
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 22, 2022

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 22, 2022, scPharmaceuticals Inc. announced its financial results for the fourth quarter and fiscal year ended December 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	Press Release issued by the registrant on March 22, 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 duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 22, 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 Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

Successfully completed all testing; plan to re-submit FUROSCIX® NDA by April 15, 2022

Commercial preparedness activities ramping up to support anticipated Q4 2022 launch of FUROSCIX, if approved

Presented key FREEDOM-HF secondary endpoint data at the Cardiovascular Research Foundation Technology and Heart Failure Therapeutics Conference 2022

Ended Q4 with cash, cash equivalents, restricted cash and investments of \$75.5 million

BURLINGTON, Mass., March 22, 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 announced financial results for the fourth quarter and full year ended December 31, 2021 and provided a business update.

Business Update

- The Company has completed, and is pleased with the results of, all testing of the West Pharmaceutical Services on-body infusor manufactured on the planned commercial line, as required by the U.S. Food and Drug Administration (FDA).
- The Company recently elected to change packaging vendors, which necessitated minor modifications to its FUROSCIX New Drug Application (NDA). As a result, the Company anticipates resubmitting its NDA by April 15th 2022. The Company is on track for a Q4 2022 commercial launch, if approved.
- The Company continues to advance its 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
 - Reinitiating commercial staffing to support anticipated Q4 2022 launch.
- The Company presented key secondary endpoint data from the Company's FREEDOM-HF study at the Cardiovascular Research Foundation Technology and Heart Failure Therapeutics Conference, which was held February 1 – 2, 2022. Highlights include:
 - Patients who received FUROSCIX had a median reduction of heart failure peptide biomarkers from study entry (day 0) to first visit (day 2 – 4) and to last visit (day 30) of 42.3% and 28%, respectively ($p < 0.01$).
 - Patients who received FUROSCIX had a 12.8-point improvement in the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) Summary Score, a measure of health-related quality of life, 30 days after study entry ($p < 0.05$).

- Ended the fourth quarter with cash, cash equivalents, restricted cash and investments of \$75.5 million.

“We are very pleased with the progress made in 2021, particularly with respect to addressing items raised in the Complete Response Letter that we received from the FDA in late 2020,” stated John Tucker, chief executive officer of scPharmaceuticals. “With the completion of the additional device testing, which met all of our expectations, and the recent change to an alternate packaging vendor, we are on track to resubmit the FUROSCIX NDA in the first half of April and continue with our focused preparation for a potential commercial launch of FUROSCIX later this year.

“We believe that FUROSCIX, if approved, represents an important new option in the treatment of congestion related to heart failure. Further, the results of our FREEDOM-HF study offer compelling pharmacoeconomic and quality of life data. We believe we are well-funded and are optimistic that we will introduce this promising new therapy to the benefit of patients, payers and providers with the potential to generate significant health system cost savings.”

Fourth Quarter and Full Year 2021 Financial Results and Financial Guidance

scPharmaceuticals ended the fourth quarter 2021 with \$75.5 million in cash, cash equivalents, restricted cash and investments, compared to \$105.3 million as of December 31, 2020.

scPharmaceuticals reported a net loss of \$7.3 million for the fourth quarter of 2021, compared to \$7.8 million for the comparable period in 2020.

Research and development expenses were \$4.5 million for the fourth quarter of 2021, compared to \$3.7 million for the comparable period in 2020. The increase in research and development expenses for the quarter ended December 31, 2021 was primarily due to an increase in clinical study activity, employee-related costs and quality and regulatory consulting, offset by a decrease in device and pharmaceutical development costs.

General and administrative expenses were \$2.2 million for the fourth quarter of 2021, compared to \$3.4 million for the comparable period in 2020. The decrease in general and administrative expenses for the quarter ended December 31, 2021 was primarily due to a decrease in legal costs and costs related to commercial preparations.

scPharmaceuticals reported a net loss of \$28.0 million for the year ended December 31, 2021, compared to \$32.2 million for the comparable period in 2020.

Research and development expenses were \$16.0 million for the year ended December 31, 2021, compared to \$18.1 million for the comparable period in 2020. The decrease in research and development expenses for the year ended December 31, 2021 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 \$9.8 million for the year ended December 31, 2021, compared to \$11.8 million for the comparable period in 2020. The decrease was primarily due to employee-related and professional service costs, including legal costs and costs related to commercial preparations. This decrease was offset by increases in public company costs, including costs related to directors and officers insurance.

Based on its current operating plan, the Company forecasts its 2022 net loss to be \$43 to \$48 million. As of December 31, 2021, scPharmaceuticals total shares outstanding was 27,366,707.

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 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 significance of the results of the FREEDOM-HF clinical trial; the interpretation and analyses of the results from the FREEDOM-HF clinical trial; the planned resubmission of the FUROSCIX NDA, including potential timing of the resubmission and expected timing of the FDA's review; the Company's planned efforts to prepare for commercialization of FUROSCIX, the timing of commercial launch, if approved, 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 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.

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scPharmaceuticals Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2020	2021	2020	2021
Operating expenses:				
Research and development	\$ 3,745	\$ 4,530	\$ 18,149	\$ 16,039
General and administrative	3,425	2,191	11,784	9,784
Total operating expenses	7,170	6,721	29,933	25,823
Loss from operations	(7,170)	(6,721)	(29,933)	(25,823)
Other income (expense)	9	17	(4)	315
Interest income	34	7	315	49
Interest expense	(657)	(621)	(2,587)	(2,575)
Net loss	\$ (7,784)	\$ (7,318)	\$ (32,209)	\$ (28,034)
Net loss per share, basic and diluted	\$ (0.28)	\$ (0.27)	\$ (1.31)	\$ (1.02)
Weighted—average common shares outstanding, basic and diluted	27,321,752	27,359,001	24,568,897	27,351,730

scPharmaceuticals Inc.

Consolidated Balance Sheet Data

(in thousands)

	AS OF DECEMBER 31,	
	2020	2021
Cash, cash equivalents, restricted cash and investments	\$ 105,277	\$ 75,460
Working capital	98,505	63,429
Total assets	109,048	79,037
Term loan	19,266	17,159
Accumulated deficit	(161,664)	(189,698)
Total stockholders' equity	82,170	56,470