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): August 11, 2021

SCPHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

001-38293	**Delaware**	**46-5184075**
(Commission File Number)	*(State or other jurisdiction of incorporation or organization)*	*(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 August 11, 2021, scPharmaceuticals Inc. announced its financial results for the second quarter ended June 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 August 11, 2021, furnished herewith.

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: August 11, 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 Second Quarter 2021 Financial Results and Provides Business Update

Received minutes from Type C meeting with the FDA confirming alignment on path toward resubmission of FUROSCIX® NDA; no additional clinical data or device modifications required at this time; on track for resubmission in Q4

Announced positive top-line 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

Ended Q2 with cash, cash equivalents, restricted cash and investments of $90.2 million, sufficient to fund operations, as currently planned, into 2023; lowered 2021 net loss guidance to $30.0 to $34.0 million

BURLINGTON, Mass., August 11, 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 second quarter ended June 30, 2021 and provided a business update.

Business Update

- Completed Type C meeting with the U.S. Food and Drug Administration (FDA) and received minutes that confirm alignment on the path toward resubmission of the FUROSCIX New Drug Application (NDA).
    - No additional clinical data or device modifications required at this time.
    - Subject to West Pharmaceutical Services' completion of its portion of the regulatory filing, the Company is targeting the resubmission of its NDA in the fourth quarter of this year and anticipates a six-month review by the FDA.
- Announced positive top-line results from the FREEDOM-HF study demonstrating that average 30-day heart failure-related costs were reduced by $17,753 per study subject in the FUROSCIX arm compared to historically matched comparators, with a very high level of statistical significance ($p<0.0001$).
    - Due to the highly statistically significant reduction in 30-day heart failure-related costs observed during the prespecified interim analysis, the decision was made to close enrollment earlier than anticipated.
    - The difference in costs was driven primarily by hospitalization costs. Per protocol, all subjects (24/24) who received FUROSCIX did not require an initial heart failure hospitalization, and all but one (95.8%) remained out of the hospital for heart failure for the subsequent 30-day period.
- FREEDOM-HF data has been accepted as a Late Breaking Clinical Trial for presentation at the upcoming Heart Failure Society of America (HFSA) Annual Scientific Meeting being held September 10 through September 13, 2021 both in Denver, Colorado and virtually.

- Continued to enroll 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 second quarter with cash, cash equivalents, restricted cash and investments of $90.2 million.

“During the second quarter and subsequent period, we made significant progress, gaining alignment with the FDA on the path toward our FUROSCIX NDA resubmission, which we are targeting for Q4” stated John Tucker, chief executive officer of scPharmaceuticals. “Importantly, the FDA is not requiring additional clinical data or modifications to the on-body infusor at this time, and we are working tirelessly to complete the additional bench testing that has been requested. If our NDA is accepted, we anticipate a six-month review, suggesting that FUROSCIX, if approved, could be available to heart failure patients in the second half of next year.

“To further support a potential commercial launch, we were extremely pleased with the top-line results from our FREEDOM-HF study which demonstrated that patients treated with FUROSCIX cost healthcare payers nearly $18,000 less over a 30-day span as compared to historically matched comparators. Given the prevalence of worsening heart failure, and the potential addressable market of 2.1 million heart failure events in the United States, this pharmacoeconomic benefit is significant and should aid in adoption of FUROSCIX, if approved.

“We ended the quarter in a strong cash position, which we believe is sufficient to fund operations through a potential launch and into 2023. We look forward to introducing this novel therapy, if approved, to the many heart failure patients who can benefit,” Mr. Tucker concluded.

Second Quarter 2021 Financial Results and Financial Guidance

scPharmaceuticals ended the second quarter with $90.2 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 second quarter of 2021, compared to $8.3 million for the comparable period in 2020.

Research and development expenses were $3.8 million for the second 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 June 30, 2021 was primarily due to a decrease in device development costs, offset by an increase in costs related to pharmaceutical development and medical affairs, as well as an increase in employee-related costs.

General and administrative expenses were $2.6 million for the second quarter of 2021, compared to $2.5 million for the comparable period in 2020. The increase in general and administrative costs for the quarter ended June 30, 2021 was primarily attributable to an increase in consulting and director and officer’s insurance costs, offset by a decrease in legal costs.

Based on its current operating plan, the Company expects its net loss for 2021 to be in the range of $30.0 to $34.0 million for the fiscal year, a decrease over prior guidance of $32.0 to $36.0 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 infusor, 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 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, 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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2020	2021	2020	2021
Operating expenses:				
Research and development	$ 5,139	$ 3,807	$ 9,285	$ 7,816
General and administrative	2,537	2,649	5,040	5,381
Total operating expenses	7,676	6,456	14,325	13,197
Loss from operations	(7,676)	(6,456)	(14,325)	(13,197)
Other (expense) income	(1)	33	(32)	288
Interest income	21	12	245	32
Interest expense	(639)	(651)	(1,275)	(1,287)
Net loss	$ (8,295)	$ (7,062)	$ (15,387)	$ (14,164)
Net loss per share, basic and diluted	$ (0.36)	$ (0.26)	$ (0.71)	$ (0.52)
Weighted—average common shares outstanding, basic and diluted	23,355,418	27,355,454	21,786,946	27,346,141

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

	DECEMBER 31, 2020	JUNE 30, 2021
Cash, cash equivalents, restricted cash and investments	$ 105,277	$ 90,203
Working capital	98,505	80,604
Total assets	109,048	93,615
Term loan	19,266	19,449
Accumulated deficit	(161,664)	(175,828)
Total stockholders' equity	82,170	69,043