

**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 8, 2023

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 8, 2023, scPharmaceuticals Inc. announced its financial results for the quarter ended September 30, 2023. 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 8, 2023
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 8, 2023

By: /s/ John H. Tucker

Name: John H. Tucker

Title: President and Chief Executive Officer

scPharmaceuticals Inc. Reports Third Quarter 2023 Financial Results and Provides Business Update

Generated net FUROSCIX® revenue of \$3.8 million

Ended Q3 2023 with cash, cash equivalents and short-term investments of \$90.2 million

Company to host investor conference call and webcast today, Wednesday, November 8, at 4:30pm ET

BURLINGTON, Mass., November 8, 2023 (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, 2023, and provided a business update.

Business Update

- For the third quarter ended September 30, 2023, scPharmaceuticals reports:
 - Net FUROSCIX revenue of \$3.8 million
 - 1,579 total FUROSCIX prescriptions written
 - 877 FUROSCIX prescriptions filled
 - 442 written prescriptions payer cleared or pending
 - 5.6 doses per prescription
 - 1,119 total and unique prescribers of FUROSCIX from launch through end of Q3, up from 631 through the end of Q2
 - 1,806 FUROSCIX in-services completed from launch through end of Q3, up from 1,129 at the end of Q2
 - Gross-to-net discount of 21% from launch through the end of Q3 versus 23% from launch through the end of Q2
 - Inventory levels at specialty pharmacy partners remained consistent from June 30 levels
- In late October 2023, we reached an agreement with one of the largest closed integrated delivery networks (IDNs) in the United States, providing unrestricted access to FUROSCIX, without prior authorization, to over 8 million lives, at a fixed copay of \$75 or less per prescription.
- As of November 1, 2023, FUROSCIX is now on formulary as a preferred brand with one of the largest government retiree payer formularies, increasing the number of lives with preferred access to FUROSCIX by an additional 1.1 million lives.
- Initiated direct sales of FUROSCIX to IDNs.
- Added an additional specialty pharmacy to our network to maximize access to FUROSCIX among national Medicaid beneficiaries.
- Reflecting positive demand trends, added 12 sales territories at the end of Q3, bringing the total field force to 66 territories, up from 54 at the end of the second quarter.
- Announced FDA feedback pertaining to the development of an 80mg/1mL auto-injector intended to provide an additional option to the on-body infusor. scPharmaceuticals plans to report data from a pivotal pharmacokinetic (PK) study in 2024, and, if successful, targets submitting a Supplemental New Drug Application (sNDA) to the FDA by the end of 2024.

- Announced FDA feedback pertaining to the potential expansion of the FUROSCIX indication to include treatment of edema in patients with chronic kidney disease (CKD). In its feedback, the agency confirmed that no additional clinical study is required and only an adequate PK and pharmacodynamic bridge to the listed drug, furosemide injection, 10 mg/mL, would be required for the expansion.
- Received favorable meeting feedback from the FDA regarding the potential expansion of the FUROSCIX indication to include New York Heart Association (NYHA) Class IV heart failure patients. The Company has filed for NYHA Class IV indication expansion.
- Ended the third quarter of 2023 with cash, cash equivalents and short-term investments of \$90.2 million.

“During the third quarter, we saw a continuation of the positive demand trends that reflect growing awareness of FUROSCIX among heart failure patients and their treating physicians,” stated John Tucker, President, and Chief Executive Officer of scPharmaceuticals. “These trends reflect not only the successful efforts of our field sales force, who continue to conduct detailed in-services to educate physicians about the many benefits of FUROSCIX, but also the ongoing need to expand the number of territories to match evolving growth in patient demand. To that end, we added 12 sales territories during the third quarter, ending the quarter with 66.”

“We continued to have productive discussions with payers. Last quarter, we announced that we had secured national Medicaid coverage effective July 1. Also, in late October, we reached an agreement with one of the largest closed integrated delivery networks in the United States, providing unrestricted access to FUROSCIX, without prior authorization, to over eight million lives at a fixed copay of \$75 or less per prescription. We are advancing late-stage discussions with additional national and regional payers and will provide further updates as appropriate.”

“In parallel, we made significant progress during the quarter and subsequent period advancing life cycle management initiatives for FUROSCIX that could help drive our longer-term growth. These include the potential expansion of the FUROSCIX indication to include NYHA Class IV heart failure patients, additional indications such as chronic kidney disease, and the introduction of greater dosing flexibility through the development of an auto-injector that would complement the current on-body infusor. We are advancing these initiatives while at the same time remaining acutely focused on driving continued uptake of FUROSCIX since its commercial launch in February,” Mr. Tucker concluded.

Third Quarter 2023 Financial Results and Financial Guidance

Product revenues were \$3.8 million, and cost of product revenues were \$1.1 million for the third quarter of 2023.

Research and development expenses were \$3.4 million for the third quarter of 2023, compared to \$3.7 million for the third quarter of 2022. The decrease in research and development expenses for the quarter ended September 30, 2023 was primarily due to a decrease in employee related costs and clinical study and medical affairs costs. The decrease was partially offset by an increase in device and pharmaceutical development costs.

Selling, general and administrative expenses were \$14.1 million for the third quarter of 2023, compared to \$6.3 million for the third quarter of 2022. The increase in selling, general and administrative expenses for the quarter ended September 30, 2023 was primarily due to an increase in employee related costs and commercial costs.

scPharmaceuticals reported a net loss of \$15.6 million for the third quarter of 2023, compared to \$10.2 million for the third quarter of 2022.

scPharmaceuticals ended the third quarter of 2023 with \$90.2 million in cash, cash equivalents and short-term investments, compared to \$118.4 million as of December 31, 2022.

As of September 30, 2023, scPharmaceuticals' total shares outstanding was 35,859,045.

Conference call and webcast information

scPharmaceuticals' management will host a conference call and webcast to review the Company's third quarter 2023 results today, Wednesday, November 8, at 4:30 p.m. ET. Participants should dial 1-855-327-6837 (domestic) or 1-631-891-4304 (international) with the conference code 10022564.

To access the Call me™ feature, which avoids having to wait for an operator, click [here](#).

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 potential market impact and benefits of FUROSCIX and the success of the commercialization of FUROSCIX, the potential expansion of the FUROSCIX indication to include NYHA Class IV heart failure patients and the timing thereof, the potential development of an auto-injector and timing thereof, the potential expansion of the FUROSCIX indication to include treatment of edema in patients with chronic kidney disease, and participation in upcoming events and presentations. 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 any unforeseen delays or setbacks in the commercialization of FUROSCIX, 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, risks related to manufacturing and quality assurances processes, and the risk that global economic factors and uncertainties, including as a result of the COVID-19 pandemic, will impact the Company's 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, 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.

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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,	
	2022	2023	2022	2023
Product revenues, net	\$ —	\$ 3,796	\$ —	\$ 7,497
Operating expenses:				
Cost of product revenues	\$ —	\$ 1,079	\$ —	\$ 2,038
Research and development	3,718	3,421	13,207	8,471
Selling, general and administrative	6,277	14,135	13,448	37,127
Total operating expenses	9,995	18,635	26,655	47,636
Loss from operations	(9,995)	(14,839)	(26,655)	(40,139)
Other (expense) income	(22)	(36)	55	1,193
Interest income	232	1,301	353	3,979
Interest expense	(377)	(2,060)	(1,343)	(6,031)
Net loss	\$ (10,162)	\$ (15,634)	\$ (27,590)	\$ (40,998)
Net loss per share, basic and diluted	\$ (0.37)	\$ (0.41)	\$ (1.01)	\$ (1.07)
Weighted—average common shares outstanding, basic and diluted	27,401,060	38,760,895	27,382,760	38,421,676

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

(in thousands)

	DECEMBER 31, 2022	SEPTEMBER 30, 2023
Cash, cash equivalents, restricted cash and investments	\$ 118,368	\$ 90,188
Working capital	115,892	93,388
Total assets	124,195	106,101
Term loan	36,794	38,262
Accumulated deficit	(226,536)	(267,534)
Total stockholders' equity	72,433	49,146