# 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): November 9, 2021**

# SCPHARMACEUTICALS INC.

**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | | |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | | |
| **001-38293** | | **46-5184075** |
| **(Commission File Number)** | | **(I.R.S. Employer Identification No.)** |
| **2400 District Avenue, Suite 310**<br>**Burlington, Massachusetts** | | **01803** |
| **(Address of principal executive offices)** | | **(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 November 9, 2021, scPharmaceuticals Inc. announced its financial results for the third quarter ended September 30, 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:

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release issued by the registrant on November 9, 2021, 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: November 9, 2021

**SCPHARMACEUTICALS INC.**

By: /s/ John H. Tucker
Name: John H. Tucker
Title: President, Chief Executive Officer,
Principal Financial Officer and Principal Executive Officer

**Exhibit 99.1**

**scPharmaceuticals Inc. Reports Third Quarter 2021 Financial Results and Provides Business Update**

*All additional testing of devices manufactured on the planned commercial line, as required by the FDA, has been successful to date*

*FUROSCIX® NDA resubmission anticipated for Q1 2022 due to COVID-19 related global supply chain logistics interruptions and travel restrictions*

*Revised NDA resubmission timeline is not expected to have an impact on anticipated Q4 2022 commercial launch of FUROSCIX, if approved*

*Ended Q3 with cash, cash equivalents, restricted cash and investments of $85.0 million, sufficient to fund operations into 2023; lowered 2021 net loss guidance to $29.0 to $31.0 million*

BURLINGTON, Mass., November 9, 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 third quarter ended September 30, 2021 and provided a business update.

**Business Update**

- Provided an updated timeline for the resubmission of its FUROSCIX New Drug Application (NDA).
    - During the Type C Meeting in June 2021, the Food and Drug Administration (FDA) did not request any additional clinical data or modifications to the on-body infusor and all testing to date on devices manufactured on the planned commercial line has been successful.
    - Travel restrictions and related global supply chain delays resulting from the pandemic caused a temporary interruption in the completion of the required device builds and testing. The FUROSCIX NDA resubmission is now planned for Q1 2022.
    - Revised NDA resubmission timeline is not expected to have an impact on anticipated Q4 2022 commercial launch of FUROSCIX, if approved.
- Presented positive results from the FREEDOM-HF study demonstrating that average 30-day heart failure related costs were reduced by $17,753 per study subject in the FUROSCIX arm compared to historically matched comparators ($p<0.0001$). This excludes the cost of FUROSCIX, as the price has yet to be established.
    - Analyses of additional secondary endpoints have been conducted that provide additional insights into the clinical effectiveness of FUROSCIX.
        - Patients who received FUROSCIX had a median reduction of heart failure peptide biomarkers from study entry (day 0) to first visit (day 2—4), and to last visit (day 30), of 42.3% and 28%, respectively ($p \leq 0.01$).

- Patients who received FUROSCIX had a 12.8-point improvement in the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) Summary Score 30 days after study entry.

- Continued to advance the AT HOME-HF PILOT study evaluating the effectiveness and safety of FUROSCIX versus continued medical therapy in patients with chronic heart failure and fluid overload requiring augmentation in diuretic therapy outside of the hospital.
- Ended the third quarter with cash, cash equivalents, restricted cash and investments of $85.0 million.

“Today, we are modestly revising the timing of our FUROSCIX NDA resubmission to Q1 2022, reflecting the impact that COVID-19 has had on our third-party partners, as they have been working to complete the additional device testing as previously requested by the FDA,” stated John Tucker, chief executive officer of scPharmaceuticals. “Importantly, the revised resubmission timeline is not expected to impact our commercial readiness or the anticipated Q4 2022 commercial launch, if approved. We plan to build out world-class commercial and market access teams that I believe can make FUROSCIX the new standard of care in heart failure pre- and post-discharge,” Mr. Tucker concluded.

**Third Quarter 2021 Financial Results and Financial Guidance**

scPharmaceuticals ended the third quarter with $85.0 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 $6.6 million for the third quarter of 2021, compared to $9.0 million for the comparable period in 2020.

Research and development expenses were $3.7 million for the third quarter of 2021, compared to $5.1 million for the comparable period in 2020. The decrease in research and development expenses for the quarter ended September 30, 2021 was primarily due to a decrease in device and pharmaceutical development costs, partially offset by an increase in quality and regulatory consulting costs.

General and administrative expenses were $2.2 million for the third quarter of 2021, compared to $3.3 million for the comparable period in 2020. The decrease in general and administrative expenses for the quarter ended September 30, 2021 was primarily due to a decrease in employee related, commercial preparation, and legal costs.

Based on its current operating plan, the Company expects a net loss for 2021 to be in the range of $29.0 to $31.0 million for the fiscal year, a decrease over prior guidance of $30.0 to $34.0 million.

**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 potential timing of, and the Company's expected progress towards, the advancement of the Company's device verification, research and validation studies; 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 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.*

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**scPharmaceuticals Inc.**
**Unaudited Consolidated Statements of Operations**
(in thousands, except share and per share data)

| | THREE MONTHS ENDED SEPTEMBER 30, | | NINE MONTHS ENDED SEPTEMBER 30, | |
|---|---|---|---|---|
| | 2020 | 2021 | 2020 | 2021 |
| Operating expenses: | | | | |
| Research and development | $ 5,119 | $ 3,694 | $ 14,404 | $ 11,509 |
| General and administrative | 3,319 | 2,211 | 8,359 | 7,593 |
| Total operating expenses | 8,438 | 5,905 | 22,763 | 19,102 |
| Loss from operations | (8,438) | (5,905) | (22,763) | (19,102) |
| Other income (expense) | 19 | 10 | (13) | 298 |
| Interest income | 36 | 10 | 281 | 42 |
| Interest expense | (655) | (667) | (1,930) | (1,954) |
| Net loss | $ (9,038) | $ (6,552) | $ (24,425) | $ (20,716) |
| Net loss per share, basic and diluted | $ (0.33) | $ (0.24) | $ (1.03) | $ (0.76) |
| Weighted—average common shares outstanding, basic and diluted | 27,319,465 | 27,355,454 | 23,644,580 | 27,349,279 |

**scPharmaceuticals Inc.**
**Unaudited Consolidated Balance Sheet Data**
(in thousands)

| | DECEMBER 31, 2020 | SEPTEMBER 30, 2021 |
|---|---|---|
| Cash, cash equivalents, restricted cash and investments | $ 105,277 | $ 85,020 |
| Working capital | 98,505 | 72,265 |
| Total assets | 109,048 | 87,531 |
| Term loan | 19,266 | 19,554 |
| Accumulated deficit | (161,664) | (182,380) |
| Total stockholders’ equity | 82,170 | 63,110 |