UNITED STATES
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): **February 5, 2021**

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 No.)

2450 Holcombe Blvd., Suite X, Houston, Texas 77021
(Address of principal executive offices, with zip code)

(832) 834-6992
(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 Instructions 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

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 February 17, 2021, Salarius Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it has completed the dose-escalation stage and established the recommended Phase 2 dose for its ongoing Phase 1/2 clinical trial in relapsed/refractory Ewing sarcoma. The full text of this press release is included as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated February 17, 2021.

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.

Date: February 17, 2021

SALARIUS PHARMACEUTICALS, INC.

By: /s/ Mark J. Rosenblum
Mark J. Rosenblum
Executive Vice President and
Chief Financial Officer

Salarius Completes Dose-Escalation Stage of Phase 1/2 Clinical Trial in Relapsed and Refractory Ewing Sarcoma Patients, Initiates Expansion Stage in Ewing and Ewing-related Sarcoma Patients

Seclidemstat safety profile affirmed; Recommended Phase 2 dose established

Demonstrated preliminary evidence of seclidemstat drug activity in subset of Ewing-related sarcoma patients

HOUSTON, February 17, 2021 (GLOBE NEWSWIRE) -- Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biopharmaceutical company developing potential new medicines for patients with pediatric cancers, solid tumors, and other cancers, announced today that it has completed the dose-escalation stage and established the recommended Phase 2 dose (RP2D) for its ongoing Phase 1/2 clinical trial in relapsed/refractory (R/R) Ewing sarcoma.

The Phase 1/2 clinical trial of seclidemstat in patients with Ewing sarcoma was designed as an open-label, multi-center, dose-finding study. The primary objectives of the study were to determine the safety and tolerability of seclidemstat. Secondary objectives were to assess the maximum-tolerated dose (MTD), the RP2D, preliminary anti-tumor activity, pharmacokinetics (PK), and pharmacodynamics.

Data from patients treated in the dose-escalation portion of the trial demonstrated seclidemstat had a manageable safety profile. The RP2D for the expansion stage has been established and, importantly, PK data from the dose-escalation portion of the trial indicated that treatment at the RP2D achieved plasma concentrations above levels where seclidemstat demonstrated activity in preclinical studies. Salarius is preparing to submit the full findings from the dose-escalation trial, including details on safety, dosing, and initial efficacy signals, for presentation at an upcoming medical conference. Conference embargo rules prevent additional disclosures at this time.

“The completion of dose escalation in Ewing sarcoma patients and establishment of the RP2D represent important milestones in our clinical development of seclidemstat,” stated David Arthur, President and CEO of Salarius Pharmaceuticals. “We are encouraged by data from the dose-escalation phase and look forward to continuing development of seclidemstat for difficult to treat cancers.”

Salarius is evaluating its lead drug candidate, seclidemstat, in patients with R/R Ewing sarcoma, a rare and deadly pediatric bone and soft tissue cancer and in a Phase 1/2 trial enrolling patients with Advanced Solid Tumors (AST). Seclidemstat is a novel, oral reversible inhibitor of the lysine-specific histone demethylase 1 enzyme (LSD1), an enzyme that has been shown to play a key role in the development and progression of certain cancers.

As previously reported, a refractory Ewing sarcoma patient treated with single-agent seclidemstat for six cycles (a cycle is 28 days), demonstrated a reduction in prospectively defined target lesions starting at end of cycle 2 with further target lesion tumor shrinkage through end of cycle 4 and cycle 6 (over 75% tumor shrinkage). The appearance of new non-target lesion at the end of cycle 2 resulted in classification of progressive disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. Salarius believes this data demonstrates preliminary drug activity in a patient with refractory Ewing sarcoma. Additional data from the dose-escalation portion of the Ewing sarcoma trial has demonstrated further evidence of drug activity, which Salarius hopes to expand upon during the upcoming dose-expansion portion of the trial by treating R/R Ewing sarcoma patients with seclidemstat.

In addition to treating R/R Ewing sarcoma patients, the expansion portion of the Phase 1/2 trial will enroll patients with additional select sarcomas that share a similar biology to Ewing sarcoma. Fusions of similar oncogenes to those that are translocated in Ewing sarcoma occur in tumors, such as myxoid liposarcoma, desmoplastic small round cell tumors, and others known as Ewing-related sarcomas or FET-translocated sarcomas. The decision to include Ewing-related sarcoma patients was supported by preclinical data and encouraging clinical data in Salarius' AST trial. Of the small subset of Ewing-related sarcoma patients with progressive disease that enrolled in the AST trial, all patients demonstrated preliminary evidence of seclidemstat drug activity at levels below the RP2D. Encouragingly, in this subset of seclidemstat treated patients, the median time to progression was above the benchmarks established for single-agent activity in the advanced, relapsed soft tissue sarcoma setting. Ewing-related sarcoma patients will continue to be treated with single-agent seclidemstat to generate more safety and early efficacy activity in this patient population. Safety and efficacy results from the AST trial are planned for presentation at an upcoming medical conference. Conference embargo rules prevent further disclosure at this time.

This study will continue to evaluate safety and antitumor activity with data readouts expected towards the end of this year and early next year.

Mr. Arthur concluded, "We are encouraged by the preliminary results from the Ewing sarcoma trial and the Advanced Solid Tumor trial that have demonstrated antitumor activity in patient populations with advanced disease. Based on the totality of the data accumulated thus far, we are optimistic about the potential of seclidemstat in multiple cancers."

About Salarius Pharmaceuticals

Salarius Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing cancer therapies for patients in need of new treatment options. Salarius' lead candidate, seclidemstat, is being studied as a potential treatment for pediatric cancers, solid tumors and other cancers with limited treatment options. Seclidemstat is currently in a Phase 1/2 clinical trial for relapsed/refractory Ewing sarcoma, for which it has received Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation from the U.S. Food and Drug Administration. Salarius is also developing seclidemstat for several cancers with high unmet medical need, with a second Phase 1/2 clinical study in advanced solid tumors, including prostate, breast, and ovarian cancers. Salarius has received financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma clinical program and was also the recipient of a Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information, please visit salariuspharma.com.

Forward-Looking Statements

This press release contains "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 press release are forward-looking statements. These forward-looking statements may be identified by terms such as "anticipate," "potential," "progress," "design," "estimate," "continue," "will," "aim," "can," "believe," "plan," "allow," "expect," "intend," "goal," "provide," "able to," "position," "project," "developing," and similar terms or expressions or the negative thereof. Examples of such statements include, but are not limited to, statements relating to the following: The status and anticipated progress and milestones of Salarius' clinical trials in relapsed and refractory Ewing sarcoma and Ewing-related sarcomas; Salarius' developing cancer therapies for patients that need them the most; Salarius'

developing seclidemstat for several cancers with high unmet medical need; Salarius' developing seclidemstat as a potential treatment for pediatric cancers, solid tumors and other cancers with limited treatment options; Salarius advancing seclidemstat to the dose-escalation stage of the Phase 1/2 clinical trial in relapsed and refractory Ewing sarcoma; the potential of seclidemstat as a treatment for Ewing-related sarcomas; the ability of seclidemstat to demonstrate drug activity; the ability and degree to which seclidemstat could have an impact on the treatment of Ewing sarcoma and Ewing-related sarcomas. Salarius 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: the sufficiency of Salarius' capital resources; the ability of, and need for, Salarius to raise additional capital to meet Salarius' business operational needs and to achieve its business objectives and strategy; Salarius' ability to project future capital needs and cash utilization and timing and accuracy thereof; the ability of Salarius to access the remaining funding available under the CPRIT grant; future clinical trial results and impact of results on Salarius; that the results of studies and clinical trials may not be predictive of future clinical trial results; the sufficiency of Salarius' intellectual property protection; risks related to the drug development and the regulatory approval process; the competitive landscape and other industry-related risks; market conditions and regulatory or contractual restrictions which may impact the ability of Salarius to raise additional capital; the possibility of unexpected expenses or other uses of Salarius' cash resources; risks related to the COVID-19 outbreak; and other risks described in Salarius' filings with the Securities and Exchange Commission, including those discussed in Salarius' quarterly report on Form 10-Q for the quarter ended September 30, 2020 and in Salarius' annual report on Form 10-K for the year ended December 31, 2019. The forward-looking statements contained in this press release speak only as of the date of this press release and are based on management's assumptions and estimates as of such date. Salarius disclaims 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.

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