
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): August 14, 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 August 14, 2018, scPharmaceuticals Inc. announced its financial results for its second quarter ended June 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:

Exhibit No.	<u>Description</u>
99.1	<u>Press Release issued by the registrant on August 14, 2018, furnished herewith.</u>

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: August 14, 2018

SCPHARMACEUTICALS INC.

By: /s/ John H. Tucker

Name: John H. Tucker

Title: President, Chief Executive Officer and
Principal Executive Officer

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

Request for Type A meeting was granted by the U.S. Food and Drug Administration to discuss the Complete Response Letter received in June 2018

Balance sheet remains strong with over \$100 million in cash

BURLINGTON, Mass., August 14, 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 second quarter ended June 30, 2018 and provided a business update.

“Since receiving the Complete Response Letter for FUROSCIX® from the U.S. Food and Drug Administration in June, we have been working to address the Agency’s questions and were granted a Type A Post-Action Meeting, scheduled for September 24, 2018,” said John Tucker, president and chief executive officer of scPharmaceuticals. “We look forward to meeting with the FDA to discuss the next steps. We remain committed to the development and commercialization of FUROSCIX and plan to update investors following receipt of minutes from our meeting with the FDA.”

Business Highlights

- **Granted Type A Post-Action Meeting with the FDA.** On June 13, 2018, scPharmaceuticals announced the Company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the 505(b)(2) application for FUROSCIX, a treatment candidate for edema, or fluid overload, in patients with heart failure. The Company submitted a request to the FDA and was granted a Type A Post-Action Meeting, scheduled for September 24, 2018. scPharmaceuticals believes the upcoming meeting will provide an opportunity to define the pathway and timing to re-submit the NDA.
- **Organizational restructuring in place to ensure financial flexibility.** Since receiving the CRL, scPharmaceuticals has implemented a companywide restructuring to align the workforce with the upcoming needs of the business and focus on activities essential to addressing the CRL and FUROSCIX development. Following the restructuring, the company has 24 full time employees.
- **Appointed three directors with deep financial, industry and regulatory experience.** Frederick Hudson, 37 years at KPMG and lead partner of KPMG’s Mid-Atlantic region healthcare audit practice; Minnie Baylor-Henry, 20 years regulatory affairs with Johnson & Johnson and with the FDA; and Dr. Mason Freeman, 5AM Ventures and Massachusetts General Hospital, all joined the scPharmaceuticals Board. Each of the three new directors brings to the Company a deep understanding of the biopharmaceutical industry in key areas including audit, clinical, and regulatory strategy that will contribute to scPharmaceuticals’ efforts as it works with the FDA and moves toward the re-submission and potential approval of FUROSCIX.

Second Quarter 2018 Financial Results and Financial Guidance

scPharmaceuticals reported a net loss of \$9.9 million in the second quarter of 2018 compared to \$6.5 million for the second quarter period of 2017. The increase in net loss for the second quarter ended June 30, 2018, was largely due to costs associated with increased headcount, the expansion of the Company's commercial organization, and costs incurred as a public company.

Research and development expenses were \$4.9 million for the second quarter of 2018 compared to \$4.1 million for the comparable period in 2017. The increase in research and development expenses for the quarter ended June 30, 2018, was largely due to increased headcount and costs associated with clinical initiatives.

General and administrative expenses were \$5.0 million for the second quarter of 2018 compared to \$2.4 million for the comparable period in 2017. The increase in general and administrative expenses for the year was primarily due to increased headcount, the expansion of the Company's commercial organization, and costs incurred as a public company.

scPharmaceuticals ended the second quarter of 2018 with \$101.0 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 \$80 - \$85 million and forecasts 2019 expenditures of \$8 - \$10 million per quarter.

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 under review by the FDA for treatment of edema, or fluid overload, in patients with heart failure. FUROSCIX has the potential to provide an outpatient alternative to IV furosemide for the treatment of worsening heart failure due to edema that would typically require hospitalization.

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 Company’s new drug application for FUROSCIX; the Company’s planned actions in response to the FDA’s Complete Response Letter, including the timing of any future public announcement; the outcome of the Company’s Type A Post-Action Meeting with the FDA; the benefits of the Company’s restructuring, including the sufficiency of its existing resources; the potential timing and advancement of our 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 cash runway. 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 risk that the Company may not be able to remediate the deficiencies identified by the FDA in the Complete Response Letter or receive regulatory approval of FUROSCIX or any other product candidates or, if approved, successfully commercialize 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		SIX MONTHS ENDED	
	JUNE 30,		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

scPharmaceuticals, Inc.**Unaudited Balance Sheet Data**

(in thousands)

	DECEMBER 31,	JUNE 30,
	2017	2018
Cash and restricted cash	\$ 118,480	\$ 100,950
Working capital	114,672	95,502
Total assets	122,048	105,009
Term loan	9,419	9,562
Accumulated deficit	(67,016)	(85,599)
Total stockholders' equity	105,997	88,592