



# Salarius Pharmaceuticals Reports Three and Nine Month 2019 Financial Results

HOUSTON, Nov. 13, 2019 (GLOBE NEWSWIRE) -- Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biotechnology company targeting the epigenetic causes of cancer, today reported its corporate and financial results for the quarter ended September 30, 2019.

## Third Quarter 2019 Financial Highlights:

- Entered \$10.9 million Stock Purchase Agreement with Aspire Capital
  - Initial \$1.0 million stock sale completed
- Three- and nine-month periods ended September 30, 2019 net loss per common share – basic and diluted - for continuing operations of \$0.73 and \$1.68, respectively
- Total cash and cash equivalents of \$4.0 million as of September 30, 2019
  - \$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:

- Closed merger with Flex Pharma; initiated trading on Nasdaq Capital Market
- Enrolled first patient in Phase 1 trial of Seclidemstat in advanced solid tumors (AST)
- Achieved dose-escalation milestones in ongoing Phase 1/2 Ewing sarcoma and Phase 1 AST clinical trials

- Added Memorial Sloan Kettering Cancer Center and Nationwide Children's Hospital as clinical sites for Phase 1/2 trial of Seclidemstat in Ewing sarcoma
- Entered a collaborative partnership with Ivy Brain Tumor Center to develop Seclidemstat for the treatment of glioblastoma

"The third quarter of 2019 was a transformative time for Salarius, highlighted by our merger with Flex Pharma and our subsequent listing on the Nasdaq Capital Market," stated David Arthur, President and Chief Executive of Salarius. "The importance of this accomplishment cannot be understated as it establishes a foundation for our future growth by providing increased exposure and access to institutional investors and a platform for Salarius to showcase the potential of our lead asset, Seclidemstat, as well as our broader clinical pipeline."

Mr. Arthur continued, "Key to Salarius' value proposition is Seclidemstat, a potent reversible inhibitor of the LSD1 enzyme. Seclidemstat is currently being tested in a Phase 1/2 clinical trial in Ewing sarcoma, a rare and deadly pediatric bone cancer for which there is no approved targeted treatment, in addition to a Phase 1 trial in advanced solid tumors. During the quarter, we achieved important dose escalation and trial enrollment events for each program, putting us on target to report early patient data from both studies in 2020."

Mr. Arthur concluded, "As a publicly-traded company, Salarius has a foundation for future growth and a means to maximize the potential of Seclidemstat, which we believe to be one of the most advanced reversible LSD1 inhibitors now in the clinic. Subject to limitations in our stock purchase agreement with Aspire Capital, Salarius has access to a flexible source of capital over the next 30 months, as well as the support from Aspire Capital, an institutional investor that recognizes our tremendous upside potential. This capital, in addition to the non-dilutive financial support Salarius receives from the National Pediatric Cancer Foundation (NPCF) and the \$9.1 million in non-dilutive funding still remaining from the \$18.7 million grant Salarius received in 2016 from the Cancer Prevention and Research Institute of Texas puts Salarius in a good financial position as we continue our work developing targeted cancer therapies. Above all and underpinning our drive as a company is a dedication to the patients around the world who are unfortunately afflicted with the devastating cancers we aim to treat. Their bravery is our inspiration."

**Third Quarter Financial Results:**

For the quarter ended September 30, 2019, Salarius' reported net loss was \$2.6 million, or \$0.73 per basic and diluted common share, compared to a net loss of \$0.3 million, or \$0.20 per basic and diluted share for the same period in 2018. The loss from operations before other income for the three-month span ended September 30, 2019 increased by \$3.4 million compared to the loss from operations before other income for the same time span last year, which was primarily due to increases of \$0.8 million in research and development expenses resulting from increased clinical expenses, and an increase of \$3.1 million in general and administrative expenses, respectively. Increased general and administrative spending resulted primarily from costs related to the merger with Flex Pharma, Inc. ("Flex Pharma"), which was completed in July 2019. These merger-related costs include a one-time success fee of \$1.35 million and \$0.8 million in professional fees.

**Nine Month Financial Results:**

For the nine-month period ended September 30, 2019, Salarius' reported net loss was \$5.1 million, or \$1.68 per basic and diluted share, compared to a net loss of \$0.6 million, or \$0.47 per basic and diluted share for the same period in 2018. The loss from operations before other income for the nine-month span ended September 30, 2019 increased by \$5.6 million compared to the loss from operations for the same time span last year, which was primarily due to an increase of \$1.9 million in research and development expenses resulting from increased clinical expenses and an increase of \$4.9 million in general and administrative expenses, respectively. Increased general and administrative spending primarily resulted from professional fees of \$1.4 million and one-time success fees totaling \$1.35 million, both related to the merger with Flex Pharma.

As of September 30, 2019, total cash, cash equivalents and restricted cash was \$4.0 million, compared to \$6.1 million as of December 31, 2018.

**Summary of Corporate and Operational Events:****Merger with Flex Pharma Completed:**

On July 19, 2019, Salarius Pharmaceuticals, LLC completed its previously-announced merger with Flex Pharma. In accordance with the terms of the merger agreement, the newly combined company was renamed Salarius Pharmaceuticals, Inc., and would be led by Salarius' then

current management team under the leadership of David Arthur, President and Chief Executive Officer of Salarius Pharmaceuticals, LLC. Former Flex Pharma President and Chief Executive Officer William McVicar, Ph.D., joined Salarius' Board of Directors upon completion of the merger.

On July 22, 2019, shares of Salarius' common stock began trading on the Nasdaq Capital Market under the ticker symbol "SLRX". The shares reflected a 25:1 reverse stock split that was effective as of the close of business on July 19, 2019.

### **Stock Purchase Agreement with Aspire Capital:**

On October 24, 2019, Salarius entered into a \$10.9 million common stock purchase agreement with Aspire Capital Fund, LLC., a Chicago-based institutional investor. Under the agreement, Aspire Capital is committed to buy shares of Salarius common stock over a 30-month span extending into 2022 at our sole discretion, subject to certain terms and conditions.

Immediately upon execution of the agreement, Aspire Capital made an initial purchase of 210,526 shares of Salarius stock for \$1.0 million, at a per-share purchase price of \$4.75, which was the closing price of Salarius shares on the date of the agreement.

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

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

On September 24, 2019, Salarius announced that the Safety Review Committees overseeing the ongoing Phase 1/2 clinical study of Seclidemstat in patients with relapsed or refractory Ewing sarcoma and the Phase 1 study of Seclidemstat in patients with advanced solid tumors resistant to standard-of-care therapies have approved the advancement of both studies to the fourth level dosing cohort.

The two clinical trials are designed as open-label dose-finding studies to characterize the pharmacokinetics (PK), the maximum tolerated dose (MTD) and initial safety profile of Seclidemstat. Thus far, early PK data suggests Seclidemstat has a desirable half-life and

plasma levels are dose proportional. Based on current projections, both studies are on track to reach maximum tolerated dose in early 2020 and report early patient data later in the same year.

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 leading cancer centers in the U.S. Meanwhile, the Phase 1 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.

### **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.

### **Partnership with Ivy Brain Tumor Center:**

On August 26, 2019, Salarius and the Ivy Brain Tumor Center at the Barrow Neurological Institute in Phoenix, AZ announced a collaborative partnership to test Seclidemstat for the treatment of glioblastoma, a rare brain cancer. Under the agreement, the organizations plan to launch what both believe to be the most comprehensive pre-clinical study to date evaluating the effect of targeting the LSD1 enzyme, which has increased expression in tumors of brain cancer patients.

### **Leadership Changes:**

On September 13, 2019, Salarius appointed Mark Rosenblum as Interim Chief Financial Officer, as well as Executive Vice President Finance. Scott Jordan, Salarius' previous Chief Financial Officer, transitioned to the new role of Chief Business Officer.

## 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. In some cancers, epigenetic regulators often become dysregulated and incorrectly turn genes on or off leading to cancer progression. Drugs that can safely modify the activity of these epigenetic regulators may correct the gene changes that are driving the disease. The company's lead candidate, Seclidemstat, is currently in clinical development for treating Ewing sarcoma, for which it has Orphan Drug designation and Rare Pediatric Disease Designation by the U.S. Food and Drug Administration. Salarius believes that Seclidemstat is one of only two reversible inhibitors of the epigenetic modulator LSD1 currently in human trials, and that it could have potential for improved safety and efficacy compared to other LSD1-targeted therapies. 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," "can," "believe," "plan," "allow," "expect," "provide," "able to," "position," 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 belief as to the potential impact of the merger with Flex Pharma and Nasdaq listing, including establishing a foundation for future growth, providing exposure and access to institutional investors, and enabling Salarius to showcase the potential of Seclidemstat and Salarius' clinical pipeline; the company's belief that the stock purchase agreement with Aspire Capital will provide additional access to capital and financing flexibility to allow the company to further advance its lead drug candidate, Seclidemstat; the potential for Seclidemstat to target the epigenetic causes of cancers including prostate, breast and ovarian cancers; expected timing and results of clinical studies, including the company's expectations

on reaching maximum tolerated dose early 2020 and reporting early patient data later in the same year; Seclidemstat's impact in Ewing sarcoma as a potential new and less toxic treatment and potential benefits to patients and their families; the company's belief that Seclidemstat is one of the most advanced LSD1 inhibitors now in the clinic; the availability of any amounts available for draw under the CPRIT grant, if at all, and whether the requirements to receive such grants will be met; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the company. 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 ability of 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; future clinical trial results; 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 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; and other risks described in Salarius' filings with the Securities and Exchange Commission, including those under the heading "Risk Factors." 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**  
**(Unaudited)**

	<b>Three Months Ended September 30, 2019</b>	<b>Three Months Ended September 30, 2018</b>	<b>Nine Months Ended September 30, 2019</b>	<b>Nine Months Ended September 30, 2018</b>
Revenue:				
Grant revenue	\$ 874,949	\$ 469,051	\$ 2,426,362	\$ 1,312,752
Operating expenses:				
<b>Research and development</b>	1,140,909	353,607	2,680,982	803,846
<b>General and administrative</b>	3,494,205	428,958	5,950,431	1,093,596
Total operating expenses	4,635,114	782,565	8,631,413	1,897,442
Loss before other income (expense)	(3,760,165)	(313,514)	(6,205,051)	(584,690)
Change in fair value of warrant liability	1,130,848	-	1,130,848	-
Interest income (expense), net	(752)	6,064	18,413	6,924
Loss from continuing operations	(2,630,069)	(307,450)	(5,055,790)	(577,766)
Income from discontinued operations	2,348	-	2,348	-
Net loss	<u><u>\$ (2,627,721)</u></u>	<u><u>\$ (307,450)</u></u>	<u><u>\$ (5,053,442)</u></u>	<u><u>\$ (577,766)</u></u>
Net loss per share attributable to common stockholders – basic and diluted				
<b>Continuing operations</b>	\$ (0.73)	\$ (0.20)	\$ (1.68)	\$ (0.47)
<b>Discontinued operations</b>	-	-	-	-
Total net loss per share	<u><u>\$ (0.73)</u></u>	<u><u>\$ (0.20)</u></u>	<u><u>\$ (1.68)</u></u>	<u><u>\$ (0.47)</u></u>
Weighted-average number of common shares used in net loss per share attributable to common stockholders – basic and diluted	<u><u>3,605,911</u></u>	<u><u>1,653,340</u></u>	<u><u>3,002,723</u></u>	<u><u>1,407,062</u></u>

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

	<b>September 30, 2019</b>	<b>December 31, 2019</b>
Cash, cash equivalents and restricted cash	\$ 3,999,676	\$ 6,131,781
Working capital (deficit)	518,471	(1,504,070)
Goodwill	8,865,909	-
Total assets	14,457,946	6,613,823
Total current liabilities	4,720,913	7,884,937
Accumulated deficit	(10,193,879)	(5,140,437)
Total shareholders' equity (deficit)	9,737,033	(1,271,114)

Source: Salarius Pharmaceuticals