

**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): April 11, 2022

scPharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38293
(Commission
File Number)

46-5184075
(IRS 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

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 April 11, 2022, scPharmaceuticals Inc. (the “Company”) issued a press release announcing that it has resubmitted its New Drug Application (“NDA”) to the U.S. Food and Drug Administration (the “FDA”) seeking marketing approval of its product candidate, FUROSCIX® (furosemide injection), for the treatment of decompensated heart failure. 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 Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by the registrant on April 11, 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.

April 11, 2022

SCPHARMACEUTICALS INC.

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

**scPharmaceuticals Inc. Announces Resubmission of FUROSCIX®
New Drug Application**

Anticipates Q4 2022 commercial launch, if approved

BURLINGTON, Mass. – April 11, 2022 – 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 has resubmitted its New Drug Application (NDA) to the US Food and Drug Administration (FDA) seeking marketing approval for FUROSCIX for the treatment of decompensated heart failure. In addition, West Pharmaceutical Services, Inc. has completed all development activities and submitted the Device Master File in support of the FUROSCIX NDA.

“The resubmission of the FUROSCIX NDA is a major milestone for our company as it is an important landmark in our transition to a commercial stage company, if approved,” stated John Tucker, chief executive officer of scPharmaceuticals. “Our clinical data package, together with the compelling cost savings recently observed in our FREEDOM-HF study, give us a high degree of conviction that, if approved, FUROSCIX could become a valuable therapy for the treatment of worsening heart failure due to congestion pre-hospital admission and/or post-discharge.”

The company is advancing its commercial readiness activities in anticipation of a potential Q4 commercial launch, if approved. These include:

- Finalizing physician, payer and pricing research;
- Communicating FUROSCIX data, including FREEDOM-HF data, to pharmacy benefit managers and health plans through its product dossier;
- Finalizing FUROSCIX distribution partners; and
- Reinitiating commercial staffing to support anticipated Q4 2022 launch, if approved.

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 review process, the significance and potential impact of the results of the FREEDOM-HF clinical trial and the clinical data; the Company's planned efforts to prepare for commercialization of FUROSCIX; and the commercial success 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 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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