

# 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): August 10, 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) 834-9144

(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 2.02 Results of Operations and Financial Condition.**

On August 10, 2023, Salius Pharmaceuticals, Inc. (the “Company”) reported financial results for the three and six months ended June 30, 2023 and other recent corporate updates. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Current Report on 8-K (including Exhibit 99.1 hereto) is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today’s date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits.****Exhibit  
Number****Description**

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99.1	<a href="#">Press Release Announcing Financial Results, dated August 10, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: August 10, 2023

**SALARIUS PHARMACEUTICALS, INC.**

By:

/s/ Mark J. Rosenblum

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Mark J. Rosenblum  
Executive Vice President of Finance and  
Chief Financial Officer

## Salarius Pharmaceuticals Reports Second Quarter 2023 Financial Results and Provides a Business Update

*FDA removed partial clinical hold for Ewing sarcoma Phase 1/2 study with seclidemstat*

*SP-3164 targeted protein degrader received Investigational New Drug clearance from FDA*

*Company to explore strategic alternatives and implement measures to extend its resources*

**HOUSTON (August 10, 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, today reported financial results for the three and six months ended June 30, 2023 and provided a business update.

### Financial and Business Highlights

- Cash and cash equivalents were \$11.5 million as of June 30, 2023, compared with \$12.1 million as of December 31, 2022
- Net loss for the second quarter of 2023 was \$3.9 million, or \$1.43 per share, compared with net loss for the second quarter of 2022 of \$4.7 million, or \$2.20 per share, reflecting lower spending on seclidemstat and lower general and administrative expenses
- Raised gross proceeds of \$6.0 million from a private placement of common stock and warrants, and an additional \$1.7 million from an At the Market facility
- Announced plans to explore strategic alternatives and implement measures to extend resources

“While the second quarter and recent weeks were highlighted by significant advancements in both of our development programs, after a review of each program’s future funding needs and the current financial markets, the Board of Directors has made the difficult decision to limit further drug development while we explore strategic alternatives for Salarius,” said David Arthur, president and chief executive officer of Salarius Pharmaceuticals.

“It was an exceptionally difficult decision to initiate our cost-savings plans and explore strategic alternatives in light of the promising early seclidemstat Ewing sarcoma clinical data, seclidemstat hematological clinical data and the recent FDA clearance to begin the SP-3164 Phase 1 trial. Unfortunately, we believe the current public financial markets make it extremely challenging to raise sufficient capital to continue meaningful clinical development activities on our own,” concluded Mr. Arthur.

The Company is conducting a comprehensive review of strategic alternatives focused on maximizing shareholder value including, but not limited to, an acquisition, merger, reverse merger, divestiture of assets, licensing or other strategic transactions involving the Company. However, there is no set timetable for this process and there can be no assurance that this process will result in the Company pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. If the Company is unable to complete a transaction it may be necessary to seek other alternatives for restructuring and resolving its liabilities, including an orderly wind-down. Salarius does not expect to disclose developments with respect to this process unless and until the evaluation of strategic alternatives has been completed or the Board of Directors has concluded that disclosure is appropriate or legally required.

In connection with the evaluation of strategic alternatives and in order to extend its resources, Salarius is implementing a cost-savings plan that includes a reduction in workforce by over 50% of its positions, with remaining employees focusing primarily on limited drug-development activities, completing the U.S. Food and Drug Administration (FDA) process to determine the clinical trial registration

requirements for the seclidemstat Ewing sarcoma program and supporting the exploration of strategic alternatives.

### **Second Quarter Financial Results**

Research and development expenses declined to \$2.4 million for the second quarter of 2023 from \$2.9 million for the second quarter of 2022, primarily due to lower spending on seclidemstat offset by higher spending on SP-3164. Spending associated with seclidemstat and SP-3164 for the second quarter of 2023 was \$1.1 million and \$1.3 million, respectively, compared with \$2.1 million and \$0.8 million, respectively, for the second quarter of 2022. General and administrative expenses were \$1.6 million for the second quarter of 2023, compared with \$1.8 million for the second quarter of 2022, with the decline due to lower annual shareholder meeting expenses and overall compensation and benefit costs.

### **Year-to-Date Financial Results**

Research and development expenses declined to \$6.1 million for the first half of 2023 from \$7.4 million for the prior-year period, primarily due to lower spending on seclidemstat offset by higher spending on SP-3164. Spending associated with seclidemstat and SP-3164 for the first half of 2023 was \$2.4 million and \$3.7 million, respectively, compared with \$4.4 million and \$3.0 million, respectively, for the prior-year period.

Net cash used for operating activities during the first half of 2023 was \$7.6 million, an increase of \$0.4 million from the same period a year ago. The increase is primarily due to a decrease in accounts payable.

As of June 30, 2023, Salarius had cash, cash equivalents and restricted cash of \$11.5 million, compared with \$12.1 million as of December 31, 2022. Current cash and cash equivalents are expected to fund the company's planned operations through the fourth quarter of 2023 and enable the evaluation and implementation of strategic alternatives.

### **Seclidemstat Highlights**

- The FDA removed its partial clinical hold on Salarius' Phase 1/2 trial evaluating seclidemstat in combination with topotecan and cyclophosphamide as a potential treatment for patients with Ewing sarcoma
- The Company initiated the process with the FDA to determine the clinical trial registration requirements for the seclidemstat Ewing sarcoma program
- Previously reported interim data showed a 60% confirmed disease control rate and 7.4 months median time to tumor progression for first-relapse Ewing sarcoma patients, with no disease progression observed in either first- or second-relapse patients who achieved confirmed disease control
- The Company continues to monitor patients in the Ewing sarcoma trial and plans to release updated survival data in the coming months
- The FDA previously granted seclidemstat Fast Track, Orphan Drug and Rare Pediatric Disease designations for Ewing sarcoma
- University of Texas MD Anderson Cancer Center (MDACC) is working to restart their investigator initiated Phase 1/2 study with seclidemstat in combination with azacytidine in patients with myelodysplastic syndrome (MDS) and chronic myelomonocytic leukemia (CMML)
- Researchers at MDACC previously reported interim clinical trial results in patients who relapsed or progressed after hypomethylating agent therapy. Of eight evaluable patients, four (50%) had an objective response. These researchers reported a 90% probability of patient survival for 11 months in patients receiving seclidemstat plus azacitidine versus an expected survival of four to six months

### **SP-3164 Highlights**

- On July 11, 2023 Salarius announced that the FDA had cleared the IND application to treat relapsed/refractory non-Hodgkin lymphoma patients with SP-3164.
- Presented NHL preclinical data at the European Hematology Association 2023 Hybrid Congress in June that showed:
  - Potent degradation of Ikaros and Aiolos (I/A) in peripheral blood mononuclear cells (PBMC) within 2 hours of dosing, which increased in a dose- and time-dependent manner over 24 hours
  - SP-3164 does not negatively impact PBMC at clinically relevant concentrations up to 96 hours post-treatment
  - In addition to having direct antitumor effects, SP-3164 also induces an anticancer immunomodulatory effect as demonstrated through the induction of cytokine secretion in human T cells following treatment
- Presented two abstracts at the AACR Annual Meeting in April:
  - One presentation demonstrated the robust protein degradation effects of SP-3164 and its anticancer activity in NHL animal models as well as SP-3164's compelling antitumor activity in animal models of follicular lymphoma, a type of NHL, as a single agent and in combination with venetoclax (Venclexta®) or tazemetostat (Tazverik®)
  - The other presentation demonstrated SP-3164's compelling anticancer activity in cell lines and animal models of multiple myeloma. In animal models, SP-3164 demonstrated superior single-agent activity compared with the approved agents lenalidomide (Revlimid®) and pomalidomide (Pomalyst®), and the combination of SP-3164 and bortezomib (Velcade®) was shown to be superior to the combination of pomalidomide and bortezomib.

### **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, an oral novel small molecule inhibitor of the LSD1 enzyme and Salarius' 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 program and was a recipient of a Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT).

Seclidemstat has received fast track, orphan drug and rare pediatric disease designations for Ewing sarcoma from the U.S. Food and Drug Administration 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 study in hematologic cancers at MD Anderson Cancer Center.

The SP-3164 Investigational New Drug (IND) application was cleared by the U.S. Food and Drug Administration (FDA) allowing a phase 1 safety clinical trial to begin. The phase 1 trial is also designed to assess the utility of a gene signature to identify patients who are potentially sensitized to SP-3164 and may be more likely to respond. For more information, please visit [salariuspharma.com](http://salariuspharma.com) or follow Salarius on Twitter and LinkedIn.

### **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 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 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 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; 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; 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 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.

**Contact:**

**LHA Investor Relations**  
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(Tables to follow)

**SALARIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>6/30/2023</u>	<u>12/31/2022</u>
	<u>(Unaudited)</u>	<u>(Audited)</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 11,541,443	\$ 12,106,435
Grants receivable from CPRIT	130,000	1,610,490
Prepaid expenses and other current assets	284,807	803,373
Total current assets	11,956,250	14,520,298
Other assets	99,048	130,501
<b>Total assets</b>	<b>\$ 12,055,298</b>	<b>\$ 14,650,799</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,287,243	\$ 2,858,330
Accrued expenses and other current liabilities	1,354,253	1,407,861
Total liabilities	3,641,496	4,266,191
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; 0 issued and outstanding	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 3,352,069 and 2,255,899 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	335	225
Additional paid-in capital	81,436,696	74,189,531
Accumulated deficit	(73,023,229)	(63,805,148)
Total stockholders' equity	8,413,802	10,384,608
<b>Total liabilities and stockholders' equity</b>	<b>\$ 12,055,298</b>	<b>\$ 14,650,799</b>



**SALARIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30		June 30	
	2023	2022	2023	2022
Operating expenses:				
Research and development	2,351,852	2,921,572	6,077,440	7,361,047
General and administrative	1,619,543	1,836,395	3,314,618	3,514,149
<b>Total operating expenses</b>	<b>3,971,395</b>	<b>4,757,967</b>	<b>9,392,058</b>	<b>10,875,196</b>
Loss before other income (expense)	(3,971,395)	(4,757,967)	(9,392,058)	(10,875,196)
Interest income, net and other	94,087	39,629	173,977	47,633
Loss from continuing operations	<b>(3,877,308)</b>	<b>(4,718,338)</b>	<b>(9,218,081)</b>	<b>(10,827,563)</b>
<b>Net loss</b>	<b>\$ (3,877,308)</b>	<b>\$ (4,718,338)</b>	<b>\$ (9,218,081)</b>	<b>\$ (10,827,563)</b>
<b>Loss per common share — basic and diluted</b>	<b>\$ (1.43)</b>	<b>\$ (2.20)</b>	<b>\$ (3.45)</b>	<b>\$ (5.42)</b>
Weighted-average number of common shares outstanding — basic and diluted	2,709,104	2,140,899	2,671,148	1,996,357

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