
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 12, 2021

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 May 12, 2021, scPharmaceuticals Inc. announced its financial results for the first quarter ended March 31, 2021. 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 May 12, 2021, 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: May 12, 2021

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 2021 Financial Results and Provides Business Update*FREEDOM clinical study on track for topline results in Q3 2021**Ended Q1 with cash, cash equivalents, restricted cash and investments of \$96.5 million*

BURLINGTON, Mass., May 12, 2021 (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, 2021 and provided a business update.

Business Update

- Conducted a Type A meeting with the U.S. Food and Drug Administration (FDA) regarding the FUROSCIX® New Drug Application (NDA) and requirements related to its resubmission.
- The Company is still in discussion with the FDA regarding the bench top testing of the West SmartDose® Gen II on-body infusor; the Company has a Type C meeting scheduled in June to discuss this in detail.
- Pending resolution of the testing plan and assuming device modifications are not required, the Company anticipates resubmitting the FUROSCIX NDA under the current 505(b)(2) approval pathway in the fall of 2021.
- Enrollment in the FREEDOM-HF clinical trial continues to progress with results expected in Q3 2021. The primary endpoint of this study is the difference in the 30-day overall and heart failure-related healthcare costs between subjects treated with FUROSCIX post-discharge from the emergency department and patients treated in the hospital.
- Enrolled first patient in the AT HOME-HF Pilot study designed to assess clinical outcomes in patients treated with FUROSCIX with worsening heart failure symptoms due to congestion.
- Announced the appointment of renowned heart failure specialist William T. Abraham, M.D., to the company's Board of Directors.
- Ended the first quarter with cash, cash equivalents, restricted cash and investments of \$96.5 million.

“During the first quarter, we were pleased to have completed a productive Type A meeting with the FDA during which we gained clarity on requirements for resubmission of the FUROSCIX 505(b)(2) NDA. We have a follow-up Type C meeting in June where we hope to finalize the testing details on the bench top testing for resubmission,” stated John Tucker, chief executive officer of scPharmaceuticals. “In parallel, our ongoing FREEDOM-HF and AT HOME-HF PILOT studies, if successful, will add to the growing body of evidence demonstrating the potential for improved clinical outcomes and reduced costs associated with treatment with FUROSCIX outside of the hospital setting. We are well financed with approximately \$97 million in cash, and we are focused on advancing this novel therapy to the many worsening heart failure patients who continue to have significant unmet need.”

First Quarter 2021 Financial Results and Financial Guidance

scPharmaceuticals ended the first quarter with \$96.5 million in cash, cash equivalents, restricted cash and investments, compared to \$105.3 million as of December 31, 2020. The Company believes its cash, cash equivalents, restricted cash and investments are sufficient to fund operations into 2023.

scPharmaceuticals reported a net loss of \$7.1 million for the first quarter of 2021, compared to \$7.1 million for the comparable period in 2020.

Research and development expenses were \$4.0 million for the first quarter of 2021, compared to \$4.1 million for the comparable period in 2020. The decrease in research and development expenses for the quarter ended March 31, 2021 was primarily due a decrease in device development costs, offset by increased clinical study and medical affairs activity, pharmaceutical development costs, and employee-related costs.

General and administrative expenses were \$2.7 million for the first quarter of 2021, compared to \$2.5 million for the comparable period in 2020. The increase in general and administrative expenses for the quarter ended March 31, 2021 was primarily attributable to employee-related and director and officer's insurance costs, offset by a decrease in legal costs.

Based on its current operating plan, the Company expects the net loss for 2021 to be in the range of \$32.0 to \$36.0 million for the fiscal year.

About FUROSCIX® (furosemide injection) for subcutaneous injection

FUROSCIX is an investigational, proprietary furosemide solution formulated to a neutral pH to allow for subcutaneous infusion via a wearable, pre-programmed on-body drug delivery system, for outpatient self-administration. FUROSCIX is currently under development for the treatment of congestion due to fluid overload in adult patients with New York Heart Association (NYHA) Class II and Class III heart failure who display reduced responsiveness to oral diuretics and who do not require hospitalization. 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 are designed to reduce healthcare costs and improve health outcomes. The Company develops, internally and through strategic partnerships, innovative products and solutions that aim to expand and advance the outpatient care of select acute conditions. The Company's lead programs focus on 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 www.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 FDA’s review requirements and potential outcomes of the Type C meeting, the planned resubmission of the FUROSCIX NDA, including potential timing of the resubmission, the potential timing of, and the Company’s expected progress towards, the advancement of the Company’s device verification, research and validation studies, including the expected timing and results of the FREEDOM-HF clinical trial and the AT-HOME-HF Pilot study, whether any modifications to the West SmartDose Gen II on-body infusor may be required, and the potential benefits, expected costs and future plans and expectations for FUROSCIX, if approved, and the Company’s projected financial guidance, including projected annual loss. 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 of the ability of the FUROSCIX On-Body Infusor to appropriately deliver therapy, the results of the above-referenced bench testing, the risk that the FDA requires modification of the West SmartDose Gen II on-body infusor device, the receipt of regulatory approval for the FUROSCIX On-Body 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, the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving our product candidates, and the risk that the current COVID-19 pandemic will impact the Company’s device validation, drug stability testing, the timing of the Company’s resubmission of the FUROSCIX NDA and other operations. 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 its Annual Report on Form 10-K for the year ended December 31, 2020 on file with the Securities and Exchange Commission, available at the Securities and Exchange Commission’s website at www.sec.gov, and 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.

Katherine Taudvin
scPharmaceuticals Inc., 781-301-6706
ktaudvin@scpharma.com

Investors:
Hans Vitzthum
LifeSci Advisors, 617-430-7578
hans@lifesciadvisors.com

scPharmaceuticals Inc.**Unaudited Consolidated Statements of Operations**

(in thousands, except share and per share data)

	THREE MONTHS ENDED	
	MARCH 31,	
	2020	2021
Operating expenses:		
Research and development	\$ 4,146	\$ 4,009
General and administrative	2,503	2,732
Total operating expenses	6,649	6,741
Loss from operations	(6,649)	(6,741)
Other (expense) income	(31)	255
Interest income	224	20
Interest expense	(636)	(636)
Net loss and comprehensive loss	\$ (7,092)	\$ (7,102)
Net loss per share, basic and diluted	\$ (0.35)	\$ (0.26)
Weighted - average common shares outstanding, basic and diluted	20,218,473	27,336,724

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

(in thousands)

	DECEMBER 31,	MARCH 31,
	2020	2021
Cash, cash equivalents, restricted cash and investments	\$ 105,277	\$ 96,509
Working capital	98,505	89,418
Total assets	109,048	100,293
Term loan	19,266	19,353
Accumulated deficit	(161,664)	(168,766)
Total stockholders' equity	82,170	75,515