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 12, 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 July 12, 2022, scPharmaceuticals Inc. issued a press release announcing results from its AT HOME-HF Pilot study. 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 12, 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.

July 12, 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

scPharmaceuticals Inc. Announces Positive Results from the AT HOME-HF Phase 2 Pilot Study in Heart Failure

Study results favor FUROSCIX® versus "treatment as usual" in composite primary endpoint and all secondary endpoints

FUROSCIX demonstrated an acceptable tolerability profile

Company on track for Q4 2022 commercial launch of FUROSCIX, if approved

BURLINGTON, Mass. – July 12, 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 positive results from the AT HOME-HF Pilot study, a Phase 2, multicenter, randomized study that compared scPharmaceuticals' investigational product, FUROSCIX (furosemide 80 mg/10 mL for subcutaneous administration), with a "treatment as usual" approach in chronic heart failure patients presenting to a heart failure clinic with worsening congestion and requiring augmented diuresis.

The study enrolled 51 subjects, of which 34 received FUROSCIX and 17 received "treatment as usual."

Data highlights:

- There was a positive trend in the Finkelstein-Schoenfeld win ratio of the hierarchal primary composite endpoint consisting of cardiovascular death, heart failure hospitalizations, emergency department visits for heart failure and % change from baseline of NT-proBNP at day seven in the FUROSCIX group compared to the "treatment as usual" group across multiple analysis populations.
- Subjects randomized to FUROSCIX had a 37% reduction in the risk of a heart failure hospitalization relative to patients randomized to "treatment as usual" at day 30.
- All pre-defined secondary endpoints measuring symptoms of congestion, quality of life and functional status favored the FUROSCIX group and included a two kilogram greater weight loss at day three and a 12-point increase in the 12 item Kansas City Cardiomyopathy Questionnaire (KCCQ-12) summary scores at day 7 and day 30.

- There were 11 subjects that experienced 21 adverse events during the 30-day study period that were determined by the investigator to be related to FUROSCIX. The most common related adverse event was infusion site pain that was mild in severity. There was one serious adverse event (dehydration) that was assessed by the investigator as possibly related to FUROSCIX, which resolved. During the 30-day study period, there was one death (sudden cardiac death) in the FUROSCIX group which occurred on study day 30 and was assessed by the investigator to be not related to FUROSCIX.

The AT HOME-HF Pilot study was descriptive only and did not include a powered statistical hypothesis test.

“We are pleased with the results from the AT HOME-HF Pilot study where, despite a small sample size, subjects treated with FUROSCIX had greater decongestion and significant improvement in symptoms and functional status compared to ‘treatment as usual,’” said Dr. Marvin Konstam, M.D., Professor of Medicine at Tufts University School of Medicine and Chief Physician Executive of the Cardiovascular Center at Tufts Medical Center. “The data from this study will be informative in designing and determining the sample size for a potential larger clinical trial.”

“With a 37% reduction in heart failure hospitalizations relative to ‘treatment as usual’ and improvement in congestion signs and symptoms observed in the AT HOME-HF Pilot study, a positive PK/PD study demonstrating 99.6% bioavailability and comparable diuresis and natriuresis for FUROSCIX compared to IV furosemide, and a reduction of approximately $17,000 in 30-day heart failure related costs with FUROSCIX observed in the FREEDOM-HF study, the totality of the available evidence regarding FUROSCIX strongly supports its value proposition,” said John Tucker, chief executive officer of scPharmaceuticals. “As we approach our October 8, 2022 PDUFA date, we are excited and look forward to commercial launch of FUROSCIX, if approved, in the fourth quarter of this year.”

About AT HOME-HF Phase 2 Pilot Study

The objective of the AT HOME-HF Pilot study was to provide pilot data on the effectiveness and safety of FUROSCIX to inform a potentially larger trial. The AT HOME-HF Pilot study is a Phase 2, multicenter, randomized, proof-of-concept study in heart failure patients with worsening congestion that was conducted to evaluate the clinical outcomes and safety of FUROSCIX compared to a “treatment as usual” approach. Eligible subjects based on inclusion and exclusion criteria were randomized to receive (in a 2:1 randomization scheme) FUROSCIX or “treatment as usual.” The primary endpoint was a 30-day hierarchal composite of cardiovascular death, heart failure hospitalizations, emergency department visits for heart failure and % change of NT-proBNP at day seven from baseline, utilizing the Finkelstein- Schoenfeld win ratio. The Finkelstein-Schoenfeld win ratio is a statistical method used to compare composite outcomes for every pair in a clinical trial from the treatment and control group. The pre-defined secondary endpoints were evaluated from baseline across the 30-day study period and included the number of days alive and heart failure event free, global assessment via visual analog scale, composite clinical congestion score, 5- and 7-point Likert dyspnea scores, health-related quality of life measured by the KCCQ-12 short form summary score, serum creatinine, weight, six-minute walk test and ReDS® (Remote Dielectric Sensing) lung fluid measurement. The study did not include a powered statistical hypothesis test. Enrollment commenced in Q2-2021 and was completed in Q1-2022.

FUROSCIX® (furosemide) 80 mg/10mL for subcutaneous administration

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 and potential impact of the results of the AT HOME-HF Pilot study and relevant data; the interpretation and analyses of the results from the AT HOME-HF Pilot study, including the potential activity and tolerability profile; the potential for a clinical trial based on the results of the AT HOME-HF Pilot study; the FREEDOM-HF clinical trial and the clinical data; the interpretation and analyses of the results from the FREEDOM-HF clinical trial; statements regarding the timing and outcome of the FDA's review of the NDA; the preparation and timing of commercial launch and the success of such commercialization, if approved; and the potential benefits, expected costs and future plans and expectations for 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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