

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): **May 16, 2022**

scPharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38293
(Commission
File Number)

46-5184075
(IRS 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**

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

- 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 16, 2022, scPharmaceuticals Inc. (the “Company”) announced its financial results for the first quarter ended March 31, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in Item 2.02 of 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 16, 2022, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document).

SIGNATURES

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

May 16, 2022

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 2022 Financial Results and Provides Business Update

FDA assigns PDUFA action date of October 8, 2022

Continuing to ramp up commercial readiness activities in advance of an anticipated Q4 2022 launch of FUROSCIX®, if approved

Ended Q1 with cash, cash equivalents, restricted cash and investments of \$65.6 million

BURLINGTON, Mass., May 16, 2022 (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 reported financial results for the first quarter ended March 31, 2022 and provided a business update.

Business Update

- Announced that the U.S. Food and Drug Administration (FDA) has accepted for review its New Drug Application (NDA) resubmission for FUROSCIX, a proprietary formulation of furosemide delivered via an on-body infusor for the treatment of congestion in patients with worsening heart failure, and has set a Prescription Drug User-Fee Act (PDUFA) target action date of October 8, 2022. The Company anticipates a Q4 2022 commercial launch, if approved.
- Continued to advance commercial readiness activities, including:
 - Finalizing physician, payer and pricing research;
 - Communicating FUROSCIX data, including FREEDOM-HF, to pharmacy benefit managers and health plans through its product dossier;
 - Finalizing FUROSCIX distribution partners; and
 - Continued commercial staffing.
- Accepted for presentation three abstracts at upcoming heart failure medical meetings, including the European Society of Cardiology Heart Failure 2022 and the American Association of Heart Failure Nurses (AAHFN) 18th Annual Meeting.
- Ended the first quarter with cash, cash equivalents, restricted cash and investments of \$65.6 million.

“The resubmission and acceptance of our FUROSCIX NDA was a significant achievement for our company and potentially gives us line-of-sight to transitioning to a commercial-stage company,” stated John Tucker, chief executive officer of scPharmaceuticals. “We believe the NDA addresses all concerns and questions raised in the Complete Response Letter that we received from the FDA in December 2020. As a result, we are preparing for a commercial launch of FUROSCIX, if approved, in the fourth quarter of this year.”

First Quarter 2022 Financial Results and Financial Guidance

scPharmaceuticals ended the first quarter of 2022 with \$65.6 million in cash, cash equivalents, restricted cash and investments, compared to \$75.5 million as of December 31, 2021. The Company believes its existing cash, cash equivalents, restricted cash and investments are sufficient to fund operations into 2023. scPharmaceuticals reported a net loss of \$7.7 million for the first quarter of 2022, compared to \$7.1 million for the comparable period in 2021.

Research and development expenses were \$4.3 million for the first quarter of 2022, compared to \$4.0 million for the comparable period in 2021. The increase in research and development expenses for the quarter ended March 31, 2022 was primarily due to an increase in clinical study activity, regulatory consulting costs, supplies, employee-related costs, device development costs, and preclinical study costs, offset by a decrease in pharmaceutical development costs and clinical consulting.

General and administrative expenses were \$2.9 million for the first quarter of 2022, compared to \$2.7 million for the comparable period in 2021. The increase in general and administrative expenses for the quarter ended March 31, 2022 was primarily due to an increase in employee-related costs and costs related to commercial preparations.

Based on its current operating plan, the Company reiterates its 2022 forecast and expects net loss to be \$43 to \$48 million. As of March 31, 2022, scPharmaceuticals total shares outstanding was 27,371,488.

About FUROSCIX® (furosemide injection) for subcutaneous injection

FUROSCIX is an investigational, proprietary furosemide solution formulated to a neutral pH, designed 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 chronic heart failure who display reduced responsiveness to oral diuretics and who do not require hospitalization. If approved, 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 timing and outcome of the FDA's review of the NDA; the significance and potential impact of the results of the FREEDOM-HF clinical trial and the clinical data; the Company's planned efforts to prepare for commercialization of FUROSCIX, the timing of commercial launch and the success of such commercialization, if approved; 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 that results of a clinical study do not necessarily predict final results and that one or more of the clinical outcomes may materially change following more comprehensive reviews of the data, and as more patient data become

available, the risk that results of a clinical study are subject to interpretation and additional analyses may be needed and/or may contradict such results, the risk of the ability of the FUROSCIX On-Body Infusor to appropriately deliver therapy, 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, 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, 2021 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.

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scPharmaceuticals Inc.
Unaudited Consolidated Statements of Operations

(in thousands, except share and per share data)

	THREE MONTHS ENDED MARCH 31,	
	2021	2022
Operating expenses:		
Research and development	\$ 4,009	\$ 4,347
General and administrative	2,732	2,893
Total operating expenses	6,741	7,240
Loss from operations	(6,741)	(7,240)
Other income	255	14
Interest income	20	13
Interest expense	(636)	(518)
Net loss and comprehensive loss	<u>\$ (7,102)</u>	<u>\$ (7,731)</u>
Net loss per share, basic and diluted	<u>\$ (0.26)</u>	<u>\$ (0.28)</u>
Weighted—average common shares outstanding, basic and diluted	<u>27,336,724</u>	<u>27,368,354</u>

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

(in thousands)	DECEMBER 31, 2021	MARCH 31, 2022
Cash, cash equivalents, restricted cash and investments	\$ 75,460	\$ 65,600
Working capital	63,429	54,051
Total assets	79,037	68,893
Term loan	17,159	14,739
Accumulated deficit	(189,698)	(197,429)
Total stockholders' equity	56,470	49,393