
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 13, 2018

SCPHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38293
(Commission
File Number)

46-5184075
(I.R.S. Employer
Identification No.)

2400 District Avenue, Suite 310
Burlington, Massachusetts
(Address of principal executive offices)

01803
(Zip Code)

Registrant's telephone number, including area code: (617) 517-0730

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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.

Item 2.02 Results of Operations and Financial Condition.

On November 13, 2018, scPharmaceuticals Inc. announced its financial results for its third quarter ended September 30, 2018. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by the registrant on November 13, 2018, furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 13, 2018

SCPHARMACEUTICALS INC.

By: /s/ John H. Tucker

Name: John H. Tucker

Title: President, Chief Executive Officer and
Principal Executive Officer

scPharmaceuticals Inc. Reports Third Quarter 2018 Financial Results and Provides Business Update

Resubmission of FURSOCIX® with the U.S. Food and Drug Administration (FDA) by year-end 2019

Balance sheet remains strong with over \$95 million in cash

BURLINGTON, Mass., November 13, 2018 (GLOBE NEWSWIRE) – scPharmaceuticals Inc. (Nasdaq: SCPH), a pharmaceutical company focused on developing and commercializing products that have the potential to optimize the delivery of infused therapies, advance patient care and reduce healthcare costs, today announced financial results for the third quarter ended September 30, 2018 and provided a business update.

“After receiving the minutes from our Type A Post-Action Meeting for FUROSCIX, we have directed our attention to the activities required to re-file our New Drug Application (NDA),” said John Tucker, president and chief executive officer of scPharmaceuticals. “FUROSCIX is a unique product with the potential to treat edema, or fluid overload, in patients with heart failure. Heart failure remains a large market opportunity with high unmet patient need and significant associated healthcare costs.”

Business Highlights

- **Provided regulatory update on FUROSCIX.** On October 18, 2018, scPharmaceuticals announced it received minutes from the Type A Post-Action Meeting held on September 24, 2018 between the Company and the FDA to discuss the Company’s NDA for FUROSCIX. As an outcome of the meeting, the FDA has asked the Company to conduct additional human factors studies and a dose delivery validation study, with the recently modified FUROSCIX Infusor. The FDA has not requested additional clinical trials at this time.
- **FDA granted Type C Meeting.** In response to the October 18, 2018 minutes from the Type A Post-Action Meeting and the FDA’s request for a dose delivery validation study, the Company requested, and was granted by the FDA, a Type C Meeting to be held on January 9, 2019 to discuss the dose delivery validation protocol.
- **Anticipate FUROSCIX NDA to be re-filed with the FDA by year-end 2019.** Based on the requirements from the FDA minutes, and pending the feedback from the Type C Meeting, the Company anticipates completing human factors and dose delivery validation studies in time to re-file the FUROSCIX NDA by year-end 2019.

Third Quarter 2018 Financial Results and Financial Guidance

scPharmaceuticals reported a net loss of \$5.8 million in the third quarter of 2018 compared to \$5.5 million for the third quarter of 2017. The increase in net loss for the third quarter ended September 30, 2018, was largely due to costs associated with increased headcount, clinical initiatives, and costs incurred as a public company.

Research and development expenses were \$3.9 million for the third quarter of 2018 compared to \$3.6 million for the comparable period in 2017. The increase in research and development expenses for the quarter ended September 30, 2018 was largely due to increased headcount and costs associated with clinical initiatives.

General and administrative expenses were \$1.9 million for the third quarter of 2018 compared to \$1.7 million for the comparable period in 2017. The increase in general and administrative expenses for the period was primarily due to costs incurred as a public company.

scPharmaceuticals ended the third quarter of 2018 with \$95.5 million in cash compared to \$118.5 million as of December 31, 2017. This change reflects the ongoing investment in product and clinical development, as well as the costs incurred in the Company's transition to a public company and costs associated with preparing for the potential commercialization of FUROSCIX.

Based on its current operating plan, scPharmaceuticals expects year end 2018 cash and cash equivalents and investment securities to be approximately \$82 - \$87 million, an increase over prior guidance of \$80 - \$85 million, and forecasts 2019 expenditures of \$8 - \$10 million per quarter, consistent with prior guidance.

About FUROSCIX

FUROSCIX is a proprietary furosemide solution formulated to a neutral pH to allow for subcutaneous infusion via the patented Infusor, a wearable, pre-programed drug delivery system that is applied to the abdomen for subcutaneous drug administration. FUROSCIX is being developed for treatment of edema, or fluid overload, in patients with heart failure. FUROSCIX has the potential to provide an outpatient alternative for the treatment of worsening heart failure due to edema.

About scPharmaceuticals

scPharmaceuticals is a clinical-stage pharmaceutical company focused on developing and commercializing products that reduce healthcare costs and improve health outcomes. The Company develops products for the subcutaneous, self-administration of IV-strength treatments in heart failure and infectious disease. scPharmaceuticals is headquartered in Burlington, MA. For more information, please visit scPharmaceuticals.com.

Forward-Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements regarding the

timing of the Company's resubmission of its NDA for FUROSCIX; the Company's plans to meet with the FDA to discuss validation study protocols; the Company's completion of human factors and dose delivery validation studies; the potential timing and advancement of the Company's ongoing or planned clinical trials and investigator-sponsored studies; the announcement of data from these trials and studies; and the Company's financial condition and results of operations for the year end 2018 and for fiscal year 2019. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the Company conducting human factors studies or a dose delivery validation study, the ability of our device to appropriately deliver therapy, the receipt of regulatory approval for FUROSCIX or any other product candidates or, if approved, the successful commercialization of such products, the risk of cessation or delay of any of the ongoing or planned clinical trials and/or our development of our product candidates, and the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving our product candidates. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K on file with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties and other important factors in the Company's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information unless required by law.

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scPharmaceuticals Inc.
Unaudited Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2017	2018	2017	2018
Operating expenses:				
Research and development	\$ 3,585	\$ 3,896	\$ 10,615	\$ 12,799
General and administrative	1,665	1,945	6,113	11,645
Total operating expenses	5,250	5,841	16,728	24,444
Loss from operations	(5,250)	(5,841)	(16,728)	(24,444)
Other income (expense)	15	(5)	82	(58)
Interest income	75	445	170	1,221
Interest expense	(329)	(360)	(461)	(1,062)
Net loss and comprehensive loss	\$ (5,489)	\$ (5,761)	\$ (16,937)	\$ (24,343)
Net loss per share, basic and diluted	\$ (5.08)	\$ (0.31)	\$ (15.76)	\$ (1.31)
Weighted—average common shares outstanding, basic and diluted	1,080,351	18,569,289	1,074,702	18,551,690

scPharmaceuticals Inc.
Unaudited Balance Sheet Data
(in thousands)

	DECEMBER 31, 2017	SEPTEMBER 30, 2018
Cash, cash equivalents and restricted cash	\$ 118,480	\$ 95,481
Working capital	114,672	89,401
Total assets	122,048	98,819
Term loan	9,419	9,631
Accumulated deficit	(67,016)	(91,360)
Total stockholders' equity	105,997	83,390