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): June 17, 2024

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) 834-9144
(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 June 17, 2024, Salarius Pharmaceuticals, Inc. (the "Company") issued a press release announcing that investigators in the Department of Leukemia at the University of Texas MD Anderson Cancer Center presented clinical data on seclidemstat in patients with myelodysplastic syndrome and chronic myelomonocytic leukemia at the 2024 European Hematology Association Annual Meeting held in Madrid from June 13 -16, 2024. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Salarius Pharmaceuticals, Inc., dated June 17, 2024
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: June 17, 2024

By: /s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer

Clinical Data on Salarius Pharmaceuticals' Seclidemstat in Patients with MDS and CMML Presented at the 2024 European Hematology Association Annual Meeting

Patients were treated in the dose-escalation portion of the Phase 1/2 study evaluating seclidemstat in combination with azacitidine

Investigators reported a 43% overall response rate among 14 predominantly higher risk myelodysplastic syndrome (MDS) and chronic myelomonocytic leukemia (CMML) patients who previously failed or relapsed after hypomethylating agent therapy

Median overall survival was 18.5 months (95% CI, range 6.1-30.9 months) with median event-free survival of 7.2 months (95% CI, range 6.3-8.2 months)

HOUSTON (June 17, 2024) – 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 investigators at the University of Texas MD Anderson Cancer Center's Leukemia department presented clinical data on seclidemstat in patients with MDS and CMML at the 2024 European Hematology Association (EHA) Hybrid Congress. The meeting was held in Madrid and virtually from June 13-16, 2024.

Seclidemstat is a novel oral, reversible, targeted LSD1 inhibitor. The poster was presented by Guillermo Montalban-Bravo, M.D. on June 14th, and is available on Salarius' website, in the Investors, Events and Presentations section.

The objective of this investigator-initiated Phase 1/2 dose-escalation study is to evaluate the safety, tolerability, maximum tolerated dose and overall response of seclidemstat in combination with azacitidine in adult patients with higher-risk MDS or CMML who previously failed or relapsed after hypomethylating agent therapy. As of May 2024, 16 patients were enrolled in this study with 14 patients evaluable for efficacy.

As presented at EHA, of the 14 evaluable patients for efficacy, 6 (43%) had an objective response including 1 complete response, 3 marrow complete responses, 1 marrow complete response plus hematological improvement and 1 hematologic improvement. The median overall survival was 18.5 months (95% CI, range 6.1-30.9 months), median event-free survival was 7.2 months (95% CI, range 6.3-8.2 months) and median follow-up time was 18.9 months (95% CI, range 0-48 months) from treatment initiation. As reported, overall survival after failing therapy with hypomethylating agents typically is 4-6 months.

15 patients were evaluable for toxicity, with a dose-limiting toxicity observed in 1 patient in the 750mg BID cohort. Per protocol, the cohort was expanded to 3 additional patients. Based upon reported data, Salarius believes adverse events observed were manageable.

The Phase 1 dose-escalation portion of this study will evaluate up to six dose levels of seclidemstat. Cohort 5 (dose level 750mg BID seclidemstat in combination with azacitidine) is currently enrolling and cohort 6, the final cohort, will receive 900mg BID seclidemstat in combination with azacitidine. The maximum tolerated dose, which will inform the Phase 2 portion of the study, has not yet been reached.

“We are encouraged by these promising results at this early stage of the study when seclidemstat is combined with azacitidine at doses below what we believe will be the recommended Phase 2 dose,” said William McVicar, Ph.D., Chairman of the Salarius Pharmaceuticals Board of Directors. “Patients who have failed prior treatments including hypomethylating agents have a poor prognosis and are in desperate need of new treatment options. With a 43% overall response rate, median overall survival of 18.5 months and median event-free survival of 7.2 months, we agree with the investigators that these results show promising early signs of activity in a high-risk MDS and CMML treatment failure population.”

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, its 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 being developed for the treatment of non-Hodgkin’s lymphoma. Salarius has received financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma 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.

In August 2023 Salarius announced a comprehensive review of strategic alternatives focused on maximizing shareholder value. While these efforts are ongoing, the Company continues to support its clinical programs, as appropriate, which includes the work being performed by the investigators at MD Anderson Cancer Center.

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 “will,” “believe,” “developing,” “expect,” “may,” “progress,” “potential,” “could,” “look forward,” “encouraging,” “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: Salarius’ expectations regarding the exploration of strategic alternatives, opportunities to extend Salarius’ resources, the Company’s expected cash runway, the Company’s expectations that the cost-savings measures will support the generation of additional data from the ongoing Phase 1/2 clinical trials in hematologic cancers and Ewing sarcoma; the future of the Company’s operations and product candidates; the future of the Company’s preclinical studies and clinical trials and development activities; the advantages of protein degraders including the value of SP-3164 as a cancer treatment; 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. Salarius may not actually achieve the plans, carry out the intentions or meet the expectations or objectives disclosed in these 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 risk that exploration of strategic alternatives may not result in any definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect our operating results, business, or investor perceptions; the potential for the Company to seek other alternatives for restructuring and resolving its liabilities, including bankruptcy proceedings, a dissolution and orderly wind-down of operations; expectations regarding future costs and expenses; our product candidates being in early stages of development; the uncertainty about the paths of our programs and our ability to evaluate and identify a path forward for those programs, particularly given the constraints we have as a small company with limited financial, personnel and other operating resources (including with respect to the allocation of our limited capital and the sufficiency of our capital in the near term for any path we do select); Salarius' ability to continue as a going concern; the sufficiency of Salarius' capital resources; availability of suitable third parties with which to conduct contemplated strategic transactions; whether the Company will be able to pursue a strategic transaction, or whether any transaction, if pursued, will be completed successfully and on attractive terms or at all; whether our cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital requirements; changes in the Company's operating plans that may impact its cash expenditures; the uncertainties inherent in research and development, future clinical data and analysis; the risks associated with reductions in workforce, including reduced morale and attrition of additional employees necessary for the strategic reprioritization; the risk of not having a full-time chief executive officer; future clinical trial results and the impact of such results on Salarius; that the results of studies and clinical trials may not be predictive of future clinical trial results; 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, 2023, 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 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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