# 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): July 1, 2021**

# 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 July 1, 2021, scPharmaceuticals Inc. (the "**Company**") issued a press release announcing the results of a Type C meeting with the U.S. Food and Drug Administration (the "**FDA**") regarding the requirements for resubmission of the Company's FUROSCIX® New Drug Application. 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 July 1, 2021. |

**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.

July 1, 2021

**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 Inc. Announces Receipt of Written Minutes from Type C Meeting with the FDA Regarding Development of FUROSCIX®**

*FDA and Company in alignment on the path forward*

*No additional clinical data or device modifications required at this time*

*FUROSCIX NDA resubmission targeted for Q4 2021*

BURLINGTON, Mass. – July 1, 2021 – 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 June 30, 2021 the Company received the minutes from its Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the requirements for resubmission of the FUROSCIX New Drug Application (NDA).

Based on guidance the Company received during the meeting and subsequently contained within the meeting minutes, the Company is moving forward with its original plan to conduct the required bench testing for the West Pharmaceutical Services'(West) SmartDose® Gen II on-body drug delivery system that is used to deliver FUROSCIX to heart failure patients. Importantly, the FDA has not requested modifications to the device.

"We are pleased with the outcome of our Type C meeting, and subsequent receipt of the meeting minutes, as this represents an important step forward as we continue to advance FUROSCIX toward potential commercialization," stated John Tucker, chief executive officer of scPharmaceuticals. "In June, West resumed making the commercial devices that will be used for the required bench testing, and subject to the completion of the Device Master File (DMF) by West, we are targeting the resubmission of our NDA in the fourth quarter of this year and anticipate a six-month review by the FDA."

"At the same time, we recently completed enrollment in our FREEDOM-HF study and anticipate topline data in July. The results, if positive, can potentially demonstrate significant cost savings from treating congestion in patients with heart failure with FUROSCIX outside of the hospital setting. We are looking forward to better understanding the potential pharmacoeconomic impact of FUROSCIX within this patient population, and the promise of reducing the burden of heart failure."

scPharmaceuticals ended the first quarter of 2021 with cash, cash equivalents, restricted cash and investments of $96.5 million. The Company believes its cash, cash equivalents, restricted cash and investments are sufficient to fund operations into 2023, unchanged from prior guidance.

**About FUROSCIX®** (furosemide injection) for subcutaneous injection

FUROSCIX is an investigational, 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 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 planned resubmission of the FUROSCIX NDA, including potential timing of the resubmission and expected timing of the FDA's review, the potential timing of the completion of the DMF by West; the potential timing of, and the Company's expected progress towards, the advancement of the Company's device verification, research and validation studies, including the expected timing and results of the FREEDOM-HF clinical trial, the Company's planned efforts to prepare for commercialization of FUROSCIX; and the Company's 2021 financial guidance. 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, 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 device validation, drug stability testing, the timing of the Company's resubmission of the 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, 2020 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