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): June 11, 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.

On August 23, 2017, scPharmaceuticals Inc. (the "Company") submitted to the U.S. Food and Drug Administration (the "FDA") a New Drug Application (the "NDA") 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. As previously disclosed, on May 30, 2018, the Company received a notification from the FDA stating that, as part of its ongoing review of the Company's NDA, the FDA had identified deficiencies that precluded discussion of labeling and postmarketing requirements/commitments at that time.

On June 11, 2018, the Company received a complete response letter from the FDA for the Company's NDA (the "CRL"), and on June 13, 2018, the Company issued a press release announcing its receipt of the CRL. 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 the Furoscix CRL, plans to resubmit the NDA for Furoscix, the timing of the FDA review process and the Company's expectations with regard to its discussions with the FDA 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, device modifications and potentially an additional clinical validation study, the ability of the Company's device to appropriately deliver therapy, the Company's ability to appropriately identify patients and implement risk assessment and mitigation strategies, 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 June 13, 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: June 13, 2018

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

Exhibit 99.1

scPharmaceuticals Receives Complete Response Letter from the FDA for FUROSCIX®

BURLINGTON, Mass., June 13, 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 the Company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the 505(b)(2) application for FUROSCIX®, a treatment candidate for edema, or fluid overload, in patients with heart failure.

The CRL indicated the need for additional human factors studies, device modifications, and potentially a clinical validation study. scPharmaceuticals intends to request a meeting with the FDA to further evaluate the deficiencies raised.

“While we are disappointed with the outcome of the review, we are committed to addressing the issues of the CRL and bringing this important product to market,” commented John Tucker, president and chief executive officer of scPharmaceuticals. “Our team will continue to work closely with the FDA to determine an appropriate path forward regarding product performance, appropriate patient identification, and risk mitigation strategies that ultimately enable a timely resubmission of the FUROSCIX NDA.”

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 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 the Furoscix CRL, plans to resubmit the NDA for Furoscix, the timing of the FDA review process and the Company’s expectations with regard to its discussions with the FDA 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, device modifications and potentially an additional clinical validation study, the ability of our device to appropriately deliver therapy, our ability to appropriately identify patients and implement risk assessment and mitigation strategies, 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 Securities and Exchange 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.

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