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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 8-K

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

**Date of report (Date of earliest event reported): July 27, 2020 (July 27, 2020)**

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# SCPHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

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**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)

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

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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))

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 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.

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**Item 8.01 Other Events.**

On July 27, 2020, scPharmaceuticals Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) has accepted the Company’s New Drug Application (“NDA”) resubmission for its product candidate, FUROSCIX® , a proprietary, subcutaneously delivered furosemide solution outpatient alternative for the treatment of worsening heart failure due to congestion. The FDA set a Prescription Drug User Fee Act target action date of December 30, 2020 for the completion of its review of the NDA. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

**Item 9.01. Exhibits**

(d) Exhibits

99.1 [Press release issued by the Company on July 27, 2020.](#)

**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: July 27, 2020

By: /s/ John H. Tucker

Name: John H. Tucker

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

# scPharmaceuticals

## **scPharmaceuticals Announces FDA Acceptance of FUROSCIX® New Drug Application Resubmission**

*FDA sets PDUFA date of December 30, 2020*

BURLINGTON, Mass. – July 27, 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 that the U.S. Food and Drug Administration (FDA) has accepted for review the company’s New Drug Application (NDA) resubmission for FUROSCIX®. scPharmaceuticals is developing FUROSCIX, a proprietary, subcutaneously delivered furosemide solution, as an outpatient alternative for the treatment of worsening heart failure due to congestion. The FDA indicated that this was a complete class 2 response and assigned a Prescription Drug User-Fee Act (PDUFA) target action date of December 30, 2020.

“The FDA’s acceptance of our FUROSCIX NDA resubmission is a significant achievement for our company. We believe we have successfully addressed the questions and concerns previously raised by the agency in its 2018 Complete Response Letter and we look forward to working with the agency during its review process,” said John Tucker, president and chief executive officer of scPharmaceuticals. “If approved, we believe FUROSCIX has the potential to benefit patients and payers alike and provide physicians a new tool in the battle to treat worsening heart failure.”

### **About FUROSCIX**

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 being developed for treatment of congestion, 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 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](http://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 timing of the FDA’s review of the FUROSCIX NDA and the Company’s planned efforts to prepare for*

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# scPharmaceuticals

*commercialization of FUROSCIX, if approved. 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 ability of the FUROSCIX On-Body Infusor to appropriately deliver therapy and the potential benefits for patients and payers, 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 planned Phase 4 study of FUROSCIX, the timing of the FDA's review 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](http://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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