

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): January 5, 2023

SALARIUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36812

(Commission File Number)

46-5087339

(IRS Employer Identification Number)

2450 Holcombe Blvd.
Suite X
Houston, TX

(Address of principal executive offices)

77021

(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 January 5, 2023, Salarius Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that, on December 27, 2022, the U.S. Patent and Trademark Office issued U.S. Patent No. 11,535,603, titled “Deuterium-enriched Piperidinonyl-oxoisoindolinyl Acetamides and Methods of Treating Medical Disorders Using Same.” The issued claims cover the composition of matter for novel molecular glue degraders including the Company’s preclinical cereblon-binding compound, SP-3204, through September 2037. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Salarius Pharmaceuticals, Inc., dated January 5, 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: January 5, 2023

By:

/s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer



Salariaus Pharmaceuticals Announces Issuance of New U.S. Patent for Next-Generation Targeted Protein Degraders

Expands intellectual property portfolio with composition-of-matter patent protection for second novel molecular glue

Protein degrader intellectual property portfolio now includes 16 issued patents across six unique patent families

HOUSTON (January 5, 2023) – Salariaus 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 that on December 27, 2022 the U.S. Patent and Trademark Office (USPTO) issued U.S. Patent No. 11,535,603, titled “Deuterium-enriched Piperidinonyl-oxoisindolinyl Acetamides and Methods of Treating Medical Disorders Using Same.” The issued claims cover the composition of matter for novel molecular glue degraders including Salariaus’ preclinical cereblon-binding compound, SP-3204, through September 2037.

Targeted protein degradation (TPD) takes advantage of the body’s own degradation system to promote the selective elimination of disease-causing proteins. The newly issued patent is based on the molecular glue eragidomide (CC-90009) that is known to target the degradation of GSPT1, a protein that is highly expressed in numerous cancers, including hematologic and solid tumors.

David Arthur, President and CEO of Salariaus, said, “We are delighted to continue building our TPD portfolio using our deuterium-enabled chiral switching platform to identify and develop potential new therapeutics. SP-3204 is our second novel molecular glue following SP-3164, our lead molecular glue that is expected to enter the clinic later this year. We believe it is important to protect and expand our intellectual property as we advance new drug candidates, and we intend to continue seeking patent protection as our research advances. I extend congratulations to the Salariaus team on this important validation of their accomplishments by the USPTO.”

About Salariaus Pharmaceuticals

Salariaus Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing therapies for patients with cancer in need of new treatment options. Salariaus’ 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 molecular glue 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. This trial is currently on a partial clinical hold and is not enrolling new patients. Seclidemstat has received fast track, orphan drug and rare pediatric disease designations for Ewing sarcoma from the U.S. Food and Drug Administration. Salariaus 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. This trial is currently on a voluntary pause and is not enrolling new patients. Salariaus 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 salariauspharma.com or follow Salariaus 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,” “may,” “progress,” “potential,” “could,” “look forward,” “encouraged,” “hopeful,” “promising,” “anticipate,” “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 advantages of seclidemstat (SP-2577) as a treatment for Ewing sarcoma, Ewing-related sarcomas, and other cancers and its ability to improve the life of patients; expected cohort readouts from the company’s clinical trials and expected therapeutic options for SP-2577 and related effects and projected efficacy, including SP-2577’s ability to inhibit LSD1; the future of the company’s Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas following the recently announced suspected unexpected severe adverse reaction (SUSAR) event and resulting partial clinical hold by the U.S. Food and Drug Administration (FDA); the advantages of protein degraders including the value of SP-3164 as a cancer treatment; the timing of 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 our product candidates; the timing of our IND submissions to the FDA and subsequent timing for initiating clinical trials; interim data related to our clinical trials, including the timing of when such data is available and made public; our growth strategy; whether the company will develop additional undisclosed cancer-fighting assets in the targeted protein degradation space; expanding the scope of our research and focus to high unmet need patient populations; and the commercial or market opportunity and expansion for each therapeutic option, including the availability and value of a pediatric priority review voucher for in-clinic treatments and potential for accelerated approval. 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: Seclidemstat’s impact in Ewing sarcoma and as a potential new and less-toxic treatment; expected dose escalation and dose expansion; 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; the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials and regulatory submissions; the ability of, and need for, us to raise additional capital to meet our business operational needs and to achieve its business objectives and strategy; future clinical trial results and the impact of such results on us; 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 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

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