SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 1, 2022

SALARIUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36812**	**46-5087339**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

2450 Holcombe Blvd.
Suite X
Houston, TX **77021**

(Address of principal executive offices) **(Zip Code)**

(832) 804-9144
(Registrant's telephone number, including area code)

N/A
(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 of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ 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	SLRX	The Nasdaq Capital 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 December 1, 2022, Salarius Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain interim clinical trial results from the Company's Phase 1/2 trial of its novel oral, reversible, targeted LSD1 inhibitor, seclidemstat, as a treatment for Ewing sarcoma and FET-rearranged sarcomas.

A copy of the press release is filed herewith as Exhibit 99.1, and the information contained therein is incorporated by reference to this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Salarius Pharmaceuticals, Inc., dated December 1, 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 duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SALARIUS PHARMACEUTICALS, INC.

Date: December 1, 2022

By: /s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer

Salarius Pharmaceuticals Announces Interim Results from Phase 1/2 Trial of Seclidemstat as a Treatment for Ewing Sarcoma and FET-Rearranged Sarcomas

60% Confirmed Disease Control Rate[1] and 7.4 Months Median Time to Tumor Progression for Ewing Sarcoma First-Relapse Patients

No Disease Progression Observed in Either First- or Second-Relapse Ewing Sarcoma Patients Who Achieved Confirmed Disease Control

HOUSTON (December 1, 2022) – Salarius Pharmaceuticals, Inc. (NASDAQ: SLRX), a clinical-stage biopharmaceutical company using targeted protein inhibition and targeted protein degradation to develop therapies for patients with cancer in need of new treatment options, announces interim clinical trial results from the company's Phase 1/2 trial of its novel oral, reversible, targeted LSD1 inhibitor, seclidemstat, as a treatment for Ewing sarcoma and FET-rearranged sarcomas.

These interim results appear to indicate that first- and second-relapse Ewing sarcoma patients treated with seclidemstat in combination with topotecan and cyclophosphamide who achieve disease control may have an increased time to tumor progression (TTP) compared with treatment of topotecan and cyclophosphamide alone, per the Phase 3 rEECur study described below. The Ewing sarcoma and FET-rearranged sarcoma trial is currently on a partial clinical hold as described below.

As of October 31, 2022, 13 first- and second-relapse Ewing sarcoma patients were evaluable for confirmed disease control rate assessment. Of these 13 patients, five patients (38%) achieved confirmed disease control with no tumor progression observed while treated with seclidemstat in combination with topotecan and cyclophosphamide. Treatment duration for the 13 patients ranged from 0.7 months to 13.8 months.

Five first-relapse Ewing sarcoma patients were treated and three (60%) achieved confirmed disease control, including one complete response, one partial response and one stable disease at 12.8 months and continuing. First-relapse patients had a median TTP of 7.4 months and treatment duration ranged from 1.4 months to 13.8 months.

At ASCO 2022, Euro Ewing Consortium presented rEECur[2] Phase 3 study results in relapsed/refractory Ewing sarcoma patients that showed median event-free survival of 3.5 months in the topotecan/ cyclophosphamide arm (n=73) compared with 5.7 months in the high-dose ifosfamide arm (n=73)[2]. The rEECur data includes approximately 80% primary refractor or first-relapse. Ewing sarcoma patients after relapse have 5-year overall survival of about 13% and 10-year overall survival of about 9%[3].

"Ewing sarcoma is a devastating bone and soft tissue cancer that affects children, adolescents and young adults, and treatment options primarily consist of chemotherapies, radiation and surgical resection," commented Damon Reed M.D., Program Leader, Adolescent Young Adult Program, Chair of Department of Individualized Cancer Management Moffitt Cancer Center and principal investigator in this sarcoma trial. "As an oncologist treating Ewing sarcoma patients, ultimately new treatments that extend a

[1] Confirmed disease control rate includes complete remission, partial remission or stable disease confirmed by both cycle 2 and cycle 4 scans. Treatment cycles are 21 days in length, with cycle 2 scans occurring on or about day 42 and cycle 4 scans occurring on or about day 84.

[2] rEECur - International Randomized Controlled Trial of Chemotherapy for the Treatment of Recurrent and Primary Refractory Ewing Sarcoma.
[3] Risk of recurrence and survival after relapse in patients with Ewing sarcoma, Pediatric Blood & Cancer, Volume 57, Issue 4. First published October 2011.

patient's time to progression, extend progression-free survival and achieve complete responses are what patients need."

David Arthur, President and CEO of Salarius, said, "These interim results are encouraging, and I believe they show the potential for seclidemstat to provide a more durable response among Ewing sarcoma patients when used in combination with topotecan and cyclophosphamide. This trial has more than 15 clinical trial sites with more than 20 locations throughout the United States, and when needed Salarius provides travel assistance to patients who want to participate in the sarcoma trial. It is our hope that the potential for seclidemstat to improve outcomes coupled with our support will make it easier for patients to participate when enrollment is restarted."

As previously reported, on October 18, 2022, enrollment of new patients in the Salarius-sponsored seclidemstat sarcoma clinical trial and the MD Anderson investigator-initiated hematologic clinical trial was voluntarily paused due to a suspected unexpected serious adverse reaction (SUSAR) observed in the sarcoma trial; patients currently enrolled in both studies are able to continue treatment after consulting with their physician. The U.S. Food and Drug Administration (FDA) subsequently agreed with Salarius' approach and placed the sarcoma trial on partial clinical hold; Salarius is working with the FDA to further analyze the available data with the goal of understanding how best to proceed and restart enrollment.

Additional interim trial results include the following:

- Among the 13 Ewing sarcoma patients treated with seclidemstat, topotecan and cyclophosphamide
    - There was a 38% confirmed disease control rate and 1.6 months median TTP which ranged from 0.7 months to 13.8 months
    - One second relapse patient with confirmed stable disease withdrew from the study with no observed progression at 3.5 months due to a non-study related adverse event
    - One second relapse patient with a confirmed partial response withdrew from the study with no observed progression at 3.1 months
- Among the five first-relapse Ewing sarcoma patients treated, three (60%) achieved confirmed disease control
    - One patient achieved a complete response and withdrew from the study at 7.4 months
    - One patient achieved a partial response with 78% target lesion reduction; this patient subsequently elected radiation treatment as consolidation and withdrew from the study at 13.8 months
    - One patient achieved stable disease and continues on treatment after 12.8 months
- Single-agent activity has not been observed in the FET-rearranged sarcoma cohort of the trial
- More than 85 patients have been treated in either the dose-escalation or the dose-expansion portions of the trial with seclidemstat as a standalone therapy or in combination with standard-of-care chemotherapy

Conference call and webcast
Salarius plans to hold an investor call in mid-December to discuss these interim results and other clinical and preclinical data following presentation at the American Society of Hematology annual meeting by MD Anderson Cancer Center and Salarius. Details about the conference call including how to participate will be provided in a separate news release.

About the Phase 1/2 Ewing's and other FET-rearranged sarcomas trial
The Phase 1/2 trial currently is in its dose-expansion stage, which includes three patient arms. The first arm is planned to enroll up to 30 patients with Ewing's sarcoma, a rare and deadly pediatric bone cancer, and will investigate seclidemstat in combination with topotecan and cyclophosphamide, a commonly used second- and third-line chemotherapy regimen. Salarius believes data released during ASCO 2021 demonstrated synergy in an Ewing's sarcoma cell line when seclidemstat was used in combination with these agents. Salarius also believes this treatment combination and its use as a second- and third-line therapy has the potential to expand the addressable patient population for seclidemstat and improve outcomes by allowing physicians to introduce seclidemstat earlier in the Ewing's sarcoma continuum of care.

The trial's second patient arm is planned to investigate seclidemstat as a single agent in up to 15 patients with myxoid liposarcoma. The third patient arm is planned to investigate seclidemstat as a single agent in up to 15 patients with select sarcomas that share a similar biology to Ewing's sarcoma, also referred to as FET-rearranged or Ewing's-related sarcomas. In data released at ASCO 2021, a subset of patients with advanced FET-rearranged sarcomas treated with single-agent seclidemstat resulted in stable disease and prolonged time to progression, which Salarius believes suggests disease control, a clinically relevant endpoint for soft tissue sarcomas.

All three patient arms are designed to evaluate safety and efficacy in patients with advanced disease.

Salarius supports patient referrals to their sarcoma trial sites and provides travel assistance for clinical trial patients and families who are evaluating and participating in the sarcoma trial.

Clinical trial sites include Seattle Cancer Care Alliance (SCCA) – which is comprised of the Fred Hutchinson Cancer Research Center, Seattle Children's Hospital and University of Washington Medical Center; Oregon Health & Sciences University Portland, OR; Johns Hopkins All Children's Hospital in St. Petersburg, FL; Children's Hospital of Los Angeles in Los Angeles, CA; Moffitt Cancer Center in Tampa, FL; Dana-Farber Cancer Institute in Boston, MA; MD Anderson Cancer Center in Houston, TX; Nationwide Children's Hospital in Columbus, OH; Memorial Sloan Kettering Cancer Center in New York NY; the Sarcoma Oncology Center in Santa Monica, CA; Virginia Cancer Specialists, Fairfax, Virginia; Cleveland Clinic, in Cleveland, OH; Washington University, St. Louis, MO and Fox Chase Cancer Center in Philadelphia PA. Information on the Salarius Sarcoma trial SALA-002-EW16 (NCT03600649) can be found at clinicaltrial.gov.

About Salarius Pharmaceuticals
Salarius Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing therapies for patients with cancer in need of new treatment options. Salarius' product portfolio includes seclidemstat, the company's lead candidate, which is being studied as a potential treatment for pediatric cancers, sarcomas and other cancers with limited treatment options, and SP-3164, an oral small molecule protein degrader. Seclidemstat is currently in a Phase 1/2 clinical trial for relapsed/refractory Ewing sarcoma and certain additional sarcomas that share a similar biology. Seclidemstat has received fast track, orphan drug and rare pediatric disease designations for Ewing sarcoma from the U.S. Food and Drug Administration. Salarius is also exploring seclidemstat's potential in several cancers with high unmet medical need, with an investigator-initiated Phase 1/2 clinical study in hematologic cancers at MD Anderson Cancer Center. Salarius has received financial support from the National Pediatric Cancer Foundation to advance the Ewing program and was a recipient of a Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). SP-3164 is currently in IND-enabling studies and anticipated to enter the clinic in 2023. For more information, please visit salariuspharma.com or follow Salarius on Twitter and LinkedIn.

Forward-Looking Statements
This announcement and the referenced presentation contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this presentation are forward-looking statements. These forward-looking statements may be identified by terms such as "will," "future," "believe," "developing," "expect," "hope," "promising," "may," "progress," "potential," "could," "look forward," "might," "should," and similar terms or expressions or the negative thereof. Examples of such statements include, but are not limited to, statements relating to the following: our future development plans for our product candidates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates and any specific impacts on the timing of our clinical development program due to clinical holds or other events that could delay our clinical trials; our expectations with respect to the release of data from our clinical trials and the expected timing thereof; the potential advantages of seclidemstat as a treatment for Ewing sarcoma, Ewing-related sarcomas, and other cancers and its ability to improve the life of patients; the potential for our product candidates to achieve success in clinical trials; and our expected financial condition, including the anticipation duration of cash runways and timing regarding needs for additional capital; and the impact that the addition of new clinical sites will have on the development of our product candidates. We may not actually achieve the plans, carry out the intentions or meet the expectations or objectives disclosed in

the forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements are subject to risks and uncertainties which could cause actual results and performance to differ materially from those discussed in the forward-looking statements. These risks and uncertainties include, but are not limited to, the following: resolution of the FDA's partial clinical hold on the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas following the SUSAR; our ability to resume enrollment in the clinical trial following its review of the available data surrounding the SUSAR; anticipated pre-clinical studies and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested product candidate; we may elect to change our strategy regarding our product candidates and clinical development activities; we may not receive the necessary regulatory approvals for the clinical development of our products; economic and market conditions may worsen; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt our clinical development programs; and other risks described in our filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as revised or supplemented by its Quarterly Reports on Form 10-Q and other documents filed with the SEC. The forward-looking statements contained in this announcement and the referenced presentation speak only as of the date of this announcement and the referenced presentation and are based on management's assumptions and estimates as of such date. We disclaim any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made.

CONTACT:

LHA Investor Relations
Kim Sutton Golodetz
kgolodetz@lhai.com
212-838-3777

# # #