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): October 16, 2018

SCPHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	
(State or other jurisdiction of incorporation or organization)	
001-38293	**46-5184075**
(Commission File Number)	**(I.R.S. 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

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))

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 8.01 Other Events.

As previously disclosed, on June 11, 2018, scPharmaceuticals Inc. (the "Company") received a complete response letter ("CRL") from the U.S. Food and Drug Administration (the "FDA") following the FDA's review of a New Drug Application submitted by the Company under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for FUROSCIX™ Infusor (furosemide), 80 mg/10 mL, drug-device combination product. On September 24, 2018, a Type A Post-Action Meeting was held between the Company and the FDA to discuss the Company's proposed plan to address the CRL, and on October 16, 2018, the Company received the official meeting minutes from the Type A Post-Action Meeting.

The Company issued a press release on October 18, 2018 announcing its receipt of the official meeting minutes. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

By filing this information, the Company makes no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of the Company's filings with the U.S. Securities and Exchange Commission (the "Commission") and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Commission, through press releases or through other public disclosure.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein which do not describe historical facts, including but not limited to statements regarding the Company's plans to meet with the FDA to discuss validation study protocols; the Company's completion of human factors and dose delivery validation studies; the Company's plans to resubmit its NDA for FUROSCIX; the potential timing and advancement of the Company's ongoing or planned clinical trials and investigator-sponsored studies; the announcement of data from these trials and studies; and the Company's financial condition and cash runway, are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include, without limitation, risks associated with the Company conducting human factors studies or a dose delivery validation study, the ability of the Company's device to appropriately deliver therapy, whether the Company will be able to address the deficiencies raised in the CRL and the receipt of regulatory approval for FUROSCIX, as well as other risks set forth under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 and its subsequent public filings with the Commission. The Company cautions investors not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Except as required by law, the Company disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release issued by the registrant on October 18, 2018.

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: October 18, 2018

By: /s/ John H. Tucker
Name: John H. Tucker
Title: President, Chief Executive Officer and Principal Executive Officer

Exhibit 99.1

scPharmaceuticals Inc. Provides Regulatory Update on FUROSCIX®

Type A Post-Action Meeting Minutes Received

BURLINGTON, Mass., October 18, 2018 (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 that, on October 16, 2018, it received minutes from the Type A Post-Action Meeting held on September 24, 2018 between the Company and the U.S. Food and Drug Administration (FDA) to discuss the Company's New Drug Application (NDA) for FUROSCIX®, scPharmaceuticals' lead program for the treatment of edema in patients with heart failure. The meeting was scheduled to allow scPharmaceuticals to present new information that the Company believes important in addressing certain issues raised by the FDA in the Complete Response Letter (CRL) received on June 13, 2018, regarding FUROSCIX.

As an outcome of the meeting, the FDA has asked the Company to conduct additional human factors studies and a dose delivery validation study with the recently modified FUROSCIX Infusor. The Company intends to submit requests for Type C meetings with the FDA to determine study protocols. The FDA has not requested any additional clinical trials.

The FDA confirmed the appropriate populations for FUROSCIX are patients with worsening NYHA Class II and III heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization. The FDA has recommended that the label for FUROSCIX, if approved, should state that the FUROSCIX Infusor should not be used as a substitute for IV diuretics for patients who require hospitalization or have been recently discharged.

"We have had productive dialogue with the FDA since receiving the CRL in June and have further clarity following receipt of the minutes from our Type A Post-Action Meeting," said John Tucker, president and chief executive officer of scPharmaceuticals. "We look forward to working with the FDA to establish the human factors and dose delivery validation protocols and NDA resubmission plan. We remain in a strong financial position with expected year-end cash of $80-85 Million, sufficient to complete the human factors and dose delivery validation studies required to re-file FUROSCIX by the end of 2019 and continue with future product and device development."

About FUROSCIX

FUROSCIX is a proprietary furosemide solution formulated to a neutral pH to allow for subcutaneous infusion via the patented Infusor, a wearable, pre-programed drug delivery system that is applied to the abdomen for subcutaneous drug administration. FUROSCIX is being developed for treatment of edema, 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 edema.

About scPharmaceuticals

scPharmaceuticals is a clinical-stage pharmaceutical company focused on developing and commercializing products that reduce healthcare costs and improve health outcomes. The Company develops products for 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 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 plans to meet with the FDA to discuss validation study protocols; the Company's completion of human factors and dose delivery validation studies; the Company's plans to resubmit its NDA for FUROSCIX; the potential timing and advancement of our ongoing or planned clinical trials and investigator-sponsored studies; the announcement of data from these trials and studies; and the Company's financial condition and 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 Company conducting human factors studies or a dose delivery validation study, the ability of our device to appropriately deliver therapy, the receipt of regulatory approval for FUROSCIX or any other product candidates or, if approved, successfully commercialize 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. 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 the Company's most recent Annual Report on Form 10-K on file with the Securities and Exchange Commission, 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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