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): May 30, 2018

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)

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

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

CHE	ck the appropriate box below it the Form 6-14 ming is intended to simultaneously satisfy the infing obligation of the registrant under any of the following
prov	visions (see General Instruction A.2. below):
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

- 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)) П
- П 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. Under the Prescription Drug User Fee Act ("PDUFA"), the FDA had set June 23, 2018 as a target date for a decision on the NDA. On May 30, 2018, the Company received a notification from the FDA (the "Notification") stating that, as part of its ongoing review of the Company's NDA, the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The FDA stated that the Notification does not reflect a final decision on the information under review.

The Notification does not specify the deficiencies identified by the FDA. The Company plans to work with the FDA to understand the nature of the deficiencies once identified and resolve them as quickly as possible.

On May 31, 2018, the Company issued a press release announcing its receipt of the Notification. A copy of Company's 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 timing of the FDA's approval of the NDA, the Company's expectations with regard to its discussions with the FDA, plans, and expectations as to the PDUFA date 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, any deficiencies the FDA may identify with respect to Furoscix and whether the Company will be able to address the issues that may relate to those deficiencies, the receipt of regulatory approval for Furoscix and the Company's other product candidates, the Company's ability to market and sell its product candidates, if approved, the Company's ability to successfully compete in the market for treatment of heart failure, the Company's ability to manufacture Furoscix or any of its other product candidates, and 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 you 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. <u>Description</u>

99.1 Press Release issued by the registrant on May 31, 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: May 31, 2018 By: /s/ John H. Tucker

Name: John H. Tucker

Title: President, Chief Executive Officer and

Principal Executive Officer

scPharmaceuticals Inc. Provides Regulatory Update on FUROSCIX®

BURLINGTON, Mass., May 31, 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 May 30, 2018, the Company received a letter from the U.S. Food and Drug Administration (FDA) as part of the FDA's ongoing review of the Company's New Drug Application (NDA) for FUROSCIX® Infusor (furosemide) 80 mg/10mL, drug-device combination product. The letter states that the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The letter further states that the notification does not reflect a final decision on the information under review.

The FDA's letter does not specify the deficiencies identified as part of its ongoing review. The Company intends to work with the FDA to understand the nature of the deficiencies once identified and resolve them as quickly as possible.

In a prior FDA communication on September 14, 2017, the FDA had set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 23, 2018 to complete its review of the 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 timing of the FDA's approval of the NDA, the Company's expectations with regard to its discussions with the FDA, plans, and expectations as to the PDUFA date 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, any deficiencies the FDA may identify with respect to Furoscix and whether the Company will be able to address the issues that may relate to those deficiencies, the receipt of regulatory approval for Furoscix and the Company's other product candidates, the Company's ability to market and sell its product candidates, if approved, the Company's ability to successfully compete in the market for treatment of heart failure, the Company's ability to manufacture Furoscix or any of its other product candidates, and 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.

Contacts:

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