
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): March 24, 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 March 24, 2020, scPharmaceuticals Inc. announced its financial results for the fourth quarter and fiscal year ended December 31, 2019. 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 | <u>Press Release issued by the registrant on March 24, 2020, furnished herewith.</u> |

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: March 24, 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 Fourth Quarter and Year Ended 2019
Financial Results and Provides Business Update**

*Remain on track to resubmit FUROSCIX® NDA with the FDA
by mid-year 2020*

Initiating FUROSCIX pre-commercialization and product positioning efforts

Strong balance sheet; ending 2019 with \$72.8 million in cash

Guiding 2020 quarterly GAAP expenses of \$9.0 to \$11.0 million

BURLINGTON, Mass., March 24, 2020 (BUSINESSWIRE) – 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 fourth quarter and year ended December 31, 2019 and provided a business update.

Business Update

- **Remain on track to resubmit the FUROSCIX New Drug Application (NDA) under the current 505(b)(2) approval pathway with the U.S. Food and Drug Administration (FDA) by mid-year 2020.** FUROSCIX is the Company's lead program for the treatment of congestion in patients with heart failure.
- **Completed summative human factors validation study of the FUROSCIX On-Body Infusor.** Two human factors studies were designed to assess and optimize user interaction with the FUROSCIX On-Body Infusor. The summative validation study included 60 participants including congestive heart failure patients, healthcare providers, and caregivers, who collectively represent the intended users of FUROSCIX. Results from the study support the use of the FUROSCIX On-Body Infusor within the intended use population and environments.
- **Device validation and drug stability testing on track to be completed prior to the resubmission of the FUROSCIX NDA.** The initial phase of the drug stability study was successfully completed with analytical testing of the drug product batches finalized for the initial timepoints. The Company also accomplished a key aspect of the device validation program in which the adhesive component of the on-body delivery system was shown to be effective in maintaining adherence to the skin of the abdomen in a simulated wear study. Final testing for both the device and drug stability remains on schedule to be completed prior to the resubmission of the FUROSCIX NDA.
- **Commenced initial activities on FUROSCIX pre-commercialization efforts.** As development activities for FUROSCIX near completion, the Company has begun to turn attention to pre-commercialization efforts. The Company will be focused on specific pre-commercialization activities including establishing a managed care advisory board, contracting with a specialty pharmacy network, and conducting market research to prepare FUROSCIX product messaging and positioning. These pre-commercialization activities will be staged as appropriate to efficiently follow FUROSCIX's regulatory progress.

As part of these efforts, the Company participated in Heart Failure Awareness Week, February 9-15, to highlight the limitations of diuretic therapy in heart failure. The campaign, “Drowning in Fluid: The Role of Congestion in Heart Failure” highlights the 3.8 million heart failure events, the 1 to 2 million hospitalizations that occur annually in the U.S., and the opportunity for an outpatient product, like FUROSCIX, to reduce hospital admissions and re-admissions.

“2019 was a very productive year for scPharmaceuticals,” said John Tucker, president and chief executive officer of the Company. “With the completion of our human factors studies and the progress on the final elements of our regulatory submission, we are in a position to resubmit the FUROSCIX NDA to the FDA by mid-year 2020. With the work to resubmit the FUROSCIX NDA nearing completion, we are excited to be now turning our attention to pre-commercialization readiness. FUROSCIX is a product that we believe can transform the treatment of heart failure and improve patient care, reduce hospitalization, and lessen healthcare costs.”

Fourth Quarter and Year End 2019 Financial Results and Financial Guidance

scPharmaceuticals reported a net loss of \$10.8 million for the fourth quarter of 2019, compared to \$5.1 million for the comparable period in 2018. Research and development expenses were \$8.3 million for the fourth quarter of 2019, compared to \$3.1 million for the comparable period in 2018. The increase in research and development expenses for the quarter ended December 31, 2019 was primarily due to increased pharmaceutical and device development activities related to the advancement of FUROSCIX. General and administrative expenses were \$2.1 million for the fourth quarter ended December 31, 2019 and for the fourth quarter ended December 31, 2018.

scPharmaceuticals reported a net loss of \$33.0 million for the year ended December 31, 2019, compared to \$29.4 million for the comparable period in 2018. Research and development expenses were \$24.6 million for the year ended December 31, 2019, compared to \$15.9 million for the comparable period in 2018. The increase in research and development expenses for the year ended December 31, 2019 was primarily due to increased pharmaceutical and device development activities related to the transition to the next generation device and the advancement of FUROSCIX. General and administrative expenses were \$8.3 million for the year ended December 31, 2019, compared to \$13.7 million for the comparable period in 2018. The decrease was primarily due to the restructuring of the commercial organization mid-year 2018.

scPharmaceuticals ended the fourth quarter with \$72.8 million in cash, cash equivalents, and restricted cash compared to \$89.7 million as of December 31, 2018. This change reflects the ongoing investment in pharmaceutical and device development. The increase from prior year-end guidance was the result of the Company accessing its at-the-market facility in the quarter ended December 31, 2019, which raised proceeds of \$3.9 million, net of commissions.

Based on the Company's current operating plan, scPharmaceuticals forecasts 2020 expenditures of \$9.0 to \$11.0 million per quarter. As of December 31, 2019, scPharmaceuticals total shares outstanding was 19,418,955.

About FUROSCIX

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 being developed for treatment of congestion, or fluid overload, in patients with heart failure. 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 planned resubmission of the FUROSCIX NDA, including potential timing of, and the Company's expected progress towards, the resubmission and the advancement of the Company's device verification and validation studies, the Company's planned efforts to prepare for commercialization of FUROSCIX, and the Company's 2020 financial guidance, including forecasted cash expenditure. 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 the Company will not resubmit the FUROSCIX NDA in the expected timeframe or at all, 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, and 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 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, 2018, its Quarterly Report on Form 10-Q for the quarters ended March 31, 2019, June 30, 2019 and September 30, 2019, and as well as discussions of potential risks, uncertainties and other important factors in the Company's subsequent filings with the SEC (including its upcoming Annual Report on Form 10-K for the year ended December 31, 2019), which are available at the SEC's website at www.sec.gov. 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.

Contacts:

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

Christopher F. Brinzey, Westwicke, an ICR Company
339-970-2843
chris.brinzey@westwicke.com

scPharmaceuticals Inc.**Consolidated Statements of Operations and Comprehensive Loss**

(in thousands, except share and per share data)

| | THREE MONTHS ENDED DECEMBER 31, | | YEAR ENDED DECEMBER 31, | |
|---|------------------------------------|-------------|----------------------------|-------------|
| | 2018 | 2019 | 2018 | 2019 |
| Operating expenses: | | | | |
| Research and development | \$ 3,149 | \$ 8,318 | \$ 15,948 | \$ 24,632 |
| General and administrative | 2,074 | 2,115 | 13,719 | 8,273 |
| Total operating expenses | 5,223 | 10,433 | 29,667 | 32,905 |
| Loss from operations | (5,223) | (10,433) | (29,667) | (32,905) |
| Other income (expense) | 2 | (45) | (56) | 16 |
| Interest income | 491 | 310 | 1,712 | 1,660 |
| Interest expense | (370) | (646) | (1,432) | (1,767) |
| Net loss and comprehensive loss | \$ (5,100) | \$ (10,814) | \$ (29,443) | \$ (32,996) |
| Net loss per share, basic and diluted | \$ (0.27) | \$ (0.58) | \$ (1.59) | \$ (1.77) |
| Weighted—average common shares outstanding, basic and diluted | 18,569,289 | 18,661,626 | 18,556,126 | 18,600,718 |

scPharmaceuticals Inc.**Consolidated Balance Sheet Data**

(in thousands)

| | AS OF DECEMBER 31, | |
|--|--------------------|-----------|
| | 2018 | 2019 |
| Cash, cash equivalents and restricted cash | \$ 89,660 | \$ 72,806 |
| Working capital | 85,220 | 70,410 |
| Total assets | 93,755 | 77,283 |
| Term loan | 9,637 | 18,915 |
| Accumulated deficit | (96,459) | (129,455) |
| Total stockholders' equity | 78,744 | 51,365 |