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): December 7, 2020 (December 3, 2020)

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 8.01. Other Events.

On December 7, 2020, scPharmaceuticals Inc. (the "**Company**") issued a press release announcing that it had received a complete response letter (the "**CRL**") from the U.S. Food and Drug Administration (the "**FDA**") on December 3, 2020 for the Company's New Drug Application (the "**NDA**") for its product candidate, FUROSCIX®, a novel formulation of furosemide delivered via an on-body infusor under development for the treatment of congestion in patients with worsening heart failure. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release issued by the registrant on December 7, 2020.

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.

December 7, 2020

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. Receives Complete Response Letter from FDA for FUROSCIX®

CRL did not identify clinical deficiencies

BURLINGTON, Mass. – December 7, 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 it received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") on December 3, 2020 regarding the Company's New Drug Application ("NDA") for FUROSCIX®.

In the CRL, the FDA cited their need to conduct pre-approval inspections at two of the company's third-party manufacturing facilities that could not be conducted due to travel restrictions. In addition, the FDA raised questions related to testing, labeling, and features of the combination product unrelated to the drug constituent. In addition, the FDA indicated that there were deficiencies at the third-party facility where the Company's off-the-shelf alcohol swabs are manufactured. scPharmaceuticals will request a Type A meeting with the FDA to discuss the issues described in the CRL and steps required for the resubmission of the NDA for FUROSCIX®.

scPharmaceuticals ended the third quarter with cash, cash equivalents, restricted cash, and investments of $114.5 million, which the Company estimates is sufficient to fund operations into 2023 at the projected burn rate.

John Tucker, Chief Executive Officer of scPharmaceuticals, stated: "While we are disappointed that these on-site inspections, and other issues raised in the CRL, will not be resolved by our previously granted December 30, 2020 PDUFA date, we are committed to working with our manufacturing partners and responding to the agency's concerns as expeditiously as possible. We continue to believe that FUROSCIX® can play a significant role in preventing heart failure hospital admissions and readmissions due to fluid overload by intervening with this novel therapy at home."

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.

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 Company's request for a Type A meeting with the FDA, the outcome of the Type A meeting, the Company's ability to address the comments raised in the Complete Response Letter and resubmit the FUROSCIX NDA, and the Company's cash runway. 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, and the risk that the current COVID-19 pandemic will impact the Company's device validation, drug stability testing, 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.

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

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