
**UNITED STATES
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, 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)

(617) 517-0730
(Registrant's telephone number, including area code)

N/A
(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 of 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 per share	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 November 9, 2022, scPharmaceuticals Inc. announced its financial results for the quarter ended September 30, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 relating to Item 2.02 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of scPharmaceuticals Inc. issued November 9, 2022
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.

SCPHARMACEUTICALS INC.

Date: November 9, 2022

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

scPharmaceuticals Inc. Reports Third Quarter 2022 Financial Results and Provides Business Update

Announced FDA marketing approval of FUROSCIX® (furosemide injection), the first and only self-administered, subcutaneous loop diuretic for the at-home treatment of congestion in chronic heart failure

Entered into a secured debt financing agreement for up to \$100 million with funds managed by Oaktree Capital

Continued to advance commercial readiness activities in support of upcoming FUROSCIX commercial launch planned in Q1 2023

Company to host inaugural investor call and webcast today, November 9, at 4:30pm ET

BURLINGTON, Mass., November 9, 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 third quarter ended September 30, 2022 and provided a business update.

Business Update

- In October 2022, announced U.S. Food and Drug Administration (FDA) marketing approval of FUROSCIX.
- In October 2022, entered into a secured debt financing agreement for up to \$100 million with funds managed by Oaktree Capital Management. The Company used a portion of the proceeds to prepay all outstanding loans under its existing credit facility and intends to use the remaining available funds, together with cash on-hand, to support its commercialization efforts for FUROSCIX and other working capital and general corporate purposes.
- Continued to advance a multi-faceted launch and commercial preparedness plan, including active outreach to the largest Medicare Part D payers resulting in securing Pharmacy & Therapeutics (P&T) committee meetings to review FUROSCIX in Q4 2022.
- Presented two posters at the Heart Failure Society of America 2022 Annual Scientific Meeting highlighting the significant potential benefits – both to patients and payers – of an alternative approach to the management of congestion in patients with heart failure outside of the hospital.
- Announced positive results from the AT HOME-HF Phase 2 pilot study in chronic heart failure patients presenting to a heart failure clinic with worsening congestion and requiring augmented diuresis. The results favor FUROSCIX over a “treatment as usual” approach in a composite primary endpoint and all secondary endpoints. Notably, subjects randomized to FUROSCIX had a 37% reduction in the risk of a heart failure hospitalization compared to patients randomized to “treatment as usual” at day 30.

- Ended the third quarter with cash, cash equivalents, restricted cash and investments of \$45.4 million. Subsequent to the end of the third quarter, the Company drew down the initial \$50 million tranche from Oaktree per the debt financing agreement announced on October 10.

“The FDA approval of FUROSCIX represents a potential game changer within the heart failure treatment paradigm by allowing patients, for the first time, to self-administer IV equivalent diuresis at home either pre-admission or post discharge from the hospital,” said John Tucker, President and Chief Executive Officer of scPharmaceuticals. “Given the demonstrable benefits to both payers and patients, we see an opportunity for rapid uptake and are preparing for a robust commercial launch in the coming months.

“With access to the funds available through our debt financing agreement with Oaktree, we are well financed for the initial launch. We believe that we have developed an effective commercialization plan that will get FUROSCIX to patients as quickly as possible and should enable us to maximize the value of this asset for our company,” Mr. Tucker concluded.

IV equivalence was established in a clinical study in which FUROSCIX demonstrated 99.6% bioavailability (90% CI: 94.8%-104.8%) and 8-hour urine output of 2.7 L which was similar to subjects receiving intravenous furosemide.

Third Quarter 2022 Financial Results and Financial Guidance

scPharmaceuticals ended the third quarter 2022 with \$45.4 million in cash, cash equivalents, restricted cash and investments (exclusive of the net funds received from Oaktree in October 2022), compared to \$75.5 million as of December 31, 2021.

scPharmaceuticals reported a net loss of \$10.2 million for the third quarter of 2022, compared to a net loss of \$6.6 million for the comparable period in 2021.

Research and development expenses were \$3.7 million for the third quarter of 2022, compared to \$3.7 million for the comparable period in 2021.

General and administrative expenses were \$6.3 million for the third quarter of 2022, compared to \$2.2 million for the comparable period in 2021. The increase in general and administrative expenses for the quarter ended September 30, 2022 was primarily attributable to an increase in employee-related costs and commercial preparation costs.

Based on its current operating plan, the Company has adjusted its 2022 net loss to \$38 to \$41 million, a decrease over prior guidance of \$43 to \$48 million.

As of September 30, 2022, scPharmaceuticals' total shares outstanding was 27,402,121.

Conference call and Webcast Information

scPharmaceuticals' management will host a conference call and webcast to review the Company's third quarter results today, November 9, at 4:30 p.m. E.T. Participants should dial 1-877-407-9208 (domestic) or 1-201-493-6784 (international) with the conference code 13732796. A link to the live webcast can be found [here](#).

Following the live webcast, a replay of the event will be archived on scPharmaceuticals' website for one year.

FUROSCIX® (furosemide injection) 80 mg/10mL for subcutaneous use

FUROSCIX® is indicated 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.

FUROSCIX is not indicated for use in emergency situations or in patients with acute pulmonary edema. The On-Body Infusor will deliver only an 80-mg dose of FUROSCIX.

IMPORTANT SAFETY INFORMATION

FUROSCIX is contraindicated in patients with anuria, patients with a history of hypersensitivity to furosemide or medical adhesives and in patients with hepatic cirrhosis or ascites.

Furosemide may cause fluid, electrolyte, and metabolic abnormalities, particularly in patients receiving higher doses, patients with inadequate oral electrolyte intake, and in elderly patients. Serum electrolytes, CO₂, BUN, creatinine, glucose, and uric acid should be monitored frequently during furosemide therapy.

Excessive diuresis may cause dehydration and blood volume reduction with circulatory collapse and possibly vascular thrombosis and embolism, particularly in elderly patients.

In patients with hepatic cirrhosis and ascites, sudden alterations of fluid and electrolyte balance may precipitate hepatic encephalopathy and coma. Treatment in such patients is best initiated in the hospital.

Furosemide can cause dehydration and azotemia. If increasing azotemia and oliguria occur during treatment of severe progressive renal disease, furosemide should be discontinued.

Cases of tinnitus and reversible or irreversible hearing impairment and deafness have been reported with furosemide. Reports usually indicate that furosemide ototoxicity is associated with rapid injection, severe renal impairment, the use of higher than recommended doses, hypoproteinemia or concomitant therapy with aminoglycoside antibiotics, ethacrynic acid, or other ototoxic drugs.

In patients with severe symptoms of urinary retention (because of bladder emptying disorders, prostatic hyperplasia, urethral narrowing), the administration of furosemide can cause acute urinary retention related to increased production and retention of urine. These patients require careful monitoring, especially during the initial stages of treatment.

The most common adverse reactions with FUROSCIX administration in clinical trials were site and skin reactions including erythema, bruising, edema, and injection site pain.

For more details, please read the full Prescribing Information at [FUROSCIX.com/prescribing-information.pdf](https://www.furoscix.com/prescribing-information.pdf) and Instructions for Use at [FUROSCIX.com/instructions-for-use.pdf](https://www.furoscix.com/instructions-for-use.pdf).

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 Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the significance and potential impact of the results of clinical trials and clinical data; the interpretation and analyses of the results from clinical trials, expectations regarding the potential market impact of FUROSCIX, the preparation for and timing of the planned commercial launch of FUROSCIX and the success of such commercialization, the potential benefits, expected costs and future plans and expectations for FUROSCIX, the expected use of proceeds from the debt facility with Oaktree, and the Company’s expected net loss for the year ending December 31, 2022. 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 any of our 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, risks related to manufacturing and quality assurances processes, 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 these and 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 sections entitled “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 and the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 on file with the Securities and Exchange Commission, available at the Securities and Exchange Commission’s website at www.sec.gov, 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.

Katherine Taudvin
scPharmaceuticals Inc., 781-301-6706
ktaudvin@scpharma.com

Investors:
Hans Vitzthum
LifeSci Advisors, 617-430-7578
hans@lifesciadvisors.com

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,	
	2021	2022	2021	2022
Operating expenses:				
Research and development	\$ 3,694	\$ 3,718	\$ 11,509	\$ 13,207
General and administrative	2,211	6,277	7,593	13,448
Total operating expenses	5,905	9,995	19,102	26,655
Loss from operations	(5,905)	(9,995)	(19,102)	(26,655)
Other income (expense)	10	(22)	298	55
Interest income	10	232	42	353
Interest expense	(667)	(377)	(1,954)	(1,343)
Net loss	\$ (6,552)	\$ (10,162)	\$ (20,716)	\$ (27,590)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.37)	\$ (0.76)	\$ (1.01)
Weighted—average common shares outstanding, basic and diluted	27,355,454	27,401,060	27,349,279	27,382,760

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

(in thousands)

	DECEMBER 31, 2021	SEPTEMBER 30, 2022
Cash, cash equivalents, restricted cash and investments	\$ 75,460	\$ 45,368
Working capital	63,429	29,993
Total assets	79,037	48,400
Term loan	17,159	9,880
Accumulated deficit	(189,698)	(217,288)
Total stockholders' equity	56,470	31,110