
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): March 23, 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 March 23, 2021, scPharmaceuticals Inc. announced its financial results for the fourth quarter and fiscal year ended December 31, 2020. 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 March 23, 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: March 23, 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 Fourth Quarter and Full Year 2020
Financial Results and Provides Business Update**

FUROSCIX® New Drug Application resubmission anticipated in Q3 2021

FREEDOM clinical study on track for topline results in Q3 2021

Ended Q4 with cash, cash equivalents, restricted cash and investments of \$105.3 million, sufficient to fund operations through potential FUROSCIX approval and launch, if approved, and into 2023

BURLINGTON, Mass. – March 23, 2021 – scPharmaceuticals Inc. (Nasdaq: SCPH) (the “Company”), 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 fourth quarter and full year ended December 31, 2020 and provided a business update.

Business Update

- Completed a Type A meeting with the U.S. Food and Drug Administration (FDA) regarding the Company’s FUROSCIX New Drug Application (NDA), and additional requirements for resubmission following the Complete Response Letter (CRL) received by the Company on December 3, 2020. The outstanding questions are primarily focused on bench testing and outstanding Pre-Approval Inspections (PAIs). Importantly, the FDA is not requiring device modifications nor is it requiring the Company to perform additional clinical studies of FUROSCIX. The Company anticipates resubmitting the FUROSCIX NDA in Q3 2021.
- Enrollment in the FREEDOM-HF clinical trial continues to progress. 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.
- Appointed renowned heart failure specialist William T. Abraham, M.D., to its Board of Directors.
- Ended the fourth quarter with cash, cash equivalents, restricted cash and investments of \$105.3 million.

“We recently completed a very productive meeting with the FDA to gain insight into the additional steps necessary to resubmit our FUROSCIX NDA and were pleased to learn that no additional clinical efficacy and safety studies will be required,” said John Tucker, president and chief executive officer. “We are moving ahead as quickly as possible to complete the required bench testing while working in parallel with our manufacturing partners to complete the necessary PAIs, and believe we are on track to resubmit the NDA during the third quarter of this year.”

“In the meantime, our FREEDOM-HF study is advancing according to plan, with a top-line readout anticipated in Q3 2021. This important study is designed to assess the economic benefit of avoiding hospital admissions by using FUROSCIX outside the hospital setting in heart failure patients initially presenting to the emergency department. If the study achieves positive results it will support the FUROSCIX value proposition.”

Fourth Quarter and Full Year 2020 Financial Results and Financial Guidance

scPharmaceuticals ended the fourth quarter with \$105.3 million in cash, cash equivalents, restricted cash and investments, compared to \$72.8 million as of December 31, 2019. This change reflects net proceeds of \$50.2 million and \$10.4 million from the Company's 2020 public offering and at-the market offering, respectively, offset by ongoing investments associated with the advancement of and potential commercialization of FUROSCIX. The Company believes its cash, cash equivalents, restricted cash and investments are sufficient to fund operations through potential FUROSCIX approval and launch, if approved, and into 2023.

scPharmaceuticals reported a net loss of \$7.8 million for the fourth quarter of 2020, compared to \$10.8 million for the comparable period in 2019.

Research and development expenses were \$3.7 million for the fourth quarter of 2020, compared to \$8.3 million for the comparable period in 2019. The decrease in research and development expenses for the quarter ended December 31, 2020 was primarily due to a decrease in device and pharmaceutical development activities.

General and administrative expenses were \$3.4 million for the fourth quarter of 2020, compared to \$2.1 million for the comparable period in 2019. The increase in general and administrative expenses for the quarter ended December 31, 2020 was primarily due to employee-related and professional service costs.

scPharmaceuticals reported a net loss of \$32.2 million for the year ended December 31, 2020, compared to \$33.0 million for the comparable period in 2019.

Research and development expenses were \$18.1 million for the year ended December 31, 2020, compared to \$24.6 million for the comparable period in 2019. The decrease in research and development expenses for the year ended December 31, 2020 was primarily due to a decrease in device and pharmaceutical development activities, offset by clinical study activity and employee-related costs.

General and administrative expenses were \$11.8 million for the year ended December 31, 2020, compared to \$8.3 million for the comparable period in 2019. The increase was primarily due to employee-related and professional service costs, including costs related to commercial preparations and increases in public company costs, including costs related to directors and officers insurance.

Based on its current operating plan, the Company forecasts its 2021 net loss to be \$32 to \$36 million. As of December 31, 2020, scPharmaceuticals total shares outstanding was 27,325,959.

About FUROSCIX® (furosemide injection) for subcutaneous injection

FUROSCIX is a 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 worsening 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, 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 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 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, 2019 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 (including its upcoming Annual Report on Form 10-K for the year ended December 31, 2020) 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.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2019	2020	2019	2020
Operating expenses:				
Research and development	\$ 8,318	\$ 3,745	\$ 24,632	\$ 18,149
General and administrative	2,115	3,425	8,273	11,784
Total operating expenses	10,433	7,170	32,905	29,933
Loss from operations	(10,433)	(7,170)	(32,905)	(29,933)
Other (expense) income	(45)	9	16	(4)
Interest income	310	34	1,660	315
Interest expense	(646)	(657)	(1,767)	(2,587)
Net loss	\$ (10,814)	\$ (7,784)	\$ (32,996)	\$ (32,209)
Net loss per share, basic and diluted	\$ (0.58)	\$ (0.28)	\$ (1.77)	\$ (1.31)
Weighted—average common shares outstanding, basic and diluted	18,661,626	27,321,752	18,600,718	24,568,897

scPharmaceuticals Inc.

Consolidated Balance Sheet Data

(in thousands)

	AS OF DECEMBER 31,	
	2019	2020
Cash, cash equivalents, restricted cash and investments	\$ 72,806	\$ 105,277
Working capital	70,410	98,505
Total assets	77,283	109,048
Term loan	18,915	19,266
Accumulated deficit	(129,455)	(161,664)
Total stockholders' equity	51,365	82,170