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): July 11, 2023

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 July 11, 2023, Salarius Pharmaceuticals, Inc. (the "Company") issued a press release announcing U.S. Food and Drug Administration clearance of the Company's investigational new drug application to commence a Phase 1 clinical trial with SP-3164 in patients with relapsed/refractory non-Hodgkin lymphoma. A copy of the press release is filed as Exhibit 99.1 to this Form 8-K and 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 July 11, 2023
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: July 11, 2023 By: /s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer

Salarius Pharmaceuticals Receives FDA Clearance of SP-3164 Investigational New Drug Application to Begin a Phase 1 Clinical Trial in Relapsed/Refractory Non-Hodgkin Lymphoma Patients

The trial will assess the safety and preliminary efficacy of Salarius' novel targeted protein degrader SP-3164; Patient dosing expected to begin in 2H 2023

The trial will also assess the utility of a gene signature to identify patients that are potentially sensitized to SP-3164 treatment and may be more likely to respond

HOUSTON (July 11, 2023) – 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, announces U.S. Food and Drug Administration (FDA) clearance of the company's investigational new drug (IND) application to commence a Phase 1 clinical trial with SP-3164 in patients with relapsed/refractory non-Hodgkin lymphoma (NHL). Salarius expects to begin treating patients in the dose-escalation portion of the trial in the second half of 2023 to evaluate safety, clinical activity, pharmacokinetics and pharmacodynamics.

"FDA clearance of the SP-3164 IND marks another significant milestone for Salarius and demonstrates our continued focus and commitment to bringing new therapies to patients in need of new treatment options," said David Arthur, president and chief executive officer of Salarius, "We now plan to enroll NHL patients in the dose-escalation portion of the clinical trial and will then focus on patients with diffuse large B-cell lymphoma (DLBCL) in the second portion of the trial."

According to the American Cancer Society, NHL is one of the most common cancers in the U.S., accounting for about 4% of all cancers[1]. RareDiseaseAdvisor estimates that DLBCL is the most common type of NHL, accounting for approximately 31% of NHL cases in Western countries[2].

During the trial, Salarius will be assessing the applicability of the gene signature in predicting response to SP-3164. Previous research with similar agents indicates that patients with an identifiable gene signature may be more likely to respond to SP-3164 treatment. SP-3164 treatment.

Mr. Arthur continued, "More than 80,000 new cases of NHL are expected to be diagnosed in the U.S. in 2023, and even with advances in cancer treatments, more than 20,000 Americans are expected to die from NHL[1]. We believe SP-3164 may provide an additional treatment option for many of these patients.

"First generation targeted protein degraders (TPD) have generated a great deal of enthusiasm within the pharmaceutical and medical communities, with first-generation TPD's such as Revlimid® and Pomalyst® together generating more than $16 billion in 2021 sales. We believe SP-3164, a next generation TPD, can build upon the success of the first-generation TPDs," Mr. Arthur concluded.

About SP-3164

SP-3164 is an oral, next-generation molecular glue that uses Salarius' deuterium-enabled chiral switching platform to stabilize the preferred (*S*)-enantiomer of avadomide, an extensively studied clinical compound that has demonstrated encouraging single-agent and combination-therapy clinical efficacy in

[1] https://www.cancer.org/cancer/types/non-hodgkin-lymphoma/about/key-statistics.html#:~:text=Non%2DHodgkin%20lymphoma%20(NHL),will%20be%20diagnosed%20with%20NH
[2] https://www.rarediseaseadvisor.com/disease-info-pages/diffuse-large-b-cell-lymphoma-epidemiology/#:~:text=For%20DLBCL%20specifically%2C%20the%20estimated,year%20in%20the%20United%20States

NHL and other hematologic malignancies. The addition of deuterium at the chiral center of the molecule prevents conversion to the unwanted *(R)*-enantiomer, allowing for isolation and development of the preferred (*S*)-enantiomer into a potential new cancer treatment.

As such, SP-3164 is a new chemical entity and has been issued a composition-of-matter patent in the U.S. and select countries around the world. Data presented in December 2022 at the American Society for Hematology Annual Meeting showed compelling SP-3164 activity in lymphoma models and supports SP-3164's potential for the Phase 1 clinical trial in NHL planned to initiate in 2H 2023. Additional supporting data were presented in April 2023 at the American Association for Cancer Research Annual Meeting showing SP-3164 demonstrates compelling antitumor activity in animal models of follicular lymphoma and multiple myeloma. Most recently, Salarius presented new data at the European Hematology Association Hybrid Conference in Frankfurt, Germany (June 2023) showing SP-3164 induces more degradation of cancer-promoting proteins than the standard-of-care agent lenalidomide (Revlimid®).

About Salarius Pharmaceuticals

Salarius Pharmaceuticals 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 that is being developed as a treatment for non-Hodgkin lymphoma.

Seclidemstat has received fast track, orphan drug and rare pediatric disease designations for Ewing sarcoma from the FDA and is currently in a Phase 1/2 clinical trial for relapsed/refractory Ewing sarcoma. Salarius is also exploring seclidemstat's potential in several cancers with high unmet medical need, with an investigator-initiated Phase 1/2 clinical trial in hematologic cancers at MD Anderson Cancer Center. 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).

Forward-Looking Statements

This press release and the referenced presentations 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 press release and the referenced presentations are forward-looking statements. These forward-looking statements may be identified by terms such as "will," "believe," "developing," "expect," "excited," "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: the future of the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas; the advantages of protein degraders including the value of SP-3164 as a cancer treatment; the timing of enrollment in clinical trials for SP-3164 and expected therapeutic options for SP-3164 and related effects and projected efficacy; the impact that the addition of new clinical sites will have on the development of Salarius' product candidates; 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: Salarius' ability to continue as a going concern; 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 the impact of such 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, 2022, 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 and the referenced presentations speak only as of the date of this press release and the referenced presentations 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.

CONTACT:

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

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