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 13, 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))

Securitiesregistered 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 13, 2021, scPharmaceuticals Inc. (the "Company") announced positive top-line results from its FREEDOM-HF study. FREEDOM-HF was a prospective clinical trial evaluating overall and heart failure-related costs of treating congestion in patients with chronic heart failure. Patients were treated with FUROSCIX®, the Company's investigational product, post-discharge from the emergency department compared to a historical comparator group that was treated with intravenous furosemide in the inpatient hospital setting. Based on the results from a planned, prespecified interim analysis conducted to confirm the final sample size, and following input from statisticians, principal investigators, payer advisors and Health Economics and Outcomes Research (HEOR) experts, enrollment was stopped on May 17, 2021, prior to the enrollment target of 34 patients. This decision was made due to the highly statistically significant reduction observed in 30-day heart failure-related costs in patients who received FUROSCIX in the interim analysis. The final analysis included 24 subjects treated with FUROSCIX and 66 matched comparators based on seven variables associated with hospitalization. Comparator patients hospitalized for 72 hours or less were identified, and costs were derived from service-level claims utilizing IBM® MarketScan® Research Databases which utilizes coding to standardize financial data from fully paid and adjudicated claims.

The mean difference in heart failure-related costs between the two groups was $17,753 per study subject, with a p-value of $p<0.0001$ (95% CI: -$23,660, -$11,846), favoring the FUROSCIX group. This difference in costs was driven primarily by hospitalization costs. Per protocol, all subjects (24/24) who were enrolled in the study and received FUROSCIX did not require an initial heart failure hospitalization, and all but one (95.8%) remained out of the hospital for heart failure for the subsequent 30-day period. In the comparator group, 100% of the patients were initially hospitalized and 10.6% had a heart failure-related readmission. As part of the study design, all FUROSCIX patients were required to have at least one heart failure related clinic visit during the study period. In the comparator group, 34.9% of subjects had a heart failure related clinic visit. Since the price for FUROSCIX has not been established, the difference in costs does not include the cost of FUROSCIX.

Additional analyses, including 30-day overall healthcare cost, quality of life as well as patient and caregiver satisfaction, are ongoing and complete data will be submitted for publication or presentation at an upcoming scientific meeting. The most common adverse events with FUROSCIX were infusion site pain, bruising and dizziness and no serious adverse events related to FUROSCIX were observed.

Statements contained under this Item 8.01 regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such 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.

Any forward-looking statements 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. Risks that contribute to the uncertain nature of the forward-looking statements 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 the Company's 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 the Company's development of the Company's product candidates, the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving the Company's 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 these and other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company's other filings with the SEC. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01. Exhibits

(d) Exhibits

99.1	Press Release Issued by the Company on July 13, 2021, furnished herewith.

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 13, 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 Positive Top-Line Results from FREEDOM-HF Study

Reduced average 30-day heart failure related costs by $17,753 (p<0.0001) per study subject in FUROSCIX® arm compared to historically matched comparators

Study halted early due to highly statistically significant reduction in 30-day heart failure-related costs observed during the prespecified interim analysis

Company to host conference call and live webcast tomorrow, July 14, at 8:30am ET

BURLINGTON, Mass. – July 13, 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 positive top-line results from its FREEDOM-HF study. FREEDOM-HF was a prospective clinical trial evaluating overall and heart failure-related costs of treating congestion in patients with chronic heart failure. Patients were treated with FUROSCIX®, our investigational product, post-discharge from the emergency department compared to a historical comparator group that was treated with intravenous furosemide in the inpatient hospital setting.

Based on the results from a planned, prespecified interim analysis conducted to confirm the final sample size, and following input from statisticians, principal investigators, payer advisors and Health Economics and Outcomes Research (HEOR) experts, enrollment was stopped on May 17, 2021, prior to the enrollment target of 34 patients. This decision was made due to the highly statistically significant reduction observed in 30-day heart failure-related costs in patients who received FUROSCIX in the interim analysis. The final analysis included 24 subjects treated with FUROSCIX and 66 matched comparators based on seven variables associated with hospitalization.

Comparator patients hospitalized for 72 hours or less were identified, and costs were derived from service-level claims utilizing IBM® MarketScan® Research Databases which utilizes coding to standardize financial data from fully paid and adjudicated claims.

Results Summary:

- The mean difference in heart failure-related costs between the two groups was $17,753 per study subject, with a p-value of p<0.0001 (95% CI: -$23,660, -$11,846), favoring the FUROSCIX group.
- This difference in costs was driven primarily by hospitalization costs. Per protocol, all subjects (24/24) who were enrolled in the study and received FUROSCIX did not require an initial heart failure hospitalization, and all but one (95.8%) remained out of the hospital for heart failure for the subsequent 30-day period.
- In the comparator group, 100% of the patients were initially hospitalized and 10.6% had a heart failure-related readmission.

- As part of the study design, all FUROSCIX patients were required to have at least one heart failure related clinic visit during the study period. In the comparator group, 34.9% of subjects had a heart failure related clinic visit.
- Since the price for FUROSCIX has not been established, the difference in costs does not include the cost of FUROSCIX.
- Additional analyses, including 30-day overall healthcare cost, quality of life as well as patient and caregiver satisfaction, are ongoing and complete data will be submitted for publication or presentation at an upcoming scientific meeting.
- The most common adverse events with FUROSCIX were infusion site pain, bruising and dizziness and no serious adverse events related to FUROSCIX were observed.

“These positive results from our pharmacoeconomic study support our hypothesis that treating heart failure patients with FUROSCIX has the potential to dramatically reduce the significant costs associated with admission or readmission to the hospital,” stated John Tucker, chief executive officer of scPharmaceuticals. “As we continue to work toward the resubmission of our new drug application (NDA) later this year, this study provides powerful evidence to payers on the potential economic benefit of FUROSCIX, if approved.”

“We currently lack a tool designed to manage worsening congestion in the outpatient setting in patients with chronic heart failure when oral diuretics are inadequate. This results in heart failure being one of the most common causes of hospital admissions in patients over 65 years of age,” stated Dan Bensimhon, MD, Medical Director Advanced Heart Failure & Mechanical Circulatory Support Program, Cone Health. “I believe FUROSCIX, if approved, could represent an important new tool to manage heart failure in the outpatient setting.”

“It has been estimated that up to 90% of patients presenting to the emergency department with symptoms of worsening heart failure are admitted to the hospital, and 50% of these admissions may be potentially avoided,” stated James Kenney, RPh, MBA, president of JTKENNEY, LLC, a managed care pharmacy consultancy. “The direct medical costs of heart failure are projected to surpass $53 billion by 2030, with 80% of these expenditures being related to hospitalization. If approved, FUROSCIX has the potential to significantly reduce such costs by shifting management of appropriate patients with congestion from the inpatient to the outpatient setting.”

Conference Call and Webcast

scPharmaceuticals’ management, Dr. Bensimhon and Mr. Kenney will host a conference call and live webcast tomorrow, July 14, at 8:30 am ET.

Investor Dial-in: 877-407-9208
Int’l Investor Dial-in: 201-493-6784
Conference ID: 13721167
Webcast: http://public.viavid.com/index.php?id=145533

About FREEDOM-HF

FREEDOM-HF (**FUROSCIX Re**al-World **E**valuation for **D**ecreasing H**o**spital Ad**m**issions in **H**eart **F**ailure) was a multicenter, prospective adaptive clinical trial to evaluate differences in heart failure and overall costs between subjects receiving FUROSCIX outside the hospital and patients receiving intravenous furosemide in the hospital setting for 30-days after being discharged from

the emergency department. Differences in costs were calculated from a comparator group who were hospitalized for 72 hours or less where subjects were matched based on 7 variables associated with heart failure hospitalization and severity derived from IBM® MarketScan® Research Databases. The study was designed to enroll up to 75 subjects in the FUROSCIX cohort to detect a statistically significant difference in 30-day overall and heart failure related costs.

***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 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. 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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