UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 23, 2021 (February 23, 2021)

scPharmaceuticals Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38293**	**46-5184075**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2400 District Avenue, Suite 310 **Burlington, Massachusetts**	**01803**
(Address of principal executive offices)	**(Zip Code)**

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

Not Applicable
(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 to 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	**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 February 23, 2021, scPharmaceuticals Inc. (the "Company") issued a press release which included certain unaudited preliminary financial results for the fourth quarter and fiscal year ended December 31, 2020 (the "Press Release"). A copy of the Press Release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information pursuant to Item 2.02 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 8.01 Other Events.

On February 23, 2021, the Company announced the results of a Type A meeting with the U.S. Food and Drug Administration (the "FDA") regarding the Company's FUROSCIX® New Drug Application ("NDA"). As a result of the meeting, the Company will run additional modified bench tests on aged commercial units of the West Pharmaceutical Services, Inc.'s SmartDose® Gen II on-body infusor. The Company also anticipates the need to conduct Pre-Approval Inspections at three of the Company's third-party manufacturing facilities.

Statements contained under this Item 8.01 regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to: statements regarding the FDA's review requirements and the Company's planned resubmission of the FUROSCIX NDA, including potential timing and preparation thereof.

Any forward-looking statements 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. Risks that contribute to the uncertain nature of the forward-looking statements include the results of the above-referenced bench testing, the receipt of regulatory approval for the FUROSCIX On-Body Infusor, 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 resubmission of the FUROSCIX NDA and other operations. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company's other filings with the SEC. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01. Exhibits

(d) Exhibits

99.1 Press Release Issued by the Company on February 23, 2021, furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

February 23, 2021

SCPHARMACEUTICALS INC.

By: /s/ John H. Tucker

Name: John H. Tucker

Title: President, Chief Executive Officer,
Principal Financial Officer and Principal Executive Officer

Exhibit 99.1

scPharmaceuticals

scPharmaceuticals Inc. Announces Results of Type A End-of-Review Meeting with FDA Regarding FUROSCIX® NDA

No additional clinical efficacy, PK or safety data required

December 31, 2020 cash, cash equivalents, restricted cash and investments estimated to be $105 million, sufficient to fund operations through potential FUROSCIX® approval and launch and into 2023

BURLINGTON, Mass. – February 23, 2021 – 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 that on February 19, 2021, the Company received the official Type A meeting minutes from the U.S. Food and Drug Administration (FDA) regarding the requirements for resubmission of the FUROSCIX® 505(b)(2) New Drug Application (NDA) following the Complete Response Letter (CRL) received on December 3, 2020.

The outstanding questions are primarily focused on Pre-Approval Inspections and bench testing. The Company will run additional modified bench tests on aged commercial units of the West Pharmaceutical Services, Inc.'s SmartDose® Gen II on-body infusor. The FDA is not requiring modifications to the device nor is it requiring the company to perform additional clinical studies to demonstrate the safety and efficacy of FUROSCIX.

The Company still anticipates the need for Pre-Approval Inspections of the West Pharmaceutical Services' facility in Scottsdale, Arizona, the Sharp Packaging Services' facility in Allentown, Pennsylvania and the third-party manufacturer of the off-the-shelf alcohol swabs.

John Tucker, Chief Executive Officer of scPharmaceuticals, stated: "We are pleased to have had a very productive meeting with the FDA to discuss key elements of the CRL. We have developed a plan that we believe will address the FDA's outstanding questions and will conduct the modified bench testing which we anticipate will allow us to resubmit our FUROSCIX NDA in the third quarter of this year.

"In parallel, our Phase 3 FREEDOM clinical trial is progressing well. This trial is 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 less than or equal to 72 hours following hospitalization. If positive, we believe these data will demonstrate compelling clinical and pharmacoeconomic benefits of FUROSCIX, as a potential intervention for worsening heart failure patients pre- and post-discharge," Mr. Tucker concluded.

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. 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.

Financial Update

The Company's estimate that it had approximately $105 million in cash, cash equivalents, restricted cash and investments as of December 31, 2020 is preliminary and has not been audited. Complete 2020 fourth quarter and full year financial results will be announced via the Company's March 2021 earnings release and Annual Report on Form 10-K. These preliminary unaudited results could change as a result of further review by the Company's management and its independent auditors.

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 FDA's review requirements, the planned resubmission of the FUROSCIX NDA, including potential timing of the resubmission, the potential timing of, and the Company's expected progress towards, the advancement of the Company's FREEDOM-HF clinical trial, including the expected timing and results thereof and the Company's projected financial guidance. 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 results of the above-referenced bench testing, 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 clinical trial, the timing of the resubmission 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.

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