

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): May 8, 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))

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 [X]

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. [X]

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

Table with 3 columns: Title of each class, Trading Symbol(s), Name of each exchange on which registered. Row 1: Common stock, par value \$0.0001, SCPH, The Nasdaq Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2019, scPharmaceuticals Inc. announced its financial results for the first quarter ended March 31, 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	Press Release issued by the registrant on May 8, 2019, 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: May 8, 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 First Quarter 2019 Financial Results and Provides Business Update

Type C Meeting to solidify re-filing plans for FUROSCIX® scheduled with the U.S. Food and Drug Administration (FDA) for June 2019

Resubmission of FUROSCIX New Drug Application (NDA) with the FDA in 2020

Balance sheet remains strong with over \$83 million in cash

BURLINGTON, Mass., May 8, 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 first quarter ended March 31, 2019 and provided a business update.

“We enter 2019 with good momentum and an increasingly clear line of sight on what we need to accomplish to refile our NDA for FUROSCIX in 2020,” said John Tucker, president and chief executive officer of scPharmaceuticals. “We look forward to working with the FDA in June to solidify refiling requirements. In the interim, we anticipate initiating our first human factors study using our next generation delivery device, the West Pharmaceutical Services, Inc. (West) SmartDose® drug delivery system with FUROSCIX. In addition, we continue to advance new development work with furosemide, the active drug in FUROSCIX, and have filed additional formulation patents for FUROSCIX, with patent protection extending to 2040. 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

- **Regulatory update on FUROSCIX.** The Company submitted a meeting package to the FDA and has scheduled a Type C Meeting that will take place in June 2019. This Type C Meeting will be the first meeting the Company has had with the FDA since the Company elected to expedite the advancement of a next-generation infusor, which includes a pre-filled cartridge and other device features expected to address prior FDA requirements. The Company believes the upcoming meeting with the FDA will solidify plans for the refiling of FUROSCIX in 2020. FUROSCIX is scPharmaceuticals’ lead product being developed for the treatment of congestion, or fluid overload, in patients with heart failure.
- **The Company plans to initiate and complete first human factors study in the second quarter of 2019.** On January 29, 2019, the Company signed a development agreement with West to incorporate West’s SmartDose drug delivery system with the Company’s subcutaneous formulation of furosemide, as the FUROSCIX Infusor. As part of the transition to the SmartDose system, the Company is required to conduct a series of human factors studies under the current 505(b)(2) approval pathway for FUROSCIX. The human factors studies are designed to evaluate FUROSCIX’s use in a real world setting to determine if the product is being used correctly and

safely by the intended users of the product. The Company plans to include the outcome of the human factors studies in the NDA resubmission.

- **Filed provisional patent of FUROSCIX that could extend protection through 2040.** The Company recently filed a provisional composition of matter patent on a liquid pharmaceutical formulation containing an increased concentration of furosemide. Additional method patents were filed on ways of treating congestion, fluid overload, or hypertension using these formulations of furosemide. Development work around a new, increased concentration of furosemide in FUROSCIX offers the potential to enable greater dosing flexibility.

First Quarter 2019 Financial Results and Financial Guidance

scPharmaceuticals reported a net loss of \$8.7 million in the first quarter ended March 31, 2019, compared to \$8.7 million for the comparable period in 2018.

Research and development expenses were \$6.5 million for the first quarter ended March 31, 2019, compared to \$4.0 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 system.

General and administrative expenses were \$2.3 million for first quarter ended March 31, 2019, compared to \$4.7 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.

scPharmaceuticals ended the first quarter of 2019 with \$83.6 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 continues to forecast 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 a wearable, subcutaneous infusor 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 clinical-stage 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 advancement of, and potential timing of regulatory filings for, FUROSCIX with the West SmartDose drug delivery system as a next-generation infusor technology; the Company’s plans with respect to its Type C Meeting with the FDA to discuss the regulatory path for FUROSCIX and the timing and outcome of the Company’s human factors studies for FUROSCIX. 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 the ability of the West SmartDose drug delivery system to appropriately deliver therapy, the receipt of regulatory approval for FUROSCIX with the West SmartDose drug delivery system 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	
	MARCH 31,	
	2018	2019
Operating expenses:		
Research and development	\$ 4,048	\$ 6,524
General and administrative	4,651	2,323
Total operating expenses	8,699	8,847
Loss from operations	(8,699)	(8,847)
Other expense	(42)	(8)
Interest income	351	490
Interest expense	(342)	(354)
Net loss and comprehensive loss	\$ (8,732)	\$ (8,719)
Net loss per share, basic and diluted	\$ (0.47)	\$ (0.47)
Weighted—average common shares outstanding, basic and diluted	18,535,432	18,575,726

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

(in thousands)

	DECEMBER 31, 2018	MARCH 31, 2019
Cash, cash equivalents and restricted cash	\$ 89,660	\$ 83,560
Working capital	85,220	75,715
Total assets	93,755	87,587
Term loan	9,637	9,684
Accumulated deficit	(96,459)	(105,178)
Total stockholders' equity	78,744	70,398