	(1,062)
Net loss and comprehensive loss	$ (5,489)	$ (5,761)	$ (16,937)	$ (24,343)
Net loss per share — basic and diluted	$ (5.08)	$ (0.31)	$ (15.76)	$ (1.31)
Weighted average common shares outstanding — basic and diluted	1,080,351	18,569,289	1,074,702	18,551,690

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

SCPHARMACEUTICALS INC.

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

	Nine Months Ended September 30,	
	2017	**2018**
Cash flows from operating activities		
Net loss	$ (16,937)	$ (24,343)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	8	29
Amortization expense - right-of-use leased assets - operating (Type B)	79	218
Stock-based compensation	570	1,682
Non-cash interest expense	111	278
Changes in operating assets and liabilities		
Prepaid expenses and other assets	(1,644)	51
Accounts payable, accrued expenses and other liabilities	1,072	(926)
Net cash used in operating activities	(16,741)	(23,011)
Cash flows from investing activities		
Purchases of property and equipment	(190)	(41)
Net cash used in investing activities	(190)	(41)
Cash flows from financing activities		
Costs related to issuance of Series B convertible preferred stock	(8)	-
Proceeds from term loan, net of costs	9,674	-
Costs related to initial public offering	-	(5)
Proceeds from the exercise of vested stock options	3	58
Purchase of restricted stock	(3)	-
Net cash provided by financing activities	9,666	53
Net decrease in cash, cash equivalents and restricted cash	(7,265)	(22,999)
Cash, cash equivalents and restricted cash at beginning of period	39,282	118,480
Cash, cash equivalents and restricted cash at end of period	$ 32,017	$ 95,481
Supplemental cash flow information		
Interest paid	$ 336	$ 738
Taxes paid	$ 34	$ 283
Supplemental non-cash information		
Acquisition of right-of-use leased assets - operating (Type B), net of disposal	$ -	$ 26

The accompanying notes are an integral part of these unaudited condensed 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 transform the way therapy is delivered, 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 June 2018, the Company received a complete response letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding its New Drug Application ("NDA"). On June 15, 2018 management implemented a restructuring plan to reduce operating costs and better align its workforce with the needs of its business following receipt of the CRL. As of September 30, 2018, the Company had paid out all severance, benefits, and related costs.

Basis of Presentation

The accompanying condensed 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. Certain information and disclosures normally included in financial statements in accordance with U.S. GAAP have been condensed or omitted. Accordingly, these condensed financial statements should be read in conjunction with the Company's audited financial statements and related notes for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K filed with the SEC on March 20, 2018. The Company has determined that it operates in one segment.

The accompanying condensed balance sheet as of September 30, 2018, the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2017 and 2018 and condensed statements of cash flows for the nine months ended September 30, 2017 and 2018 are unaudited. The unaudited condensed 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 financial statements. The operating results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results expected for the full year ending December 31, 2018.

2. Significant Accounting Policies

Stock Split

On November 6, 2017, the Company effectuated a 1-for-7.180193 reverse stock split of its outstanding common stock, which was approved by the Company's board of directors on October 27, 2017 and by the Company's stockholders on November 6, 2017. The reverse stock split resulted in an adjustment to the preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented. The shares of common stock retained a par value of $0.0001 per share. Accordingly, the stockholders' equity reflects the reverse stock split by reclassifying from common stock to additional paid-in capital an amount equal to the par value of the decreased shares resulting from the reverse stock split.

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, 2018, 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 8). Cash, cash equivalents and restricted cash consists of the following:

	December 31, 2017	September 30, 2018
Cash and cash equivalents	$ 118,298	$ 95,299
Restricted cash	182	182
Cash, cash equivalents and restricted cash	$ 118,480	$ 95,481

Fair Value of Financial Instruments

Assets and liabilities that are carried at fair value are to be classified and disclosed in one of the following three categories:

Level 1: Observable quoted market prices in active markets for identical assets or liabilities;

Level 2: Observable inputs other than Level 1, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are observable for the asset or liability; and

Level 3: Unobservable inputs for the asset or liability that are significant to the fair value of the assets or liabilities.

The Company does not have any recurring fair value measurements as of September 30, 2018. The carrying values of the Company's cash, cash equivalents and restricted cash, prepaid expenses, 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 approximates current market rates for instruments with similar characteristics.

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 also includes any lease payments made and 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, 2018, the Company had no such accruals.

Recently Issued Accounting Standards

In May 2014, the FASB and the International Accounting Standards Board jointly issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASC 606"), which supersedes the revenue recognition requirements in ASC 605 and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. The update also requires additional disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASC 606 is effective for public entities for annual and interim periods within those annual periods beginning after December 15, 2017. The Company has adopted ASC 606 as of January 1, 2018. The future impact of ASC 606 will be dependent on the nature of the Company's future revenue contracts and arrangements, if any.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases that extend more than twelve months on the balance sheet. This accounting update also requires additional disclosures surrounding the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for financial statements issued for annual and interim periods beginning after December 15, 2018 for public business entities. Early adoption is permitted. The Company elected to early adopt ASU 2016-02 as of January 1, 2018 with retrospective application to January 1, 2016, the beginning of the earliest period to be presented in the Annual Report on Form 10-K for the year ended December 31, 2018. The Company has elected the package of practical expedients permitted in ASC Topic 842. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC Topic 842, (b) whether classification of the operating leases would be different in accordance with ASC Topic 842, or (c) whether the unamortized initial direct costs before transition adjustments (as of December 31, 2015) would have met the definition of initial direct costs in ASC Topic 842 at lease commencement. In addition, the Company does allocate the consideration between lease and non-lease components. As a result of the adoption of the new lease accounting guidance, the Company recognized on January 1, 2016 (a) a lease liability of approximately $409,000, which represents the present value of the remaining lease payments of approximately $540,000, discounted using the Company's incremental borrowing rate of 9.63%, and (b) a right-of-use asset of approximately $396,000 which represents the lease liability of $409,000 adjusted for accrued rent of approximately $13,000. Adoption of the standard requires the Company to restate certain previously reported results, including the recognition of additional ROU assets and lease obligations for operating leases. This standard did not have a material impact on the Company's balance sheets or cash flows from operations and had no impact on the Company's operating results. The most significant impact was the recognition of ROU assets and lease obligations for operating leases.

In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases ("ASU 2018-10"). ASU 2018-10 is intended to address questions on the application of ASU No. 2016-02 and to clarify its guidance. ASU 2018-10 is effective for financial statements issued for annual and interim periods beginning after December 15, 2018 for public business entities. For entities who have early adopted ASU No. 2016-02, the guidance is effective upon the issuance of ASU 2018-10. The Company adopted ASU 2018-10 in July 2018 and there was no impact to the Company's financial statements.

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,	
	2017	2018	2017	2018
Net loss and comprehensive loss	$ (5,489)	$ (5,761)	$ (16,937)	$ (24,343)
Weighted-average shares used in computing net loss per share	1,080,351	18,569,289	1,074,702	18,551,690
Net loss per share, basic and diluted	$ (5.08)	$ (0.31)	$ (15.76)	$ (1.31)

The Company's potentially dilutive securities, which include stock options and convertible preferred 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,	
	2017	2018	2017	2018
Convertible preferred stock, on an as-converted basis	10,126,771	-	10,126,771	-
Stock options to purchase common stock	1,046,879	1,746,287	1,046,879	1,746,287
Unvested restricted stock	852	-	852	-
Total	11,174,502	1,746,287	11,174,502	1,746,287

4. Property and Equipment

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

	ESTIMATED USEFUL LIFE	December 31, 2017	September 30, 2018
Office equipment	5 years	$ 10	$ 10
Office furniture	7 years	116	116
Machinery & equipment	5 years	-	41
Computer equipment	3 years	8	8
Leasehold improvements	Life of lease	95	95
		229	270
Less: Accumulated depreciation		(26)	(55)
Property and equipment, net		$ 203	$ 215

Depreciation expense for the three months ended September 30, 2017 and September 30, 2018 was $5,000 and $10,000, respectively. Depreciation expense for the nine months ended September 30, 2017 and September 30, 2018 was $8,000 and $29,000, respectively.

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

	ESTIMATED USEFUL LIFE	December 31, 2017	September 30, 2018
Right-of-use lease assets - operating (Type B)	Lease term	$ 2,014	$ 2,024
Less: Accumulated amortization		(241)	(442)
Right-of-use lease assets - operating (Type B), net		$ 1,773	$ 1,582

Amortization expense for the three months ended September 30, 2017 and September 30, 2018 was $30,000 and $74,000, respectively.

Amortization expense for the nine months ended September 30, 2017 and September 30, 2018 was $79,000 and $218,000, respectively.

5. Accrued Expenses

Accrued expenses consist of (in thousands):

	December 31, 2017	September 30, 2018
Contract research and development	$ 1,610	$ 985
Consulting and professional service fees	287	251
Employee compensation and related costs	871	795
State taxes	192	123
Financing related costs	90	-
Other	13	58
Total accrued expenses	$ 3,063	$ 2,212

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 and other stock-based awards. The Company's 2014 Stock Incentive Plan (the "2014 Stock Plan") was terminated in November 2017 effective upon the completion of the Company's initial public offering. No further additional options will be granted under the 2014 Stock Plan. At September 30, 2018, there were 1,022,219 options outstanding under the 2014 Plan.

As of September 30, 2018, there were 2,252,980 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan.

At September 30, 2018, there were 1,528,912 options available for issuance and 724,068 options outstanding under the 2017 Stock Plan. Options granted under the 2017 Plan have a term of ten years. Vesting of options 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,	
	2017	2018
Risk-free interest rate	1.89%-2.20%	2.42%-2.86%
Expected dividend yield	0%	0%
Expected life	5.8-6.7 years	5.5-7.0 years
Expected volatility	78%-84%	76%-86%
Weighted-average grant date fair value	$ 2.67	$ 7.57

The following table summarizes information about stock option activity during the nine months ended September 30, 2018 (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, 2017	1,195,495	$ 5.38		
Granted	939,296	10.54		
Exercised	(34,561)	1.69		
Forfeited	(353,943)	11.59		
Outstanding,	1,746,287	$ 6.97	8.69	$ 1,808
Vested and exercisable, September 30, 2018	519,580	$ 5.30	7.93	$ 748
Vested and expected to vest, September 30, 2018	1,482,527	$ 6.93	8.62	$ 1,565

Unrecognized compensation expense related to unvested awards as of September 30, 2018 was $4.5 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 2.8 years.

During the nine months ended September 30, 2018, as part of the restructuring plan (Note 1), the Company extended the exercise period to one year for 21,820 vested options of those affected, with a weighted average exercise price of $7.95, and recorded incremental stock-based compensation expense of $33,000.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2017 and 2018 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2018	2017	2018
Research and development	$ 35	$ 154	$ 109	$ 394
General and administrative	199	409	461	1,288
Total	$ 234	$ 563	$ 570	$ 1,682

7. 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 has a maturity date of May 1, 2021. Debt issuance costs for the 2017 Loan Agreement will 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 is LIBOR plus 8.45%, and there is an interest-only period until November 30, 2018, followed by a 30-month principal and interest period. 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.

The Company entered into an exit fee agreement in connection with the 2017 Loan Agreement for an aggregate payment of 4% of the loan commitment, or $400,000, to the lenders upon the occurrence of an exit event, including an initial public offering. 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 $392,000 as a debt discount and as a derivative liability in the Company’s balance sheet. The Company paid the fee in November 2017 in conjunction with the Company’s IPO.

As of September 30, 2018, unpaid borrowings under the 2017 Loan Agreement totaled $10.0 million. 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. For the three and nine months ended September 30, 2017 the Company recorded $59,000 and $79,000, respectively, related to the amortization of debt discount associated with the 2017 Loan Agreement.

The 2017 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 initially 3% reducing to 1% following the one year anniversary would be assessed on the outstanding principal. A final payment fee of $250,000 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, 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. For the three and nine months ended September 30, 2017, the Company recorded $23,000 and $32,000, respectively, related to the amortization of the final payment fee associated with the 2017 Loan Agreement.

In an event of default under the 2017 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 2017 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, 2018
Face value	$ 10,000
Less: discount	(369)
Total	$ 9,631
Less: current portion	(3,210)
Total	$ 6,421

As of September 30, 2018, future principal payments due under the 2017 Loan Agreement are as follows (in thousands):

Year ended:	
December 31, 2018	$ 333
December 31, 2019	4,000
December 31, 2020	4,000
December 31, 2021	1,667
Total	$ 10,000

8. 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 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, 2018 (in thousands):

Year ended:	
December 31, 2018	$ 128
December 31, 2019	513
December 31, 2020	528
December 31, 2021	537
December 31, 2022	496
Total minimum lease payments	$ 2,202

	Nine Months Ended September 30,	
	2017	2018
Lease cost:		
Operating lease cost	$ 167	$ 348
Short-term lease cost	2	6
Sublease income	-	(26)
Total lease cost	$ 169	$ 328
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 68	$ 302
Operating cash flows from operating leases	$ 46	$ 55
Weighted-average remaining lease term - operating leases	5.2 years	4.2 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.

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 financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017 (the "Annual Report") filed with the Securities and Exchange Commission on March 20, 2018. 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 transform the way therapy is delivered, advance patient care and reduce healthcare costs. Our proprietary platform 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 subcutaneous formulation of furosemide delivered via our sc2Wear Infusor and is under development for treatment of worsening, or decompensated, heart failure outside of the inpatient setting. We filed a new drug application, or NDA, for Furoscix, with the U.S. Food and Drug Administration, or FDA, in August 2017. In June 2018, we received a Complete Response Letter from the FDA for our NDA. The Complete Response Letter indicated the need for additional human factors studies, device modifications, and potentially a clinical validation study. In September 2018, a Type A Post-Action Meeting was held with the FDA to discuss and evaluate the deficiencies raised in the Complete Response Letter. We received minutes from the FDA for this Type A Meeting in October 2018. As reflected in these minutes, the FDA requested that we conduct additional human factors studies and a dose delivery validation study with our recently modified sc2Wear Infusor. We submitted a request for a Type C meeting with the FDA to determine the device delivery validation protocol and were granted a meeting on January 9, 2019. In addition, the FDA confirmed the appropriate population for Furoscix and recommended labelling specifications. Specifically, the FDA confirmed the appropriate populations for Furoscix are patients with worsening NYHA Class II and III heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization. The FDA has recommended that the label for Furoscix, if approved, should state that Furoscix should not be used as a substitute for IV diuretics for patients who require hospitalization or have been recently discharged. We believe Furoscix, if approved by the FDA after we address the deficiencies identified in the Complete Response Letter, would allow heart failure patients who do not require hospitalization or have not been recently discharged from the hospital to receive IV-strength diuresis outside of the high-cost hospital setting.

We have funded our operations from inception through September 30, 2018 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, 2018, we had an accumulated deficit of $91.4 million. We expect to continue to incur net losses for the foreseeable future as we resolve the deficiencies with Furoscix identified by the FDA in the Complete Response Letter, develop product candidates and move towards commercializing our products, if approved, in the United States, continue research and development efforts, scale-up manufacturing, and seek regulatory approval for new product candidates and product enhancements. We will need additional funding to pay expenses relating to commercialization of a product candidate, if approved. 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:

- address the deficiencies with Furoscix identified in the Complete Response Letter;
- 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.

We expect G&A expenses to increase for the foreseeable future primarily due to increased expenses related to the audit, legal and compliance, regulatory, investor relations and tax-related services associated with maintaining compliance with the requirements of the Securities and Exchange Commission and the Nasdaq Stock Market, as well as healthcare laws and compliance requirements, director and officer insurance premiums and other costs associated with operating as a publicly-traded company.

Results of Operations

Comparison of Three Months Ended September 30, 2017 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2017 and 2018 (in thousands):

	Three Months Ended September 30,		Increase
	2017	2018	(Decrease)
Operating expenses:			
Research and development	$ 3,585	$ 3,896	$ 311
General and administrative	1,665	1,945	280
Total operating expenses	5,250	5,841	591
Loss from operations	(5,250)	(5,841)	591
Other income (expense), net	15	(5)	20
Interest income	75	445	370
Interest expense	(329)	(360)	31
Net loss	$ (5,489)	$ (5,761)	$ 272

Research and development expenses. R&D expenses were $3.9 million for the three months ended September 30, 2018, compared to $3.6 million for the three months ended September 30, 2017. The increase of $0.3 million was primarily attributable to a $0.3 million increase in employee-related costs associated with headcount, a $0.4 million increase in supplies and contract services for clinical and medical affairs, and a $0.2 million increase in pharmaceutical development in preparation for commercial validation batches. The increase was partially offset by a $0.1 million decrease in regulatory consulting, a $0.4 million decrease in device development costs, and a $0.1 million decrease in patent related costs.

General and administrative expenses. G&A expenses were $1.9 million for the three months ended September 30, 2018, compared to $1.7 million for the three months ended September 30, 2017. The increase of $0.2 million was primarily attributable to a $0.4 million increase in costs incurred as a public company offset by a decrease of $0.1 million in recruiting costs and $0.1 million in commercial consulting and professional services during the three months ended September 30, 2018.

Other (expense) income. Other expense was $5,000 for the three months ended September 30, 2018, compared to other income of $15,000 for the three months ended September 30, 2017. The increase in expense of $20,000 was primarily attributable to foreign exchange losses due to activity denominated in foreign currency combined with foreign currency fluctuations.

Interest income. Interest income was $0.4 million for the three months ended September 30, 2018, compared to $75,000 for the three months ended September 30, 2017. The increase of $0.4 million was primarily attributable to higher cash balances for the three months ended September 30, 2018 following our initial public offering in November 2017.

Interest expense. Interest expense increased $31,000 from the three months ended September 30, 2017 to $0.4 million for the three months ended September 30, 2018. This increase was attributable to increased rates on the $10.0 million loan entered into in May 2017 with Solar Capital Ltd. and Silicon Valley Bank.

Comparison of Nine Months Ended September 30, 2017 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2017 and 2018 (in thousands):

	Nine Months Ended September 30,		Increase
	2017	2018	(Decrease)
Operating expenses:			
Research and development	$ 10,615	$ 12,799	$ 2,184
General and administrative	6,113	11,645	5,532
Total operating expenses	16,728	24,444	7,716
Loss from operations	(16,728)	(24,444)	7,716
Other income (expense), net	82	(58)	140
Interest income	170	1,221	1,051
Interest expense	(461)	(1,062)	601
Net loss	$ (16,937)	$ (24,343)	$ 7,406

Research and development expenses. R&D expenses were $12.8 million for the nine months ended September 30, 2018, compared to $10.6 million for the nine months ended September 30, 2017. The increase of $2.2 million was primarily attributable to a $1.3 million increase in employee-related expenses associated with additional headcount, a $1.5 million increase in supplies and contract services for clinical and medical affairs, $0.9 million increase in pharmaceutical development in preparation for commercial validation batches, and $0.2 million in additional facility costs during the nine months ended September 30, 2018. This was partially offset by a decrease of $0.7 million in regulatory consulting and a $1.0 million decrease in device development costs.

General and administrative expenses. G&A expenses were $11.6 million for the nine months ended September 30, 2018, compared to $6.1 million for the nine months ended September 30, 2017. The increase of $5.5 million was primarily attributable to a $1.6 million increase in market research and professional services and a $1.0 million increase in employee-related costs due to product launch preparation within our commercial organization, a $1.0 million increase in other employee-related expenses associated with employee recruiting and additional headcount, and a $1.9 million increase related to costs incurred as a public company during the nine months ended September 30, 2018.

Other (expense) income. Other expense was $58,000 for the nine months ended September 30, 2018, compared to other income of $82,000 for the nine months ended September 30, 2017. The increase in expense of $140,000 was primarily attributable to foreign exchange losses due to activity denominated in foreign currency combined with foreign currency fluctuations.

Interest income. Interest income was $1.2 million for the nine months ended September 30, 2018, compared to $0.2 million for the nine months ended September 30, 2017. The increase of $1.0 million was primarily attributable to higher cash balances for the nine months ended September 30, 2018 following our initial public offering in November 2017.

Interest expense. Interest expense increased $0.6 million from the nine months ended September 30, 2017 to $1.1 million for the nine months ended September 30, 2018. This increase was attributable to the $10.0 million loan entered into in May 2017 with Solar Capital Ltd. and Silicon Valley Bank.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through September 30, 2018 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, 2018, we had received net cash proceeds of $92.7 million from our initial public offering, $56.7 million from sales of our preferred stock, and $13.5 million in net proceeds from convertible notes payable. Additionally, in May 2017 we incurred $10.0 million of debt under our loan and security agreement with Solar Capital Ltd. and Silicon Valley Bank. As of September 30, 2018, we had cash and restricted cash of $95.5 million.

We expect to increase expenditures in the near future to support our operations and address the deficiencies identified in the Complete Response Letter. 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 to bear significant costs and expenses in the future as we develop our product candidates and advance them towards regulatory approval, including resubmitting the NDA for Furoscix, and as we prepare for and, if approved, commence U.S. commercialization of our product candidates, including Furoscix, and 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:

- our efforts to resolve the deficiencies with Furoscix, including as we attempt to address those identified in the Complete Response Letter;
- the costs of device-related research and development efforts, including conducting validation studies to support our NDA resubmission;
- 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 costs and timing of developing variations of our sc2Wear Infusor and, if necessary, obtaining FDA approval of such variations;
- 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)	**2017**	**2018**
Net cash (used in) provided by:		
Operating activities	$ (16,741)	$ (23,011)
Investing activities	(190)	(41)
Financing activities	9,666	53
Net decrease in cash and restricted cash	$ (7,265)	$ (22,999)

Net Cash Used in Operating Activities

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 an increase in net operating assets of $0.9 million. This was offset by non-cash charges of $2.2 million. The increase in net operating assets 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.

During the nine months ended September 30, 2017, net cash used in operating activities was $16.7 million, consisting primarily of a net loss of $16.9 million and an increase in net operating assets of $0.6 million, offset by non-cash charges of $0.8 million. The increase in net operating assets primarily consisted of an increase in deferred financing costs, offset by an increase in accrued expenses related to employee costs. 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

During the nine months ended September 30, 2017 and 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, 2018, net cash provided by financing activities was $53,000, consisting primarily of stock option exercises.

During the nine months ended September 30, 2017, net cash provided by financing activities was $9.7 million, consisting primarily of net proceeds from the 2017 Loan Agreement.

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, 2017.

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.

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, 2018, our aggregate outstanding indebtedness was $10.0 million, which bears interest at the rate equal to LIBOR plus 8.45%. 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, 2018, 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, 2018 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, 2017, which was filed with the SEC on March 20, 2018 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, which was filed with the SEC on August 14, 2018. There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K other than with respect to the risk factors identified below.

Risks Related to Our Business, Financial Position and Need for Additional Capital

We have not generated any revenue from Furoscix and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from Furoscix, and we do not know when, or if, we will generate any revenue. Furthermore, the Complete Response Letter will delay any potential commercialization of Furoscix, potentially indefinitely. On September 24, 2018, we held a post-action Type A meeting with the FDA to discuss the topics covered in the Complete Response Letter and to clarify the path towards resubmission of the NDA for Furoscix. There can be no guarantee that our efforts to resolve the deficiencies identified in the Complete Response Letter will be supportive of, or guarantee, a NDA resubmission, or result in our successfully obtaining FDA approval of Furoscix in a timely fashion, if at all.

We do not expect to generate significant revenue unless or until we obtain marketing approval of, and begin to sell, Furoscix. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- address the deficiencies of the NDA for Furoscix identified in the Complete Response Letter;
- obtain marketing approval for Furoscix;
- set an acceptable price for Furoscix, if approved;
- obtain commercial quantities of Furoscix, if Furoscix is approved, at acceptable cost levels;
- commercialize Furoscix, if approved, by developing our own sales force for commercialization in the United States or in other key territories by entering into partnership or co-promotion arrangements with third parties;
- obtain third-party coverage or adequate reimbursement for Furoscix, if approved;
- achieve market acceptance of Furoscix, if approved, in the medical community and with third-party payers, including placement in accepted clinical guidelines for the conditions for which Furoscix is intended to target; and
- delay the introduction by third parties of alternate versions of Furoscix, if approved.

If Furoscix is approved for commercial sale, we expect to incur significant sales and marketing costs as we prepare for its commercialization. Even if we receive marketing approval and expend these costs, Furoscix may not be a commercially successful device-drug combination. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing our product programs is a time-consuming, expensive and uncertain process that takes years to complete. In the post-action Type A meeting held with the FDA to discuss the Complete Response Letter for our lead product candidate, Furoscix, the FDA asked us to conduct additional human factors studies and a dose delivery validation study with the recently modified sc2Wear Infusor. These actions will require further use of capital, and even if we are successful will require time and effort that will delay our ability to begin generating revenue. Even if Furoscix or any of our other product candidates are approved, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We plan to continue to use our existing unrestricted cash (including the net proceeds from our completed initial public offering) primarily for the continued development of Furoscix to address the deficiencies identified in the Complete Response Letter, including conducting additional human factors and dose delivery validation studies, to implement the automation necessary to increase capacity for our sc2Wear Infusor, research and development, including for our infectious diseases program and for working capital and other general corporate purposes. We will be required to expend significant funds in order to commercialize Furoscix, as well as other product candidates we may seek to develop. In any event, our existing unrestricted cash (including the net proceeds from our completed initial public offering) may not be sufficient to fund all of the efforts that we plan to undertake, including the development of any of our other product candidates. Accordingly, we may be required to obtain further funding through public or private equity offerings, debt financings, royalty-based financing arrangements, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the time and expense required to continue to develop Furoscix to address the deficiencies identified in the Complete Response Letter;
- the outcome, timing and costs of seeking regulatory approvals for Furoscix and other product candidates that we may develop;
- the costs of commercialization activities for Furoscix and any other of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of Furoscix or any other of our current and future product candidates;
- the pricing and reimbursement of Furoscix, if approved, and of other product candidates that may be approved;
- the number of future product candidates that we pursue and their development requirements;
- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, our other product candidates;
- our ability to enter into, and the terms and timing of, any collaborations, licensing or other arrangements;
- our headcount growth and associated costs as we establish a commercial infrastructure and continue our research and development activities;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

Risks Related to the Regulatory Approval and Commercialization of Our Lead Product Candidate, Furoscix

We are heavily dependent on the success of our product candidates and, in particular, our lead product candidate, Furoscix, for which regulatory approval is pending. We cannot give any assurance that we will receive regulatory approval for this product candidate or any other product candidates, which is necessary before they can be commercialized.

To date, we have expended significant time, resources and effort on the development of our product candidates, and a substantial majority of our resources are now focused on seeking marketing approval for and planning for potential commercialization of our most advanced product candidate, Furoscix, in the United States. Our business and future success are substantially dependent on our ability to successfully and timely obtain regulatory approval for and commercialize Furoscix for the treatment of decompensated heart failure. All of our other product candidates are in earlier stages of development and subject to the risks of failure inherent in developing drug products. Accordingly, our ability to generate significant product revenues in the near term will depend almost entirely on our ability to successfully obtain marketing approval for and commercialize Furoscix.

We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. In June 2018, we received a Complete Response Letter with respect to the NDA for Furoscix that we previously submitted in August 2017. This Complete Response Letter delays any potential approval by the FDA of our NDA for Furoscix, and it remains a possibility that the FDA may never approve Furoscix. Unless Furoscix obtains regulatory approval, it may never be commercialized. Satisfaction of regulatory requirements can be protracted, is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. For example, Furoscix is considered to be a drug-device combination product by the FDA, and its NDA thus

will require review and coordination by FDA's drug and device centers prior to approval. Furthermore, the FDA has already identified deficiencies with Furoscix in the Complete Response Letter. The Complete Response Letter indicated the need for additional human factors studies, device modifications, and potentially a clinical validation study. In September 2018, a Type A Post-Action Meeting was held with the FDA to discuss and evaluate the deficiencies raised in the Complete Response Letter. We received minutes from the FDA for this Type A Meeting in October 2018. In the minutes, the FDA requested that we conduct additional human factors studies and a dose delivery validation study with our recently modified sc2Wear Infusor. We cannot predict whether we will be able to address these deficiencies to obtain regulatory approval to commercialize Furoscix or any of our other product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any further delay or setback in the regulatory approval or commercialization of any of these product candidates will adversely affect our business.

Our ability to successfully commercialize any of our products candidates will depend, among other things, on our ability to:

- address the deficiencies identified by the FDA in the Complete Response Letter;
- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;
- establish and maintain commercial manufacturing arrangements with third-party manufacturers;
- build and maintain sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates;
- successfully complete our clinical trials for our product candidates under clinical development;
- establish collaborations with third parties for the commercialization of our product candidates in countries outside the United States and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- secure acceptance of our product candidates from physicians, healthcare payers, patients and the medical community; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize Furoscix or any of our other product candidates in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize Furoscix, and our ability to generate revenue will be materially impaired.

Furoscix and the activities associated with its development and commercialization, including its design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain marketing approval for Furoscix will prevent us from commercializing it.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither Furoscix nor any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example the FDA has already delayed our timeline to commercialization of Furoscix with the Complete Response Letter. Additionally, with respect to the resubmission of our NDA for Furoscix, the FDA:

- could determine that any action we take with respect to the deficiencies in the Complete Response Letter do not adequately address deficiencies;
- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway for Furoscix;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of Furoscix or any of our product candidates for any indication;

- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that there are unacceptable risks associated with the device component of Furoscix or that there are deficiencies with the information submitted to demonstrate the safety, effectiveness and reliability of the device component;
- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for Furoscix or any of our other product candidates is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously-approved drugs with the same conditions of approval as Furoscix (e.g., subcutaneous injection);
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

For example, in our Phase 3 product design clinical validation, or PDCV, study, Furoscix did not meet its specified primary endpoints of the absence of major product and major system related failures leading to inadequate delivery of drug product, due to four cases in which the Furoscix administered doses fell below the predefined criteria. We discussed these data with the FDA at a pre-NDA meeting in June 2017. As part of our NDA submission, the FDA requested that a high-level safety assurance case be submitted just prior to the NDA submission, which request we had complied with, and that certain updated risk analyses be submitted concurrently with our NDA. In addition, the FDA requested that our NDA include an assessment of the data generated from all of our studies. Even with our efforts to address these requests, the FDA issued a Complete Response Letter in response to the Furoscix NDA, which indicated the need for additional human factors studies, device modifications, and potentially a clinical validation study. In September 2018, a Type A Post-Action Meeting was held with the FDA to discuss and evaluate the deficiencies raised in the Complete Response Letter. We received minutes from the FDA for this Type A Meeting in October 2018. In the minutes, the FDA requested that we conduct additional human factors studies and a dose delivery validation study with our recently modified sc2Wear Infusor. We submitted a request for a Type C meeting with the FDA to determine the device delivery validation protocol and were granted a meeting on January 9, 2019. In addition, the FDA confirmed the appropriate population for Furoscix and recommended labelling specifications. However, there can be no assurance that we will be able to satisfy the FDA that we have addressed the deficiencies identified in the Complete Response Letter. Failing to obtain regulatory approval for Furoscix would harm our business, results of operations and prospects significantly.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, may impose distribution or use restrictions, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

We have supported and continue to support investigator sponsored clinical trials evaluating novel approaches utilizing Furoscix to manage patients with worsening heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization. We do not control the design or administration of investigator-sponsored trials, and the investigator-sponsored trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated, identify significant

concerns with respect to Furoscix that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities. All completed and ongoing studies are registered at www.clinicaltrials.gov. To the extent the results of these or other investigator sponsored trials are inconsistent with, or different from, the results of our company- sponsored trials or raise concerns regarding Furoscix, the FDA or a foreign regulatory authority may question the results of the company-sponsored trials or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing approval of Furoscix.

We expect to rely on third-party consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish Furoscix's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. If we cannot successfully obtain approval of or commercialize Furoscix, our business will be materially harmed and the price of our common stock will be adversely affected.

The commercial success of Furoscix and any other product candidates, if approved, depends upon attaining market acceptance by hospital networks, physicians, patients, third-party payers and the medical community.

Even if our current and future product candidates are approved for commercialization by the appropriate regulatory authorities, physicians may not prescribe our approved product candidates, in which case we would not generate the revenues we anticipate. Market acceptance of any of our product candidates by physicians, patients, third-party payers and the medical community depends on, among other things:

- our ability to provide acceptable evidence of safety and efficacy, at least equivalent to IV-level treatments;
- perceived advantages of our product candidates over alternative treatments, such as oral and IV formulations;
- relative convenience as well as ease of administration of our product candidates compared to existing treatments;
- any labeling restrictions placed upon each product candidate in connection with its approval;
- the prevalence and severity of the adverse side effects of each of our product candidates;
- the clinical indications for which each of our product candidates is approved, including any potential additional restrictions placed upon each product candidate in connection with its approval;
- prevalence of the disease or condition for which each product candidate is approved;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which each product is approved for use at, or included on formularies of, hospitals and managed care organizations;
- any negative publicity related to our or our competitors' products or other formulations of products that we administer subcutaneously, including as a result of any related adverse side effects;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness; and
- the availability of coverage and adequate reimbursement by third parties.

For example, in the minutes from the Type A meeting we held with the FDA on September 24, 2018, the FDA confirmed the appropriate populations for Furoscix are patients with worsening NYHA Class II and III heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization. The FDA also recommended that the label for Furoscix, if approved, should state that Furoscix should not be used as a substitute for IV diuretics for patients who require hospitalization or have been recently discharged.

Additionally, if Furoscix or any of our other product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products, require us to take our approved product off the market or ask us to voluntarily remove the product from the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

- regulatory authorities may impose conditions under a risk evaluation and mitigation strategy, or REMS, including distribution of a medication guide to patients outlining the risks of such side effects or imposing distribution or use restrictions;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

Successful commercialization will also depend on whether we can adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe upon their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the emergence of new or existing products as competition, which may be proven to be more clinically effective and cost-effective.

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

On November 16, 2017, we completed an initial public offering ("IPO"), in which we issued and sold 6,400,000 shares of common stock at a public offering price of $14.00 per share, resulting in net proceeds to us of $81.0 million after deducting $6.3 million of underwriting discounts and commissions and offering costs of $2.3 million. On November 29, 2017, we completed the sale of an additional 894,968 shares of our common stock to the underwriters under the underwriters' option in the IPO to purchase additional shares of our common stock, resulting in net proceeds to us of $11.7 million after deducting underwriting discounts and commissions of $0.9 million. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-221077), which was declared effective by the SEC on November 16, 2017.

Jeffries LLC, Leerink Partners LLC and BMO Capital Markets Corp. acted as joint book-running managers of the offering and as representatives of the underwriters. No offering expenses were paid directly or indirectly to any of our directors or officers, or their associates, or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

As of September 30, 2018, none of the net offering proceeds from the IPO had been used. We are holding the net proceeds from the IPO in cash. As described in our final prospectus filed with the SEC on November 17, 2017 pursuant to Rule 424(b) under the Securities Act of 1933, as amended, we expect to use the net proceeds from our IPO to address deficiencies with Furoscix identified by the FDA in the Complete Response Letter; for pre-commercial planning and commercialization of Furoscix, if approved, including the development of our sales and marketing infrastructure; the automation necessary to increase manufacturing capacity for our sc2Wear Infusor; research and development, including for our infectious diseases program; as well as for working capital and other general corporate purposes.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	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.

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 13, 2018

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

Date: November 13, 2018

By: /s/ Troy Ignelzi
Troy Ignelzi
Chief Financial Officer
(Principal Financial and Accounting 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, 2018 of SCPHARMACEUTICALS INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 13, 2018

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

Exhibit 31.2

Certification

I, Troy Ignelzi, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2018 of SCPHARMACEUTICALS INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 13, 2018

/s/ Troy Ignelzi
Troy Ignelzi
Chief Financial Officer
(Principal Financial and Accounting 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, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John H. Tucker, President and Chief Executive Officer (Principal Executive Officer) hereby certify, pursuant to 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 13, 2018

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of scPharmaceuticals Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Troy Ignelzi, Chief Financial Officer (Principal Financial and Accounting 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 13, 2018

/s/ Troy Ignelzi
Troy Ignelzi
Chief Financial Officer
(Principal Financial and Accounting Officer)