
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 7, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001	SCPH	The Nasdaq Global Select Market

Indicate by check mark whether the registrant 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 7, 2019, scPharmaceuticals Inc. announced its financial results for the first quarter ended June 30, 2019. 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	<u>Press Release issued by the registrant on August 7, 2019, 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 7, 2019

SCPHARMACEUTICALS INC.

By: /s/ John H. Tucker

Name: John H. Tucker

Title: President, Chief Executive Officer,
Principal Financial Officer and Principal Executive Officer

scPharmaceuticals Inc. Reports Second Quarter 2019 Financial Results and Provides Business Update

Type C Meeting confirmed that FDA does not believe additional clinical safety, efficacy, or pharmacology studies will be required to support NDA resubmission

Company successfully completed the first of two planned human factors studies

Company accelerates timeline and now expects resubmission of FUROSCIX® NDA with the FDA by mid-year 2020

Balance sheet remains strong with \$79.6 million in cash

BURLINGTON, Mass., August 7, 2019 (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, 2019 and provided a business update.

“We are encouraged by the most recent interactions with the U.S. Food and Drug Administration (FDA) and believe we are in a position to resubmit FUROSCIX by mid-2020,” said John Tucker, president and chief executive officer of scPharmaceuticals. “With confirmation from the FDA that no additional clinical studies are required to resubmit our New Drug Application (NDA), we now look to further advance our human factors studies, device verification and validation, and drug stability work, which are all currently underway. With a strong balance sheet to support the work required to refile the NDA for FUROSCIX, we remain committed to our focus of transforming the treatment of heart failure to improve patient care, reduce hospitalizations, and lessen healthcare costs.”

Business Highlights

- **Received FDA regulatory update on FUROSCIX.** The Company received minutes from the Type C Guidance Meeting held on June 18, 2019, between the Company and the FDA, to discuss the Company’s NDA for FUROSCIX, scPharmaceuticals’ lead program for the treatment of congestion in patients with heart failure. As an outcome of the meeting, the Company believes they have confirmed with the FDA that it will not be necessary to conduct additional clinical safety, efficacy, or pharmacology studies as part of its NDA for FUROSCIX. The FDA further provided recommendations on the Company’s device verification and validation plan for the FUROSCIX Infusor.
- **Successfully completed the first of two planned human factors studies.** Two human factors studies designed to assess and optimize user interaction with the FUROSCIX Infusor interface are to be conducted under the current 505(b)(2) approval pathway for FUROSCIX. The first study was successfully completed and the Company has submitted the protocol for the second study to the FDA. This human factors study will evaluate the usability of FUROSCIX by patients, caregivers, and healthcare providers. The Company anticipates initiating the second human factors study in the third quarter of 2019.

- **FUROSCIX resubmission with the FDA by mid-year 2020.** As a result of the Type C Meeting, scPharmaceuticals is accelerating its timeline and now expects resubmission of the existing FUROSCIX NDA with the FDA by mid-year 2020.

Second Quarter 2019 Financial Results and Financial Guidance

scPharmaceuticals reported a net loss of \$7.3 million in the second quarter ended June 30, 2019, compared to \$9.9 million for the comparable period in 2018.

Research and development expenses were \$5.5 million for the second quarter ended June 30, 2019, compared to \$4.9 million for the comparable period in 2018. The increase in research and development expenses for the quarter was primarily due to costs associated with the transition to the SmartDose® drug delivery system.

General and administrative expenses were \$1.8 million for the second quarter ended June 30, 2019, compared to \$5.0 million for the comparable period in 2018. The decrease in general and administrative expenses for the quarter was primarily due to the restructuring of the Company's commercial organization that occurred in the second quarter of 2018.

scPharmaceuticals ended the second quarter of 2019 with \$79.6 million in cash, cash equivalents, and restricted cash compared to \$89.7 million as of December 31, 2018. This change reflects the ongoing investment in product development.

Based on its current operating plan, scPharmaceuticals expects year end 2019 cash and cash equivalents and investment securities to be approximately \$55-\$58 million.

About FUROSCIX

FUROSCIX is a proprietary furosemide solution formulated to a neutral pH to allow for subcutaneous infusion via a wearable, subcutaneous injector with an integrated drug delivery system, for outpatient self-administration. FUROSCIX is being developed for treatment of congestion, 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 congestion.

About scPharmaceuticals

scPharmaceuticals is a pharmaceutical company focused on developing and commercializing products that reduce healthcare costs and improve health outcomes. The Company develops, internally and through strategic partnerships, 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 planned resubmission of the FUROSCIX NDA, including potential timing of the resubmission, the advancement of the Company’s human factors and device verification and validation 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 ability of the FUROSCIX Infusor to appropriately deliver therapy, the receipt of regulatory approval for FUROSCIX Infusor or any of our 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 Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2018	2019	2018	2019
Operating expenses:				
Research and development	\$ 4,855	\$ 5,496	\$ 8,903	\$ 12,020
General and administrative	5,049	1,839	9,700	4,162
Total operating expenses	9,904	7,335	18,603	16,182
Loss from operations	(9,904)	(7,335)	(18,603)	(16,182)
Other expense	(11)	(14)	(53)	(22)
Interest income	424	463	775	953
Interest expense	(359)	(369)	(701)	(723)
Net loss and comprehensive loss	\$ (9,850)	\$ (7,255)	\$ (18,582)	\$ (15,974)
Net loss per share, basic and diluted	\$ (0.53)	\$ (0.39)	\$ (1.00)	\$ (0.86)
Weighted—average common shares outstanding, basic and diluted	18,549,978	18,580,430	18,542,745	18,578,091

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

(in thousands)

	<u>DECEMBER 31, 2018</u>	<u>JUNE 30, 2019</u>
Cash, cash equivalents and restricted cash	\$ 89,660	\$ 79,649
Working capital	85,220	68,241
Total assets	93,755	83,459
Term loan	9,637	9,710
Accumulated deficit	(96,459)	(112,433)
Total stockholders' equity	78,744	63,469