

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 5, 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 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 2.02 Results of Operations and Financial Condition.

On August 5, 2021, Salarius Pharmaceuticals, Inc. (the “Company”) reported financial results for the three and six months ended June 30, 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) 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 No.	Description
99.1	<u>Press Release Announcing Financial Results, dated August 5, 2021</u>

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 5, 2021

SALARIUS PHARMACEUTICALS, INC.

By: /s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer

Salarius Pharmaceuticals Reports Second Quarter 2021 Financial Results and Highlights Recent Company Progress

Clinical Trial in Hematologic Cancers Initiated and Initial Patients Enrolled in Expanded Sarcoma Clinical Trial; Multiple Potential Data Readouts Expected in 2021 and 2022

Preliminary Efficacy Findings from Sarcoma and Advanced Solid Tumor Trials Presented at American Society of Clinical Oncology

Cash and Cash Equivalents of \$33.1 Million, Sufficient to Fund Completion of Ongoing Clinical Trials for Lead Drug Candidate Seclidemstat

Conference Call and Live Audio Webcast Scheduled for Today, August 5, 2021, 10:00 a.m. ET

HOUSTON, August 5, 2021 (GLOBE NEWSWIRE) – Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biopharmaceutical company developing potential new medicines for patients with sarcomas, pediatric cancers, and other hematologic and solid cancers, today reported important corporate events and its financial results for the second quarter ended June 30, 2021.

“The second quarter and recent weeks have continued a period of substantial development for Salarius, highlighted by significant progress in our clinical programs leading to multiple data readouts in 2021 and 2022. Importantly, we ended the quarter with \$33.1 million in cash and cash equivalents which, based on our current operating plan, we believe is sufficient to support the achievement of these readouts,” stated David Arthur, Chief Executive Officer of Salarius Pharmaceuticals.

Mr. Arthur continued, “We have added the Fox Chase Cancer Center as our ninth sarcoma clinical trial site and are now actively recruiting and treating patients with seclidemstat in clinical trials across five patient groups, three in high unmet need sarcomas and two in high unmet need hematologic cancers. In addition, the data unveiled during ASCO 2021 demonstrated exactly what we wanted to see, and our Ewing sarcoma program is now providing the opportunity to explore seclidemstat in combination with chemotherapy agents where synergistic drug activity has been demonstrated. This combination with a commonly used second- or third-line chemotherapy, offers the opportunity for introducing seclidemstat earlier in the treatment continuum while improving patient outcomes and achieving objective responses. In the near future, we plan to initiate additional clinical programs in cancer indications where LSD1 overexpression is known to be a factor. In summary, we are pleased with how Salarius is positioned for the second half of 2021 and beyond.”

Recent Business and Corporate Highlights:

- MD Anderson Cancer Center in Houston, TX activated and is enrolling patients in an investigator-initiated trial in hematologic cancers, a Phase 1/2 study to determine safety, tolerability, maximum tolerated dose and overall response rate of seclidemstat in combination with azacytidine as a treatment for Myelodysplastic Syndromes (MDS) and Chronic Myelomonocytic Leukemia (CMML).

- In roughly 1 in 3 patients, MDS or CMML can progress to a rapidly growing cancer of bone marrow cells called Acute Myeloid Leukemia (AML) which the American Cancer Association estimates had more than 19,000 new cases diagnosed in the U.S. in 2020.
- Fox Chase Cancer Center in Philadelphia, Pennsylvania added as an active clinical trial site in the ongoing dose-expansion stage of the Phase 1/2 sarcoma trial.
 - Nine sites now actively recruiting for three patient groups across Ewing sarcoma and FET-rearranged sarcomas.
 - Initial patients enrolled across both Ewing sarcoma and FET-rearranged sarcoma cohorts.
- Investor event showcased key opinion leaders (KOLs) in cancer research that we believe supports LSD1 inhibition and the potential of seclidemstat as a differentiated treatment for Ewing sarcoma, FET-rearranged sarcomas, and hematologic or blood cancers.
- Clinical trial data presented at ASCO showed seclidemstat has a manageable safety profile, has favorable pharmacokinetics that support twice-daily oral dosing, and established recommended Phase 2 dose at 900 mg BID.
 - Evidence of preliminary anti-tumor activity in advanced, heavily pre-treated patient populations.
 - Data supports continued exploration of seclidemstat in both Ewing sarcoma and FET-rearranged sarcomas.

Financial Highlights:

- Three-month period ended June 30, 2021, net loss per common share – basic and diluted – for continuing operations of \$0.07, compared to \$0.13 for the same period last year.
- Total working capital of \$36.8 million as of June 30, 2021

Mr. Arthur concluded, “Key opinion leaders in cancer research recently noted that seclidemstat specifically inhibits the scaffolding properties of LSD1. This capability could prove effective against a broad range of cancers, including solid tumors, potentially further differentiating seclidemstat from other LSD1 inhibitors. Our ultimate aim as a company is to maximize the potential of seclidemstat as a treatment for cancer and we look forward to expanding the scope of our research into additional high unmet need patient populations. We are looking forward to updating investors and patients throughout 2021 and beyond.”

Three-Month Financial Results:

For the three-month period ended June 30, 2021, Salarius’ reported net loss was \$3.1 million, or \$0.07 per basic and diluted share, compared to a net loss of \$1.8 million, or \$0.13 per basic and diluted share for the same period in 2020. The loss before other income for the three-month period ended June 30, 2021, increased by \$1.2 million compared to the loss before other income for the same time span last year, primarily due to lower grant revenue and overall higher operating expenses.

Net cash used for operating activities during the three-month period ended June 30, 2021 totaled \$3.2 million, an increase of approximately \$0.7 million compared to the same span last year due to higher overall spending during the second quarter 2021.

Conference Call Information:

Salarius Pharmaceuticals will host a conference call and live audio webcast on Thursday, August 5, 2021, at 10:00 a.m. ET, to discuss its corporate and financial results for the second 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: 8985036

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 11:00 a.m. ET, on August 5, 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, sarcomas, 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 exploring seclidemstat's potential in several cancers with high unmet medical need, with a second Phase 1/2 clinical study in hematologic 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 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 "aim," "believe," "can," "continue," "developing," "estimate," "expect," "look forward to," "opportunity," "potential," "progress," "could prove," "plan," "position," "will," 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 an alternative treatment for Ewing sarcoma, Ewing-related sarcomas and other cancers; the effectiveness of seclidemstat when compared to other LSD1 inhibitors; expanding the scope of the Company's research and focus to high unmet need patient populations; the status and anticipated progress and milestones of the company's clinical trials; initiating additional clinical programs in new indications; 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 use of seclidemstat in combination with chemotherapy agents; introducing seclidemstat earlier in the treatment continuum to improve patient outcomes;. 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 Salarius to raise additional capital; the possibility of unexpected expenses or other uses of Salarius' cash resources; risks related to the COVID-19 outbreak; and other risks described in Salarius' 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. 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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**SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS**

	<u>6/30/2021</u> (Unaudited)	<u>12/31/2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 33,079,389	\$ 11,118,614
Grants receivable from CPRIT	4,794,919	3,855,996
Prepaid expenses and other current assets	432,502	822,050
Total current assets	<u>38,306,810</u>	<u>15,796,660</u>
Property and equipment, net	15,260	22,639
Other assets	216,786	247,113
Goodwill	8,865,909	8,865,909
Total assets	<u>\$ 47,404,765</u>	<u>\$ 24,932,321</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,275,879	\$ 1,853,756
Accrued expenses and other current liabilities	214,677	383,138
Note payable	—	477,028
Warrant liability	63,079	59,211
Total liabilities	<u>1,553,635</u>	<u>2,773,133</u>
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; 44,778,794 and 23,810,541 shares issued at June 30, 2021 and December 31, 2020, and 44,778,794 and 23,808,546 shares outstanding at June 30, 2021 and December 31, 2020, respectively	4,477	2,381
Additional paid-in capital	70,201,872	41,585,761
Accumulated deficit	(24,355,219)	(19,428,954)
Total stockholders' equity	<u>45,851,130</u>	<u>22,159,188</u>
Total liabilities and stockholders' equity	<u>\$ 47,404,765</u>	<u>\$ 24,932,321</u>

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

	Three Months Ended June 30	
	2021	2020
Revenue:		
Grant revenue	\$ 571,387	\$ 1,243,310
Operating expenses:		
Research and development	2,096,302	1,443,322
General and administrative	1,591,905	1,700,942
Total operating expenses	3,688,207	3,144,264
Loss before other income (expense)	(3,116,820)	(1,900,954)
Change in fair value of warrant liability	42,186	(62,635)
Government grants and other income	—	179,027
Interest income (expense), net	265	304
Loss from continuing operations	(3,074,369)	(1,784,258)
Net loss	\$ (3,074,369)	\$ (1,784,258)
Loss per common share — basic and diluted	\$ (0.07)	\$ (0.13)
Weighted-average number of common shares outstanding — basic and diluted	44,756,201	13,951,283