
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 16, 2020

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 16, 2020, scPharmaceuticals Inc. announced its financial results for the third quarter ended September 30, 2020. 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 November 16, 2020, 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: November 16, 2020

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 Third Quarter 2020 Financial Results and Provides Business Update

Commercialization preparedness activities continuing ahead of December 30 PDUFA date for FUROSCIX® (furosemide injection) for subcutaneous administration

Enrolled first patient in FREEDOM-HF Phase 3 clinical trial

Projected annual net loss for 2020 narrows to \$34-37M

BURLINGTON, Mass. – November 16, 2020 – 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, 2020 and provided a business update.

Business Update

- Continued FUROSCIX commercialization preparedness activities in advance of the company's December 30, 2020 Prescription Drug User-Fee Act (PDUFA) target action date
- Submitted 12-month drug stability data to the U.S. Food and Drug Administration (FDA). Pursuant to an agreement with the FDA, the company was permitted to submit its New Drug Application (NDA) with nine months of drug stability data and submit the remaining three months of drug stability data during the FDA's review of the FUROSCIX NDA. All drug stability data has now been submitted.
- Participated in three virtual poster presentations at the Heart Failure Society of America Virtual Annual Scientific Meeting 2020
- Hosted a successful Key Opinion Leader webinar. The webinar featured presentations by Dan Bensimhon, M.D. of Cone Health Medical Group and Nihar Desai, M.D., MPH from the Yale School of Medicine who discussed FUROSCIX, the current treatment landscape and the unmet medical need that exists in treating patients with worsening heart failure due to congestion.
- Enrolled the first patient in FREEDOM-HF (Furoscix Real-World Evaluation for Decreasing Hospital Admissions in Heart Failure), a prospective Phase 3 clinical trial evaluating overall and heart failure-related costs for subjects treated with FUROSCIX for 30 days post-discharge from the emergency department compared to patients who remain in the hospital for 24 to 72 hours following hospitalization. Data is expected in the second quarter of 2021 to support the planned commercial launch of FUROSCIX, if approved.
- Ended the third quarter with cash, cash equivalents, restricted cash and investments of \$114.5 million

“We are rapidly approaching our December 30 PDUFA date for FUROSCIX which, if approved, will be a transformational event for our company,” said John Tucker, president and chief executive officer. “We are actively engaged with the FDA in their ongoing review of our NDA. Pending approval, we look forward to executing a successful commercial launch to provide this important therapy to the millions of heart failure patients that suffer every day.”

“In parallel with our commercial preparedness activities, we were pleased to have enrolled the first patient in our FREEDOM-HF study. The results of FREEDOM-HF, if positive, will demonstrate the significant economic benefits of treating patients who present to the emergency department with worsening heart failure due to congestion with FUROSCIX outside the hospital setting,” Mr. Tucker concluded.

Third Quarter 2020 Financial Results and Financial Guidance

scPharmaceuticals reported a net loss of \$9.0 million for the third quarter of 2020, compared to \$6.2 million for the comparable period in 2019.

Research and development expenses were \$5.1 million for the third quarter of 2020, compared to \$4.3 million for the comparable period in 2019. The increase in research and development expenses for the quarter ended September 30, 2020 was primarily due to clinical study activity and employee-related costs, offset by a decrease in device and pharmaceutical development activities.

General and administrative expenses were \$3.3 million for the third quarter of 2020, compared to \$2.0 million for the comparable period in 2019. The increase was primarily attributable to employee-related and professional service costs, including costs related to commercial preparations.

scPharmaceuticals ended the third quarter with \$114.5 million in cash, cash equivalents, restricted cash, and investments, compared to \$72.8 million as of December 31, 2019.

Based on its current operating plan, the Company expects the net loss for 2020 to be lower than prior guidance and in the range of \$34.0 to \$37.0 million for the fiscal year.

About FUROSCIX® (furosemide injection) for subcutaneous injection

FUROSCIX is a proprietary furosemide solution formulated to a neutral pH 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 worsening New York Heart Association (NYHA) Class II and Class III heart failure who display reduced responsiveness to oral diuretics and who do not require hospitalization. The FDA has assigned FUROSCIX a PDUFA date of December 30, 2020. 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 expected timing of the FDA's review of the FUROSCIX NDA, the potential timing of, and the Company's expected progress towards, the advancement of the Company's device verification, research and validation studies, including the expected timing and results of the FREEDOM-HF clinical trial, the Company's planned efforts to prepare for commercialization of FUROSCIX and the success of such commercialization, and the potential benefits, expected costs and future plans and expectations for FUROSCIX, if approved, and the Company's 2020 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 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 FDA's review of the Company's 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, 2019 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.

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

Investors:
[Hans Vitzthum](#)
[LifeSci Advisors, 617-430-7578](#)
hans@lifesciadvisors.com

Media:
 Kate Coyle
 ICR Inc., 203-682-8210
kate.coyle@icrinc.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,	
	2019	2020	2019	2020
Operating expenses:				
Research and development	\$ 4,293	\$ 5,119	\$ 16,314	\$ 14,404
General and administrative	1,996	3,319	6,158	8,359
Total operating expenses	6,289	8,438	22,472	22,763
Loss from operations	(6,289)	(8,438)	(22,472)	(22,763)
Other income (expense)	83	19	61	(13)
Interest income	397	36	1,350	281
Interest expense	(398)	(655)	(1,121)	(1,930)
Net loss	\$ (6,207)	\$ (9,038)	\$ (22,182)	\$ (24,425)
Net loss per share, basic and diluted	\$ (0.33)	\$ (0.33)	\$ (1.19)	\$ (1.03)
Weighted—average common shares outstanding, basic and diluted	18,584,327	27,319,465	18,580,192	23,644,580

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

	DECEMBER 31, 2019	SEPTEMBER 30, 2020
Cash, cash equivalents, restricted cash and investments	\$ 72,806	\$ 114,521
Working capital	70,410	108,491
Total assets	77,283	116,960
Term loan	18,915	19,170
Accumulated deficit	(129,455)	(153,880)
Total stockholders' equity	51,365	89,815