UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 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;
- deficiencies the FDA has identified in its Complete Response Letter and may identify in the future with respect to Furoscix and whether we will be able to address the issues that relate to those deficiencies;
- 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.

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. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, then actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

SCPHARMACEUTICALS INC.

INDEX

PART I — FINANCIAL INFORMATION

SCPHARMACEUTICALS INC.

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

	December 31, 2017	June 30, 2018
Assets		
Current assets		
Cash	$ 118,298	$ 100,768
Prepaid expenses	823	1,608
VAT receivable	655	438
Other current assets	107	151
Total current assets	119,883	102,965
Restricted cash	182	182
Property and equipment, net	203	225
Right-of-use lease assets - operating (Type B), net	1,773	1,629
Deposits and other assets	7	8
Total assets	$ 122,048	$ 105,009
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,591	$ 2,358
Accrued expenses	3,063	2,565
Term loan, short term	314	2,231
Current portion of lease obligation - operating (Type B)	242	309
Other current liabilities	1	-
Total current liabilities	5,211	7,463
Term loan, long term	9,105	7,331
Long term lease obligation - operating (Type B)	1,683	1,514
Other liabilities	52	109
Total liabilities	16,051	16,417
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 June 30, 2018; 18,534,240 and 18,569,289 shares issued and outstanding as of December 31, 2017 and June 30, 2018, respectively	2	2
Additional paid-in capital	173,011	174,189
Accumulated deficit	(67,016)	(85,599)
Total stockholders' equity	105,997	88,592
Total liabilities and stockholders' equity	$ 122,048	$ 105,009

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 June 30,		Six Months Ended June 30,	
	2017	2018	2017	2018
Operating expenses:				
Research and development	$ 4,145	$ 4,855	$ 7,030	$ 8,903
General and administrative	2,374	5,049	4,448	9,700
Total operating expenses	6,519	9,904	11,478	18,603
Loss from operations	(6,519)	(9,904)	(11,478)	(18,603)
Other income (expense)	57	(11)	67	(53)
Interest income	58	424	95	775
Interest expense	(132)	(359)	(132)	(701)
Net loss and comprehensive loss	$ (6,536)	$ (9,850)	$ (11,448)	$ (18,582)
Net loss per share — basic and diluted	$ (6.09)	$ (0.53)	$ (10.68)	$ (1.00)
Weighted average common shares outstanding — basic and diluted	1,072,940	18,549,978	1,071,822	18,542,745

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

SCPHARMACEUTICALS INC.

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

	Six Months Ended June 30,	
	2017	**2018**
Cash flows from operating activities		
Net loss	$ (11,448)	$ (18,582)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	3	19
Amortization expense - right-of-use leased assets - operating (Type B)	49	144
Stock-based compensation	336	1,119
Non-cash interest expense	29	188
Changes in operating assets and liabilities		
Prepaid expenses and other assets	(749)	(613)
Accounts payable, accrued expenses and other liabilities	923	179
Net cash used in operating activities	(10,857)	(17,546)
Cash flows from investing activities		
Purchases of property and equipment	(12)	(41)
Net cash used in investing activities	(12)	(41)
Cash flows from financing activities		
Costs related to issuance of Series B convertible preferred stock	(8)	-
Proceeds from term loan, net of costs	9,679	-
Costs related to initial public offering	-	(1)
Proceeds from the exercise of vested stock options	-	58
Purchase of restricted stock	(3)	-
Net cash provided by financing activities	9,668	57
Net decrease in cash and restricted cash	(1,201)	(17,530)
Cash and restricted cash at beginning of period	39,281	118,480
Cash and restricted cash at end of period	$ 38,080	$ 100,950
Supplemental cash flow information		
Interest paid	$ 89	$ 513
Taxes paid	$ 28	$ 259

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. Under this restructuring plan, the Company reduced its workforce by approximately 36%, to 27 employees. The Company recorded a charge of $572,000 during the three months ended June 30, 2018 related to the restructuring plan including severance, benefits and related costs. $147,000 and $425,000 was recorded in research and development expenses and general and administrative expenses, respectively. The Company paid $115,000 of these costs during the three months ended June 30, 2018 and expects to pay $424,000 in the third quarter of 2018. The remainder of the restructuring charge consists of a non-cash charge related to the modification of stock options (Note 6). As of June 30, 2018, the Company had a balance of $424,000 in accrued expenses related to 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 June 30, 2018, the condensed statements of operations and comprehensive loss for the three and six months ended June 30, 2017 and 2018 and condensed statements of cash flows for the six months ended June 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 six months ended June 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.

Restricted Cash

As of June 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).

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 June 30, 2018. The carrying values of the Company's cash 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 is near 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 June 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 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.

3. Net Loss per Share

Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share of common stock (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2018	2017	2018
Net loss and comprehensive loss	$ (6,536)	$ (9,850)	$ (11,448)	$ (18,582)
Weighted-average shares used in computing net loss per share	1,072,940	18,549,978	1,071,822	18,542,745
Net loss per share, basic and diluted	$ (6.09)	$ (0.53)	$ (10.68)	$ (1.00)

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 June 30,		Six Months Ended June 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	1,052,542	1,610,651	1,052,542	1,610,651
Unvested restricted stock	1,218	-	1,218	-
Total	11,180,531	1,610,651	11,180,531	1,610,651

4. Property and Equipment

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

	ESTIMATED USEFUL LIFE	December 31, 2017	June 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)	(45)
Property and equipment, net		$ 203	$ 225

Depreciation expense for the three months ended June 30, 2017 and June 30, 2018 was $1,000 and $9,000, respectively. Depreciation expense for the six months ended June 30, 2017 and June 30, 2018 was $3,000 and $19,000, respectively.

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

	ESTIMATED USEFUL LIFE	December 31, 2017	June 30, 2018
Right-of-use lease assets - operating (Type B)	Lease term	$ 2,014	$ 2,014
Less: Accumulated amortization		(241)	(385)
Right-of-use lease assets - operating (Type B), net		$ 1,773	$ 1,629

Amortization expense for the three months ended June 30, 2017 and June 30, 2018 was $25,000 and $73,000, respectively.
Amortization expense for the six months ended June 30, 2017 and June 30, 2018 was $49,000 and $144,000, respectively.

5. Accrued Expenses

Accrued expenses consist of (in thousands):

	December 31, 2017	June 30, 2018
Contract research and development	$ 1,610	$ 1,170
Consulting and professional service fees	287	275
Employee compensation and related costs	871	986
State taxes	192	82
Financing related costs	90	-
Other	13	52
Total accrued expenses	$ 3,063	$ 2,565

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 June 30, 2018, there were 1,025,605 options outstanding under the 2014 Plan.

As of June 30, 2018, there were 2,249,594 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan.

At June 30, 2018, there were 1,664,548 options available for issuance and 585,046 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:

	Six Months Ended June 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%	77%-86%
Weighted-average grant date fair value	$ 2.67	$ 8.54

The following table summarizes information about stock option activity during the six months ended June 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	764,950	11.83		
Exercised	(34,561)	1.69		
Forfeited	(315,233)	11.99		
Outstanding, June 30, 2018	1,610,651	$ 7.23	8.85	$ 1,471
Vested and exercisable, June 30, 2018	451,663	$ 5.36	8.14	$ 587
Vested and expected to vest, June 30, 2018	1,358,562	$ 7.12	8.78	$ 1,274

Unrecognized compensation expense related to unvested awards as of June 30, 2018 was $4.7 million and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 3.0 years.

During the three months ended June 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 six months ended June 30, 2017 and 2018 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2018	2017	2018
Research and development	$ 38	$ 54	$ 74	$ 240
General and administrative	190	443	262	879
Total	$ 228	$ 497	$ 336	$ 1,119

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 June 30, 2018, unpaid borrowings under the 2017 Loan Agreement totaled $10.0 million. For the three and six months ended June 30, 2018 the Company recorded $75,000 and $144,000, respectively, related to the amortization of debt discount associated with the 2017 Loan Agreement. For the three and six months ended June 30, 2017 the Company recorded $20,000 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 six months ended June 30, 2018, the Company recorded $23,000 and $44,000, respectively, related to the amortization of the final payment fee associated with the 2017 Loan Agreement. For the three and six months ended June 30, 2017, the Company recorded $9,000 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):

	June 30, 2018
Face value	$ 10,000
Less: discount	(438)
Total	$ 9,562
Less: current portion	(2,231)
Total	$ 7,331

As of June 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 June 30, 2018 (in thousands):

Year ended:	
December 31, 2018	$ 234
December 31, 2019	499
December 31, 2020	512
December 31, 2021	524
December 31, 2022	496
Total minimum lease payments	$ 2,265

	Six Months Ended June 30,	
	2017	2018
Lease cost:		
Operating lease cost	$ 96	$ 237
Short-term lease cost	2	4
Sublease income	-	(13)
Total lease cost	$ 98	$ 228
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 51	$ 194
Operating cash flows from operating leases	$ 13	$ 43
Weighted-average remaining lease term - operating leases	5.4 years	4.5 years
Weighted-average discount rate - operating leases	9.6%	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 May 2018, we received a notification from the FDA stating that, as part of its ongoing review of the Company's NDA, the FDA had identified deficiencies that precluded discussion of labeling and postmarketing requirements/commitments at that time. 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. The FDA has granted our request for a Type A Post-Action Meeting, scheduled for September 24, 2018, to further discuss and evaluate the deficiencies raised. We believe Furoscix, if approved by the FDA after we address the deficiencies in the Complete Response Letter, would allow heart failure patients to receive IV-strength diuresis with earlier discharge from, or potentially without admission to, the high-cost hospital setting.

We have funded our operations from inception through June 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 June 30, 2018, we had an accumulated deficit of $85.6 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 or 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.

Following the receipt of the Complete Response Letter, we anticipate that our G&A expenses will decrease as we reduce our corporate and commercial infrastructure to extend our cash runway and address the Complete Response Letter. Additionally, we anticipate 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 June 30, 2017 and 2018

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

	Three Months Ended June 30,		Increase
	2017	2018	(Decrease)
Operating expenses:			
Research and development	$ 4,145	$ 4,855	$ 710
General and administrative	2,374	5,049	2,675
Total operating expenses	6,519	9,904	3,385
Loss from operations	(6,519)	(9,904)	3,385
Other income (expense), net	57	(11)	68
Interest income	58	424	366
Interest expense	(132)	(359)	227
Net loss	$ (6,536)	$ (9,850)	$ 3,314

Research and development expenses. R&D expenses were $4.9 million for the three months ended June 30, 2018, compared to $4.1 million for the three months ended June 30, 2017. The increase of $0.7 million was primarily attributable to a $0.5 million increase in employee-related expenses associated with additional headcount and severance, a $0.8 million increase in supplies and contract services for clinical and medical affairs, $0.5 million increase in pharmaceutical development in preparation for commercial validation batches, and a $0.1 million increase in consulting for serialization during the three months ended June 30, 2018. The increase was partially offset by a $0.5 million decrease in regulatory consulting and a $0.7 million decrease in device development costs. We anticipate our research and development expenses to increase in the near future as we address deficiencies with Furoscix identified by the FDA in the Complete Response Letter.

General and administrative expenses. G&A expenses were $5.0 million for the three months ended June 30, 2018, compared to $2.4 million for the three months ended June 30, 2017. The increase of $2.7 million was primarily attributable to a $0.8 million increase in consulting and professional services due to the expansion of our commercial organization, a $1.1 million increase in employee-related expenses associated with additional headcount, severance, and recruiting, and $0.8 million related to costs

incurred as a public company during the three months ended June 30, 2018. We anticipate that our G&A expenses will decrease in the near future as we reduce our commercial infrastructure to extend our cash runway.

Other (expense) income. Other expense was $11,000 for the three months ended June 30, 2018, compared to other income of $57,000 for the three months ended June 30, 2017. The increase in expense of $68,000 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 June 30, 2018, compared to $58,000 for the three months ended June 30, 2017. The increase of $0.4 million was primarily attributable to higher cash balances for the three months ended June 30, 2018 following our initial public offering in November 2017.

Interest expense. Interest expense increased $0.2 million from the three months ended June 30, 2017 to $0.4 million for the three months ended June 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.

Comparison of Six Months Ended June 30, 2017 and 2018

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

	Six Months Ended June 30,		Increase (Decrease)
	2017	2018	
Operating expenses:			
Research and development	$ 7,030	$ 8,903	$ 1,873
General and administrative	4,448	9,700	5,252
Total operating expenses	11,478	18,603	7,125
Loss from operations	(11,478)	(18,603)	7,125
Other income (expense), net	67	(53)	120
Interest income	95	775	680
Interest expense	(132)	(701)	569
Net loss	$ (11,448)	$ (18,582)	$ 7,134

Research and development expenses. R&D expenses were $8.9 million for the six months ended June 30, 2018, compared to $7.0 million for the six months ended June 30, 2017. The increase of $1.9 million was primarily attributable to a $1.0 million increase in employee-related expenses associated with additional headcount and severance, a $1.2 million increase in supplies and contract services for clinical and medical affairs, $0.7 million increase in pharmaceutical development in preparation for commercial validation batches, $0.2 million in additional facility costs, and a $0.1 million increase in consulting for serialization during the six months ended June 30, 2018. This was partially offset by a decrease of $0.6 million in regulatory consulting and a $0.7 million decrease in device development costs. We anticipate our research and development expenses to increase in the near future as we address deficiencies with Furoscix identified by the FDA in the Complete Response Letter.

General and administrative expenses. G&A expenses were $9.7 million for the six months ended June 30, 2018, compared to $4.4 million for the six months ended June 30, 2017. The increase of $5.3 million was primarily attributable to a $1.8 million increase in consulting and professional services due to the expansion of our commercial organization, a $1.9 million increase in employee-related expenses associated with additional headcount, severance and recruiting, $1.5 million related to costs incurred as a public company, and $0.1 million in additional facility costs during the six months ended June 30, 2018. We anticipate that our G&A expenses will decrease in the near future as we reduce our commercial infrastructure to extend our cash runway.

Other (expense) income. Other expense was $53,000 for the six months ended June 30, 2018, compared to other income of $67,000 for the six months ended June 30, 2017. The increase in expense of $120,000 was primarily attributable to foreign exchange losses due to activity denominated in foreign currency combined with foreign currency fluctuations.

Interest income. Interest income was $0.8 million for the six months ended June 30, 2018, compared to $0.1 million for the six months ended June 30, 2017. The increase of $0.7 million was primarily attributable to higher cash balances for the six months ended June 30, 2018 following our initial public offering in November 2017.

Interest expense. Interest expense increased $0.6 million from the six months ended June 30, 2017 to $0.7 million for the six months ended June 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 June 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 June 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 June 30, 2018, we had cash and restricted cash of $101.0 million.

We expect to reduce expenditures in the near future as we scale back our commercial infrastructure to extend our cash runway. 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 prepare for and, if approved, commence U.S. commercialization of our product candidates, including Furoscix, and as we continue to make substantial expenditures on research and development, including to increase our manufacturing capacity and for conducting clinical trials of our product candidates. Additionally, we will incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- our efforts to resolve the deficiencies with Furoscix identified in the Complete Response Letter;
- 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:

(in thousands)	Six Months Ended June 30, 2017	2018
Net cash (used in) provided by:		
Operating activities	$ (10,857)	$ (17,546)
Investing activities	(12)	(41)
Financing activities	9,668	57
Net decrease in cash and restricted cash	$ (1,201)	$ (17,530)

Net Cash Used in Operating Activities

During the six months ended June 30, 2018, net cash used in operating activities was $17.5 million, consisting primarily of a net loss of $18.5 million and an increase in net operating assets of $0.5 million. This was offset by non-cash charges of $1.5 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, stock-based compensation expense and non-cash interest expense related to amortization of debt discount associated with the 2017 Loan Agreement.

During the six months ended June 30, 2017, net cash used in operating activities was $10.9 million, consisting primarily of a net loss of $11.4 million, offset by a decrease in net operating assets and non-cash charges of $0.6 million. The decrease in net operating assets primarily consisted of increased accruals for employee costs, regulatory consulting and pharmaceutical development, offset by a decrease in accounts payable for clinical trials and device engineering costs. The non-cash charges primarily consisted of stock-based compensation expense, depreciation and amortization related to our right of use leased assets.

Net Cash Used in Investing Activities

During the six months ended June 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 six months ended June 30, 2018, net cash provided by financing activities was $57,000, consisting primarily of stock option exercises.

During the six months ended June 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 June 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 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 June 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 six months ended June 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. 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 a history of significant operating losses and expect to incur significant and increasing losses for the foreseeable future; we may never achieve or maintain profitability.

We do not expect to generate revenue or profitability that is necessary to finance our operations in the short term. We incurred net losses of $10.5 million, $24.4 million and $23.8 million for the years ended December 31, 2015, 2016 and 2017, respectively. In addition, our accumulated deficit as of December 31, 2015, 2016 and 2017 was $18.8 million, $43.2 million and $67.0 million, respectively. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, if any, of our current or future product candidates, if approved, we may never attain profitability in the future. We have devoted substantially all of our financial resources and efforts to date to research and development, including preclinical studies and our clinical trials, and preparation for commercialization of our lead product candidate, Furoscix, if approved.

We anticipate that our expenses will increase substantially if and as we:

- pursue regulatory approval of Furoscix, including as we seek to address the deficiencies identified in the Complete Response Letter;
- prepare to establish sales, marketing, distribution and other commercial infrastructure and manufacture commercial inventory in anticipation of the potential regulatory approval of Furoscix;
- initiate and continue research, preclinical and clinical development efforts for any additional or future product candidates, including subcutaneous ceftriaxone;
- seek to identify additional product candidates;
- seek regulatory and marketing approvals for other product candidates that successfully complete clinical trials;
- manufacture larger quantities of product candidates for clinical development and, potentially, commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, quality control, commercial and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add equipment and physical infrastructure to support our research and development.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for, and successfully commercialize, Furoscix or any other product candidates that we may develop. Successful commercialization will require achievement of key milestones, including

addressing the deficiencies identified in the Complete Response Letter with respect to our NDA for Furoscix, completing clinical trials of our product candidates that are under clinical development, obtaining marketing approval for our product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payers. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

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. 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. We only recently received a Complete Response Letter with respect to the NDA for our lead product candidate, Furoscix, and addressing the deficiencies identified therein 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, 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.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We commenced operations in 2013. Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and clinical trials for our product candidates. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

In addition, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control.

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. 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. The FDA has granted our request for a Type A Post-Action Meeting, scheduled for September 24, 2018, to discuss the Complete Response Letter. 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.

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.

A number of academic institutions have or are also currently conducting and sponsoring clinical trials relating to Furoscix, including the Johns Hopkins Heart Failure Bridge Clinic and the Duke Clinical Research Institute. 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.

Two of the investigator sponsored trials of our product candidates are currently ongoing. 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.

We intend to utilize the 505(b)(2) pathway for the regulatory approval of Furoscix. Final marketing approval of Furoscix or any of our other product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

We are pursuing a regulatory pathway pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, for the approval of Furoscix, which allows us to rely on existing clinical data for the drug for our resubmission. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, and permits the submission (or resubmission) of an NDA where at least some of the information required for approval comes from

preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission (or resubmission) of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA has already provided a Complete Response Letter identifying deficiencies with respect to our NDA for Furoscix, and with future submissions, they could refuse to file our NDA submissions (or resubmissions), request additional information before accepting our submissions (or resubmissions) for filing or require additional information to sufficiently demonstrate safety and efficacy to support approval.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA recently adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's new interpretation, the approval of Furoscix may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with Furoscix, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

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 June 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: August 14, 2018

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

Date: August 14, 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 June 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: August 14, 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 June 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: August 14, 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 June 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: August 14, 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 June 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: August 14, 2018

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