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): October 18, 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) 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 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 October 18, 2022, Salarius Pharmaceuticals, Inc. (the "Company") issued a press release announcing that, as per protocol, the Company is voluntarily pausing new patient enrollment in the Company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas due to an FET-rearranged sarcoma patient death which was classified as a suspected unexpected serious adverse reaction. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and 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 October 18, 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: October 18, 2022

By: /s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer

Salarius Pharmaceuticals Announces Pause in New Patient Enrollment in its Phase 1/2 Trial of Seclidemstat in Ewing Sarcoma and FET-Rearranged Sarcomas

HOUSTON (October 18, 2022) – Salarius Pharmaceuticals, Inc. (NASDAQ: SLRX), a clinical-stage biopharmaceutical company using protein inhibition and protein degradation to develop cancer therapies for patients in need of new treatment options, today announced that, as per protocol design, it is voluntarily pausing new patient enrollment in the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas.

The pause in new patient enrollment is due to a metastatic FET-rearranged sarcoma patient death that was classified as a suspected unexpected serious adverse reaction (SUSAR). Upon review of the SUSAR and available information by the company's independent Safety Review Committee for the clinical trial, patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician.

Salarius communicated the details of the SUSAR to the U.S. Food and Drug Administration (FDA) and intends to further analyze the available data with the goal of understanding how best to proceed and restart enrollment as soon as possible. Salarius continues to plan to release interim sarcoma clinical trial results later this year.

"Patient safety is our primary concern, and this is reflected in the design of our clinical trial protocol, which automatically paused enrollment based upon this SUSAR," said David Arthur, chief executive officer of Salarius. "Unfortunately, pauses to enrollment occur in early-stage drug development, but these pauses allow time to understand new data and adjust clinical protocols and development plans as needed. We plan to restart enrollment as soon as possible."

About the Phase 1/2 Ewing sarcoma 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 patient arm is enrolling up to 30 patients with Ewing 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 a Ewing 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 could greatly expand the addressable patient population for seclidemstat and improve outcomes by allowing physicians to introduce seclidemstat earlier in the Ewing sarcoma continuum of care.

The trial's second patient arm is investigating seclidemstat as a single agent in up to 15 patients with myxoid liposarcoma. The third patient arm is investigating seclidemstat as a single agent in up to 15 patients with select sarcomas that share a similar biology to Ewing sarcoma, also referred to as FET-rearranged or Ewing-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. Per protocol design, new patient enrollment will be stopped, or paused, when 1) any death or life-threatening adverse experience deemed possibly or definitely related to the investigational product is observed, or 2) it is determined that the protocol precipitates multiple patient non-compliance beyond reasonably missed visits.

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, also referred to as Ewing-related or FET-rearranged sarcomas. 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 underway at MD Anderson Cancer Center. Salarius has received financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma clinical program and was a recipient of a Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information, please visit salariuspharma.com or follow Salarius on Twitter and LinkedIn.

Forward-Looking Statements
This letter 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 letter are forward-looking statements. These forward-looking statements may be identified by terms such as "believe," "developing," "expect," "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: the future of the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas following the SUSAR; impact that the addition of new clinical sites will have on the development of Salarius' product candidates; the timing of Salarius' IND submissions to the U.S. Food and Drug Administration and subsequent timing for initiating clinical trials; interim data related to Salarius' clinical trials, including the timing of when such data is available and made public; Salarius' growth strategy; the value of seclidemstat as a treatment for Ewing sarcoma, Ewing-related sarcomas, and other cancers and its ability to improve the life of patients; expanding the scope of Salarius' research and focus to high unmet need patient populations; milestones of Salarius' current and future clinical trials, including the timing of data readouts. 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: FDA may impose additional restrictions on the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas following the SUSAR, including a partial or full clinical hold; Salarius' ability to resume enrollment in the clinical trial following its review of the available data surrounding the SUSAR; 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; 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; risks related to the drug development and the regulatory approval process; the competitive landscape and other industry-related risks; and other risks described in Salarius' 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 letter speak only as of the date of this letter 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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