

**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): **March 23, 2020**

**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**  
(I.R.S. Employer Identification No.)

**2450 Holcombe Blvd.**  
**Suite J-608**  
**Houston, TX 77021**  
(Address of principal executive offices) (Zip Code)

**(346) 772-0346**  
(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 obligations of the registrant under any of the following provisions:

- 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:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value	SLRX	The Nasdaq Stock Market LLC

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 March 23, 2020, Salarius Pharmaceuticals, Inc. (the “Company”) reported financial results for the year ended December 31, 2020 and other recent corporate updates. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated by reference.

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.

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	<u>Press release issued on March 23, 2020.</u>

**SIGNATURE**

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, thereunto duly authorized.

Dated: March 27, 2020 SALARIUS PHARMACEUTICALS, INC.

By: /s/ David J. Arthur  
David J. Arthur  
President and Chief Executive Officer

## **Salariaus Pharmaceuticals Reports Fourth Quarter and Full-Year 2019 Financial Results**

*Seclidemstat Achieves Dose-Escalation Milestone in Phase 1/2 Ewing Sarcoma Clinical Trial*

*Sixth Level Dosing Cohort Now Proceeding; On Track To Report Topline Data in 2020*

HOUSTON, March XX, 2020 (GLOBE NEWSWIRE) – Salariaus Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biotechnology company targeting cancers caused by dysregulated gene expression, today reported its corporate and financial results for the fourth quarter and full-year ended December 31, 2019.

### **Financial Highlights:**

- In February 2020, closed \$11 million underwritten public offering
- In October 2019, entered Stock Purchase Agreement
  - \$2.6 million stock sales completed in 2019
- 12-month period ended December 31, 2019 net loss per common share – basic and diluted - for continuing operations of \$2.12, compared to \$1.16 for the same period ended December 31, 2018
- Total cash and cash equivalents of \$3.7 million as of December 31, 2019
  - Up to \$9.1 million remains available to draw from the Cancer Prevention and Research Institute of Texas grant (CPRIT), upon meeting certain requirements

### **Recent Business Highlights:**

- Advanced to the sixth level dosing cohort in Phase 1/2 study of Seclidemstat in Ewing sarcoma
- Seclidemstat granted Fast Track Designation by FDA for relapsed or refractory Ewing sarcoma
- Scientific paper published highlighting potential of combining Seclidemstat with checkpoint inhibitors
  - Data from *in vitro* studies conducted by Sunil Sharma, M.D., Salariaus' scientific founder
- Added Memorial Sloan Kettering Cancer Center and Nationwide Children's Hospital as clinical sites for Phase 1/2 trial of Seclidemstat in Ewing sarcoma

“Salariaus achieved much during 2019 and has entered 2020 well positioned to maximize the potential of our lead drug candidate, Seclidemstat,” stated David Arthur, President and Chief Executive of Salariaus. “Key to this was the completion of our merger with Flex Pharma and the subsequent listing of our stock on the Nasdaq Capital Market. We believe these developments were important in elevating our visibility among investors and providing resources that have allowed us to advance Seclidemstat.”

Mr. Arthur continued, “Our ultimate aim as a company is to maximize the potential of Seclidemstat and bring hope to the patients around the world afflicted with cancers resulting from dysregulated gene expression. In this regard, the Phase 1/2 dose-escalation trial of Seclidemstat in Ewing sarcoma, our lead clinical program, continues to advance at trial sites across the country, as has a Phase 1/2 dose-escalation trial in advanced solid tumors. Both clinical trials are expected to report important data

milestones this year. In addition to these clinical programs, Salarius is also exploring Seclidemstat as a treatment for other cancers and in combination with cancer immunotherapies.”

Mr. Arthur continued, “Validating our Seclidemstat development strategy, we were pleased that the FDA granted Seclidemstat Fast-Track status in Ewing sarcoma, a rare and deadly pediatric bone cancer for which there is no approved targeted treatment. Coupled with the previously granted Orphan Drug Designation and Rare Pediatric Disease Designation, we believe Salarius is well-positioned to leverage the FDA’s expedited programs for drug development and review.”

Mr. Arthur continued, “Meanwhile, the recently completed \$11 million public offering combined with \$2.6 million from our stock purchase agreement with Aspire Capital represent only a portion of the funds at our disposal. With the non-dilutive financial support Salarius receives from the National Pediatric Cancer Foundation (NPCF) and the up to \$9.1 million in non-dilutive funding that remains to be drawn down from the \$18.7 million grant we received in 2016 from the Cancer Prevention and Research Institute of Texas (CPRIT), we believe Salarius has the resources to advance both our Ewing sarcoma and AST programs into the second half of 2021.”

Mr. Arthur concluded, “In closing, we must acknowledge that the coronavirus or COVID-19 outbreak is impacting every corner of society and business. We are thankful to report that thus far Salarius’ operations continue with minimal interruption, however the ever-changing nature of the situation makes it challenging to forecast what may occur. This includes the Seclidemstat clinical trials where the health and safety of the patients and their families is paramount. Should developments occur, we will communicate such information.”

#### **12-Month Financial Results:**

For the 12-month period ended December 31, 2019, Salarius’ reported net loss was \$6.9 million, or \$2.12 per basic and diluted share, compared to a net loss of \$1.8 million, or \$1.16 per basic and diluted share for the same period in 2018. The loss from operations before other income for the twelve-month span ended December 31, 2019 increased by \$6.6 million compared to the loss from operations for the same time span last year, which was primarily due to an increase of \$2.7 million in research and development expenses resulting from increased clinical expenses and an increase of \$5.4 million in general and administrative expenses, respectively. Increased general and administrative spending resulted primarily from costs related to the merger between Salarius Pharmaceuticals, LLC and Flex Pharma, Inc. (“Flex Pharma”), which was completed in July 2019, and financing activities. These merger-related costs include a one-time success fee of \$1.35 million and \$0.8 million in professional fees.

As of December 31, 2019, total cash, cash equivalents and restricted cash was \$3.7 million, compared to \$3.2 million as of December 31, 2018.

#### **Summary of Corporate and Operational Events:**

##### **\$11 Million Underwritten Public Offering**

On February 11, 2020, Salarius completed a public offering with total gross proceeds of approximately \$11 million, which includes the full exercise of the underwriter’s over-allotment option to purchase an additional 1,252,173 shares and warrants prior to deducting underwriting discounts and commissions

and offering expenses payable by Salarius. Salarius intends to use the net proceeds from the offering for general corporate purposes, including working capital.

The offering is comprised of 7,101,307 Class A units, priced at a public offering price of \$1.15 per unit, with each unit consisting of one share of common stock and a five-year warrant to purchase one share of common stock at an exercise price of \$1.15 per share, and 1,246,519 Class B units, priced at a public offering price of \$1.15 per unit, with each unit consisting of one share of Series A convertible preferred stock and a five-year warrant to purchase one share of common stock with an exercise price of \$1.15 per share.

The convertible preferred stock issued in this transaction includes a beneficial ownership limitation on conversion but has no dividend rights (except to the extent that dividends are also paid on the common stock). The conversion price of the Series A convertible preferred stock in the offering, as well as the exercise price of the warrants are fixed and do not contain any variable pricing features, or any price-based anti-dilutive features.

### **Stock Purchase Agreement**

On October 24, 2019, Salarius entered into a \$10.9 million common stock purchase agreement with a Chicago-based institutional investor. Since then, Salarius has completed stock sales totaling \$2.6 million. Under the agreement, and more recently the terms of the capital raise, Salarius may sell shares of its common stock over a 30-month span extending into 2022, but in very limited circumstances including limitations based on the price of Salarius common stock.

### **Update on Seclidemstat Clinical and Pre-Clinical Programs:**

#### **Seclidemstat Clinical Trials in Ewing Sarcoma and Advanced Solid Tumors:**

The Safety Review Committee overseeing the ongoing Phase 1/2 clinical study of Seclidemstat in patients with relapsed or refractory Ewing sarcoma has approved the advancement of the study to the sixth dosing cohort, which is now open for patient enrollment.

Salarius is conducting two Phase 1/2 clinical trials for Seclidemstat – one in Ewing sarcoma and the second in patients with advanced solid tumors (AST) resistant to standard-of-care therapies. The trials are designed as open-label dose-finding studies to characterize the pharmacokinetics (PK), maximum tolerated dose (MTD), and initial safety profile of Seclidemstat. Thus far, early PK data from the trials suggest that plasma drug levels measuring the concentration of Seclidemstat in a patient's plasma remain dose proportional. Based on current projections, Salarius believes both studies are on track to reach maximum tolerated dose in 2020, and shortly after, begin the dose expansion phase of the study. Salarius expects to report early topline patient data before year-end 2020.

The Phase 1/2 clinical trial of Seclidemstat in Ewing sarcoma opened patient enrollment in Q3 2018 and is currently enrolling patients of 12 years of age or older at eight leading cancer centers in the U.S. Meanwhile, the Phase 1/2 AST clinical trial began enrolling patients in June 2019 with a focus on prostate, breast, ovarian, melanoma, colorectal, non-Ewing's sarcomas and other cancers where Seclidemstat demonstrated single-agent preclinical activity.

#### **Seclidemstat Granted Fast-Track Status by FDA**

On December 16, 2019, Salarius announced that the U.S. Food and Drug Administration has granted Seclidemstat Fast Track Designation for the treatment of patients with Ewing sarcoma who have

relapsed or are refractory to standard-of-care therapy. Fast Track is a process designed by the FDA to expedite the development and review of new drugs with the potential to treat serious or life-threatening conditions and fill unmet medical needs. The program aims to streamline regulatory submissions and enable more frequent communications with the agency to assure that questions and issues are resolved quickly, which often leads to earlier drug approval and access by patients.

**New Clinical Trial Sites Added to Ewing Sarcoma Study:**

On October 8, 2019, Salarius announced the addition of Memorial Sloan Kettering Cancer Center (MSKCC) in New York City and Nationwide Children's Hospital (Nationwide Children's) in Columbus, OH as trial sites in the Phase 1/2 clinical trial of Seclidemstat in Ewing sarcoma patients. This brings the number of active sites to eight and helps facilitate enrollment as the trial advances.

**About Salarius Pharmaceuticals** Salarius Pharmaceuticals, Inc. is a clinical-stage oncology company targeting the epigenetic causes of cancers and is developing treatments for patients that need them the most. Epigenetics refers to the regulatory system that affects gene expression. Salarius' lead candidate, Seclidemstat, is currently in clinical development for treating Ewing sarcoma, for which it has received Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation 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 clinical study in advanced solid tumors, including prostate, breast and ovarian cancers. Salarius receives financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma clinical program and is also the recipient of an \$18.7 million Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information, please visit [salariuspharma.com](http://salariuspharma.com).

**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," "aim," "can," "believe," "plan," "allow," "expect," "intend," "goal," "provide," "able to," "position," "project," 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 anticipated impact of the Flex Pharma merger and Nasdaq listing on Salarius' visibility with investors and Salarius' resources and ability to advance its clinical programs for Seclidemstat; expectations regarding the reporting of data milestones from the company's Phase 1/2 dose-escalation trials of Seclidemstat in Ewing sarcoma and advanced solid tumors; and results and timing thereof; status of the Ewing sarcoma trial; Salarius' belief that it is well-positioned to leverage the FDA's expedited programs for drug development and review; Salarius' aim to maximize potential of Seclidemstat and exploration of Seclidemstat as a potential treatment for other cancers and in combination with cancer immunotherapies; Salarius' belief as to the sources and sufficiency of funds at its disposal, including its belief regarding its resources to advance both its Ewing sarcoma and AST programs well into 2021; Salarius' intended use of proceeds from its recent public offering; the commitment and limitations regarding the stock purchase agreement with Aspire Capital; the status, enrollment, and expectations for the company's two Phase 1/2 clinical trials for Seclidemstat in Ewing sarcoma and advanced solid tumors and suggestions from early PK data from the trials; Salarius' belief that based on current projections, both studies are on track to reach maximum tolerated dose in 2020, and shortly after, begin the dose expansion phase of the study and that Salarius

expects to report early topline patient data before year-end 2020; potential impact of the FDA Fast-Track Designation for Seclidemstat; Salarius' ongoing development of Seclidemstat for several cancers with high unmet medical need; and the potential impact of the COVID-19 outbreak on the company and its business and operations. 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 accuracy thereof; 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 sell stock to Aspire 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 annual report on Form 10-K for the year ended December 31, 2019. 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.  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**



	<b>Twelve Months Ended December 31, 2019</b>	<b>Twelve Months Ended December 31, 2018</b>
Revenue:		
Grant revenue	\$ 3,465,055	\$ 1,951,351
Operating expenses:		
Research and development	4,018,951	1,287,621
General and administrative	7,711,181	2,348,361
Total operating expenses	11,730,132	3,635,982
Loss before other income (expense)	(8,265,077)	(1,684,631)
Change in fair value of warrant liability	1,311,333	—
Interest income, net	15,648	14,994
Loss from continuing operations	(6,938,096)	(1,669,637)
Income from discontinued operations	1,833	—
Net loss	<u>\$ (6,936,263)</u>	<u>\$ (1,669,637)</u>
Loss from continuing operations	\$ (6,938,096)	\$ (1,669,637)
Preferred dividends	—	(123,727)
Loss from continuing operations attributable to common stockholders	<u>\$ (6,938,096)</u>	<u>\$ (1,793,364)</u>
Loss per common share — basic and diluted		
Continuing operations	\$ (2.12)	\$ (1.16)
Discontinued operations	—	—
Total net loss per share	<u>\$ (2.12)</u>	<u>\$ (1.16)</u>
Weighted-average number of common shares outstanding — basic and diluted	<u>3,268,637</u>	<u>1,539,388</u>

**SALARIUS PHARMACEUTICALS, INC.**  
**SELECTED CONSOLIDATED BALANCE SHEETS DATA**  
**(Unaudited)**

	<u>December 31, 2019</u>	<u>December 31, 2018</u>
Cash, cash equivalents and restricted cash	\$ 3,738,900	\$ 3,228,288
Working capital (deficit)	1,381,255	(1,504,070)
Goodwill	8,865,909	---
Total assets	13,894,398	6,613,823
Total current liabilities	3,313,544	7,884,937
Accumulated deficit	(12,076,700)	(5,140,437)
Total shareholders' equity (deficit)	10,580,854	(1,271,114)