

---

**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): **May 12, 2021**

---

**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 No.)

**2450 Holcombe Blvd., Suite X, Houston, Texas 77021**  
(Address of principal executive offices, with 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 Instructions 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 May 12, 2021, Salarius Pharmaceuticals, Inc. (the “Company”) reported financial results for the three months ended March 31, 2021 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**

99.1

---

[Press Release Announcing Financial Results, dated May 12, 2021.](#)

**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: May 12, 2021

**SALARIUS PHARMACEUTICALS, INC.**

By:

/s/ David J. Arthur

\_\_\_\_\_  
David J. Arthur  
President and Chief Executive Office

## **Salius Pharmaceuticals Reports First Quarter Financial Results with Business Highlights**

*Cash and Cash Equivalents of \$36.6M, More Than Sufficient to Fund Completion of the Current Clinical Trials of Lead Drug Candidate, Seclidemstat*

*Conference Call and Live Audio Webcast Scheduled for Today, Wednesday, May 12, 2021, 5:00 p.m. ET*

HOUSTON, May 12, 2021 (GLOBE NEWSWIRE) – Salius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biopharmaceutical company developing potential new medicines for patients with pediatric cancers, solid tumors, and other cancers, today reported important corporate events and its financial results for the first quarter ended March 31, 2021.

### **Financial Highlights:**

- Total cash and cash equivalents of \$36.6 million as of March 31, 2021 resulting from financing activities including \$23.0 million gross proceeds in an underwritten public offering closed March 8, 2021; Cash position sufficient to fund the current seclidemstat clinical trials through completion
- Three-month period ended March 31, 2021 net loss per common share – basic and diluted - of \$0.06, compared to \$0.22 for the same period ended March 31, 2020

“The first quarter of 2021 and recent months were a period of significant activity for Salius, with the company accomplishing several key milestones, including strengthening our capital position with more than \$30 million gross proceeds raised during the quarter, the completion of the dose-escalation stage of the Phase 1/2 trial of seclidemstat in Ewing sarcoma, and the initiation of the dose-expansion stage of the trial, which now also includes FET-rearranged sarcomas, also known as Ewing-related sarcomas which share biology similar to Ewing sarcoma,” said David Arthur, President and CEO of Salius. “As a result, Salius is operating from a position of strength as we work to advance our clinical trials exploring seclidemstat as a potential treatment for Ewing sarcoma, select FET-rearranged sarcomas, advanced solid tumors and hematologic cancers. By mid-year 2021, we expect up to three total active clinical trials in up to five patient populations evaluating single-agent seclidemstat and up to three combination therapies.”

### **Recent Business and Corporate Events:**

- Completion of dose escalation in Phase 1/2 Ewing sarcoma clinical trial determined seclidemstat's safety profile and established recommended Phase 2 dose (RP2D)
  - A refractory Ewing sarcoma patient treated with single-agent seclidemstat for 168 days (six 28-day cycles) demonstrated preliminary signal of drug activity
  - Full findings from dose escalation to be disclosed in poster presentation session followed by a poster discussion during the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting; one of three abstracts accepted for poster presentation during the ASCO Annual Meeting

- Preliminary efficacy from an ongoing Phase 1 dose-escalation trial of seclidemstat in patients with advanced solid tumors (AST) supports inclusion of FET-rearranged sarcomas in Ewing sarcoma trial
  - Subset of FET-rearranged sarcoma patients treated with seclidemstat in the AST clinical trial demonstrated encouraging signs of drug activity
  - Preliminary efficacy findings from the dose-escalation stage of AST trial to be reported in a poster session during 2021 ASCO Annual Meeting
- Dose expansion initiated; actively recruiting three patient groups across Ewing sarcoma and FET-rearranged sarcomas; data expected in 2022
  - Ewing sarcoma patients to be treated with seclidemstat in combination with topotecan and cyclophosphamide as a second- or third-line therapy
  - FET-rearranged sarcoma patients, including myxoid liposarcoma, to be treated with single-agent seclidemstat as second-, third- or fourth-line therapy

Mr. Arthur continued, "With initiation of the dose-expansion stage of the trial in Ewing and FET-rearranged sarcomas, we have positioned seclidemstat as a second- and third-line Ewing sarcoma therapy in combination with a common chemotherapy treatment. This increases the number of available patients and should make it easier for physicians to treat patients earlier in the continuum of patient care. Expanding the trial to include myxoid liposarcoma and other FET-rearranged sarcoma patients provides a potential new therapy for patients who are relapsed or refractory to standard of care treatment. Our goal is to make a difference in the lives of patients fighting cancer, and we believe making seclidemstat available to these patients is a step forward in this journey. In the coming months, we look forward to announcing new clinical trials studying seclidemstat in additional patient populations."

#### **Three-Month Financial Results:**

For the three-month period ended March 31, 2021, Salariaus' reported net loss was \$1.9 million, or \$0.06 per basic and diluted share, compared to a net loss of \$2.1 million, or \$0.22 per basic and diluted share for the same period in 2020. The loss before other income for the three-month period ended March 31, 2021 decreased by \$0.6 million compared to the loss before other income for the same time span last year, primarily due to lower general and administrative costs that more than offset an increase in research and development costs.

Net cash used for operating activities during the three-month period ended March 31, 2021 totaled \$2.7 million, a decline of approximately \$1.0 million compared to the same span last year due to a \$0.9 million payment received under the Company's contract with the Cancer Prevention and Research Institute of Texas (CPRIT).

#### **Conference Call Information:**

Salariaus Pharmaceuticals will host a conference call and live audio webcast on Wednesday, May 12, 2021, at 5:00 p.m. ET, to discuss its corporate and financial results for the first quarter 2021. Interested participants and investors may access the conference call by dialing either:

- (833) 423-0481 (U.S.)
- (918) 922-2375 (international)
- Conference ID: 9062629

An audio webcast will be accessible via the Investors Events and Presentations section of the Company's website <http://investors.salariuspharma.com/>. An archive of the webcast will remain available for 90 days beginning at approximately 5:30 p.m. ET, on May 12, 2021.

### **About Salarius Pharmaceuticals**

Salarius Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing cancer therapies for patients in need of new treatment options. Salarius' lead candidate, seclidemstat, is being studied as a potential treatment for pediatric cancers, solid tumors and other cancers with limited treatment options. Seclidemstat is currently in a Phase 1/2 clinical trial for relapsed/refractory Ewing sarcoma and select additional sarcomas that share a similar biology to Ewing sarcoma, also referred to as Ewing-related or FET-rearranged sarcomas. Seclidemstat has received Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation for Ewing sarcoma from the U.S. Food and Drug Administration. Salarius is also developing seclidemstat for several cancers with high unmet medical need, with a second Phase 1/2 clinical study in advanced solid tumors, including prostate, breast, and ovarian cancers. Salarius has received financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma clinical program and was also a recipient of a Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). 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 "anticipate," "potential," "progress," "design," "estimate," "continue," "will," "aim," "can," "believe," "plan," "allow," "expect," "intend," "goal," "provide," "able to," "position," "look forward to," "project," "developing," 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 company's growth strategy; the value of seclidemstat as a potential treatment for Ewing sarcoma, Ewing-related sarcomas and other cancers; the status and anticipated progress and milestones of the company's clinical trials in Advanced Solid Tumors and Ewing sarcoma; the expansion of the company's clinical trials to include Ewing-related sarcomas; the company's belief as to being well-capitalized through the completion of its clinical trials for seclidemstat and beyond; the number of active clinical trials and timing related thereto; the announcement of new clinical trials; Salarius' ability to maximize the potential of seclidemstat including the number of possible patients that could benefit from seclidemstat; and the development of seclidemstat for several cancers with high unmet medical need. 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 sufficiency of the company's capital resources; the ability of, and need for, the company to raise additional capital to meet the company's business operational needs and to achieve its business objectives and strategy; the company's ability to project future capital needs and cash utilization and timing and accuracy thereof; the ability of the company to access the remaining funding available under the CPRIT grant; future clinical trial results and impact of results on the company; that the results of studies and clinical trials may not be predictive of future clinical trial results; the sufficiency of Salarius' intellectual property protection; risks related to the drug development and the regulatory approval process; the competitive landscape and other industry-related risks; market conditions and regulatory or contractual restrictions which may impact the ability

of Salius to raise additional capital; the possibility of unexpected expenses or other uses of Salius' cash resources; risks related to the COVID-19 outbreak; and other risks described in Salius' filings with the Securities and Exchange Commission, including those discussed in the company's quarterly report on Form 10-Q for the quarter ended March 31, 2021 and in the company's annual report on Form 10-K for the year ended December 31, 2021. 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. Salius 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**

Tiberend Strategic Advisors, Inc.

Maureen McEnroe, CFA/Miriam Miller (investors)

(212) 375-2664 / 2694

[mmcenroe@tiberend.com](mailto:mmcenroe@tiberend.com)

[mmiller@tiberend.com](mailto:mmiller@tiberend.com)

Johanna Bennett (media relations)

(212) 375-2686

[jbennett@tiberend.com](mailto:jbennett@tiberend.com)

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

	<u>3/31/2021</u>	<u>12/31/2020</u>
	<b>(Unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 36,612,288	\$ 11,118,614
Grants receivable from CPRIT	4,223,532	3,855,996
Prepaid expenses and other current assets	814,816	822,050
Total current assets	41,650,636	15,796,660
Property and equipment, net	18,950	22,639
Goodwill	8,865,909	8,865,909
Other assets	232,027	247,113
Total assets	<u>\$ 50,767,522</u>	<u>\$ 24,932,321</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,573,961	\$ 1,853,756
Accrued expenses and other current liabilities	118,858	383,138
Note payable	191,395	477,028
Warrant liability	105,265	59,211
Total liabilities	1,989,479	2,773,133
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; 44,734,328 and 23,810,541 shares issued at March 31, 2021 and December 31, 2020, and 44,734,328 and 23,808,546 shares outstanding at March 31, 2021 and December 31, 2020, respectively	4,473	2,381
Additional paid-in capital	70,054,420	41,585,761
Accumulated deficit	(21,280,850)	(19,428,954)
Total stockholders' equity	48,778,043	22,159,188
Total liabilities and stockholders' equity	<u>\$ 50,767,522</u>	<u>\$ 24,932,321</u>



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

	Three Months Ended March 31	
	2021	2020
Revenue:		
Grant revenue	\$ 1,268,829	\$ 1,132,830
Operating expenses:		
Research and development	1,740,655	1,643,371
General and administrative	1,332,769	1,859,017
Total operating expenses	3,073,424	3,502,388
Loss before other income (expense)	(1,804,595)	(2,369,558)
Change in fair value of warrant liability	(46,054)	283,070
Interest income (expense), net	(1,247)	2,672
Loss from continuing operations	<b>(1,851,896)</b>	<b>(2,083,816)</b>
<b>Net loss</b>	<b>\$ (1,851,896)</b>	<b>\$ (2,083,816)</b>
<b>Loss per common share — basic and diluted</b>	<b>\$ (0.06)</b>	<b>\$ (0.22)</b>
Weighted-average number of common shares outstanding — basic and diluted	30,551,316	9,534,842