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): May 16, 2022

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 May 16, 2022, 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 formulation of furosemide delivered via an on-body infusor for the treatment of congestion in patients with worsening heart failure. The FDA set a Prescription Drug User-Fee Act target action date of October 8, 2022 for the completion of its review of the NDA. A copy of the press release referenced above is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release issued by the registrant on May 16, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document).

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.

May 16, 2022

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 FDA Acceptance of FUROSCIX® New Drug Application

PDUFA action date set for October 8, 2022

Company preparing for Q4 commercial launch, if approved

BURLINGTON, Mass., May 16, 2022 (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 the Company's New Drug Application (NDA) for FUROSCIX, a proprietary formulation of furosemide delivered via an on-body infusor for the treatment of congestion in patients with worsening heart failure, has been accepted for filing by the U.S. Food and Drug Administration (FDA). The FDA assigned a Prescription Drug User-Fee Act (PDUFA) target action date of October 8, 2022.

"The acceptance of our FUROSCIX NDA is a significant achievement for our company and the culmination of many years of tireless work by the scPharmaceuticals team to get us to this critical point," stated John Tucker, chief executive officer of scPharmaceuticals. "We believe FUROSCIX, if approved, will address a significant need along the heart failure care continuum. By providing a new option for the treatment of congestion related to heart failure, all stakeholders – patients, payers and providers – stand to benefit, and there is the potential to generate significant healthcare system cost savings. We look forward to engaging with the FDA and continue to prepare for a successful Q4 2022 commercial launch should FUROSCIX be approved," Mr. Tucker concluded.

About FUROSCIX® (furosemide injection) for subcutaneous injection

FUROSCIX is an investigational, proprietary furosemide solution formulated to a neutral pH, designed 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 chronic heart failure who display reduced responsiveness to oral diuretics and who do not require hospitalization. If approved, 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 timing and outcome of the FDA's review of the NDA, expectations regarding the potential label or market impact of FUROSCIX, if approved, and the Company's planned efforts to prepare for commercialization of FUROSCIX. 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 that results of a clinical study do not necessarily predict final results and that one or more of the clinical outcomes may materially change following more comprehensive reviews of the data, and as more patient data become available, the risk that results of a clinical study are subject to interpretation and additional analyses may be needed and/or may contradict such results, 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, 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, 2021 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.

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