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): September 10, 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 September 10, 2021, scPharmaceuticals Inc. issued a press release announcing additional results from its FREEDOM-HF study to be presented at the Heart Failure Society of America Annual Scientific Meeting 2021. 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 September 10, 2021.
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.

September 10, 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

scPharmaceuticals Inc. Presents Late-breaking FREEDOM-HF Study Data at the Heart Failure Society of America Annual Scientific Meeting 2021

Data show statistically significant and meaningful reduction in both heart failure-related and overall healthcare costs for patients treated with FUROSCIX® versus a historical comparator group

Company on track to resubmit FUROSCIX NDA in the fourth quarter 2021

BURLINGTON, Mass. – September 10, 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 data from its recently-completed FREEDOM-HF clinical trial will be presented at the Heart Failure Society of America (HFSA) Annual Scientific Meeting 2021. In the FREEDOM-HF study, heart failure (HF) patients with mild to moderate volume overload (despite oral diuretic use) and treated with subcutaneous FUROSCIX were successfully managed in the outpatient setting resulting in significantly reduced HF-related and overall healthcare costs through reduction of HF-related hospitalizations and rehospitalizations.

“We are pleased to present these very compelling results from the FREEDOM-HF study at this year’s HFSA meeting,” stated John Tucker, chief executive officer of scPharmaceuticals. “In this study, there was a highly statistically significant and meaningful cost savings associated with treating HF patients with FUROSCIX. These data provide a strong pharmacoeconomic case for the broad adoption of FUROSCIX as a viable HF treatment pre-admission or post-discharge, if approved by the Food and Drug Administration (FDA).

Following our Type-C meeting with the FDA in June, we are aligned with the agency on the regulatory path forward, are well financed with more than $90 million on hand as of June 30, 2021, and remain on track to re-submit our New Drug Application (NDA) in the fourth quarter of this year.”

FREEDOM-HF was a prospective clinical trial evaluating 30-day heart failure-related and overall costs of treating congestion in patients with chronic HF. Patients were treated with FUROSCIX, the Company’s investigational product, post-discharge from the emergency department compared to a historical comparator group that was managed in the hospital setting.

The HFSA Annual Scientific Meeting 2021 is being held virtually and in a hybrid format in Denver, Colorado from September 10-14, 2021. A copy of the poster can be accessed under the News and Events section of the Company’s website.

Late-breaking HFSA Poster Presentation Details and Data:

Title: Significantly Reduced Healthcare Costs with Home FUROSCIX Versus in Hospital IV Diuresis: Results from the FREEDOM-HF Study

Presenter: Daniel Bensimhon, MD

Session: Session PV.01 - Poster Viewing Session I

Date: Friday, September 10, 2021

Time: 6:36-6:46pm MT (8:36-8:46pm ET)

90 subjects were enrolled in the study, 24 in the FUROSCIX group and 66 in the comparator group.

Comparators were hospitalized for £72 hours and were selected from a claims database matched to seven variables associated with HF-related hospitalization and severity. Baseline patient characteristics (key matching variables) were similar between the study groups, as were the incidence of co-morbidities and HF medication use.

FUROSCIX utilization led to a statistically significant reduction in 30-day HF-related and overall healthcare costs.

- Mean 30-day HF-related costs were $17,753 lower in the FUROSCIX treated group ($2,920) versus the comparator group ($20,673, p-value<0.0001).
- Similarly, mean 30-day total healthcare costs were $30,568 lower in the FUROSCIX treated group ($7,090) versus the comparator group ($37,658, p-value<0.0001).
- There were no serious adverse events (SAEs) attributed to study drug, and there were no deaths or study withdrawals due to an SAE.
- Injection site bruising (29%), discomfort (29%) and dizziness (13%) were the most common side effects of FUROSCIX; all were mild in severity and none led to study withdrawal.
- This analysis excludes the cost of FUROSCIX, as the price has yet to be established.

Authors' Conclusion:

HF patients with mild to moderate volume overload (despite oral diuretic use) can be safely discharged from the emergency department with subcutaneous FUROSCIX, enabling outpatient decongestion. FUROSCIX use was associated with statistically significant reduced overall and HF-related healthcare costs through a reduction in HF-related hospitalizations.

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 infusor, 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 significance of the results of the FREEDOM-HF clinical trial; the interpretation and analyses of the results from the FREEDOM-HF clinical trial; 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, and the Company's expected progress towards, the advancement of the Company's device verification, research and validation studies; and the Company's planned efforts to prepare for commercialization of FUROSCIX and the success of such commercialization, 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, 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.

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