Salarius Pharmaceuticals Reports Business Highlights and Third Quarter 2020 Financial Results

Conference Call and Live Audio Webcast Scheduled for Today, November 11, 2020, at 4:30 p.m. ET

HOUSTON, November 11, 2020 (GLOBE NEWSWIRE) – Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biopharmaceutical company developing potential new medicines for children and adults with pediatric cancers, solid tumors and other cancers, today reported its corporate and financial results for the third quarter ended September 30, 2020.

Recent Business and Corporate Events:

- Ewing sarcoma Phase 1/2 clinical trial is completing dose escalation to establish maximum tolerated dose (MTD) and is expected to advance into Phase 2 dose-expansion in Q1 2021
- Ewing sarcoma clinical trial expansion phase expanded to include patients with Ewing-related sarcomas such as myxoid liposarcoma, desmoplastic small round cell tumors and other sarcomas with similar biology to Ewing sarcoma
    - Ewing sarcoma and Ewing-related sarcomas represent rare cancers affecting both children and adults where there is a high unmet need for additional treatment options

Financial Highlights:

- Total cash and cash equivalents of $9.6 million as of September 30, 2020 due in part to $6.2 million gross proceeds in an underwritten public offering closed August 3, 2020
- Three-month period ended September 30, 2020 net loss per common share – basic and diluted - of $0.10, compared to $0.73 for the same period ended September 30, 2019

“The events of the third quarter of 2020 affirm the company’s growth strategy and demonstrate the potential of seclidemstat as a treatment for cancers with high unmet need,” said David Arthur, President and CEO of Salarius. “Our lead clinical program in Ewing sarcoma continues to advance, and we expect to reach the maximum tolerated dose (MTD) in the Phase 1 portion of the clinical trial and, as planned, begin the Phase 2 dose-expansion portion of the trial in Q1 2021. This is an important milestone as it allows us to establish the recommended Phase 2 dosing regimen for the trial and begin treating a broader group of patients with Ewing and Ewing-related sarcomas.”

Mr. Arthur continued, “Ewing sarcoma and advanced solid tumors (AST) remain our most advanced development programs, but we believe seclidemstat offers the opportunity to address numerous cancers where additional treatment options are needed. In this regard, we recently expanded the dose-expansion phase of the Ewing sarcoma clinical trial to include several additional sarcomas. This decision was based on preclinical data and early clinical data observations from the ongoing clinical trials that suggest seclidemstat may demonstrate drug activity and have applicability in other sarcomas that have a similar gene arrangement to Ewing sarcoma, known as Ewing-related sarcomas. Among those observations, Salarius previously disclosed that a refractory Ewing sarcoma patient treated with seclidemstat for six months demonstrated a reduction of over 80% in prospectively defined target lesions, which generally represent a patient’s largest measurable tumors.”

Ewing Sarcoma Clinical Trial Expanded

On July 29, 2020, Salarius announced the expansion of its ongoing Phase 1/2 clinical trial of seclidemstat in Ewing sarcoma to include additional select sarcomas that share a similar biology to Ewing sarcoma, also known as Ewing-related sarcomas. Sarcomas of interest include myxoid liposarcoma, desmoplastic small round cell tumors and other sarcomas that harbor similar FET family gene rearrangements to Ewing sarcoma.

These Ewing-related sarcomas were chosen based on their underlying biology as well as preclinical data and early clinical observations involving seclidemstat that suggest the drug may demonstrate activity and may have applicability in several sarcomas that share key characteristics of Ewing sarcoma. As Salarius previously disclosed, a refractory Ewing sarcoma patient treated with seclidemstat for six months demonstrated a reduction of over 80% in prospectively defined target lesions. Target lesions generally represent a patient's largest measurable tumors. However, at eight weeks, an increase in non-target lesions resulted in an overall patient classification of progressive disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST).

The amendment to the ongoing clinical trial will allow up to 30 patients with Ewing-related sarcomas to enroll in the trial's upcoming dose-expansion phase, which is in addition to the 20 Ewing sarcoma patients also planned to be treated in the dose-expansion phase.

Additional Clinical Trials to Expand Development Program

Mr. Arthur concluded, "In addition, in the third quarter we continued preparatory work on two additional clinical trials and look forward to announcing the initiation of these trials soon. These additional clinical trials support our growth strategy focused on maximizing the market potential of seclidemstat."

Three-Month Financial Results:

For the three-month period ended September 30, 2020, Salarius' reported net loss was $1.7 million, or $0.10 per basic and diluted share, compared to a net loss of $2.6 million, or $0.73 per basic and diluted share for the same period in 2019. The loss before other income for the three-month period ended September 30, 2020 decreased by $2.0 million compared to the same time span last year, primarily due to a $2.2 million decrease in general and administrative expenses which more than offset the increase of $0.7 million in research and development expenses. Increased research and development costs resulted from increased clinical trial expenses and drug manufacturing costs. The decrease in general and administrative costs resulted from the absence of costs related to Salarius' one-time transformation into a public company during 2019 which did not reoccur in the current period.

As of September 30, 2020, total cash, cash equivalents and restricted cash were $9.6 million, compared to $3.7 million at year-end 2019. Increases in cash balances result from the Company's public offerings of stock in the first quarter and third quarter 2020. The Company expects its cash and cash equivalents to fund its operations into the third quarter of 2021.

$6.2 Million Underwritten Public Offering

On August 3, 2020, Salarius completed an underwritten public offering with total gross proceeds of approximately $6.2 million, prior to deducting underwriting discounts and commissions and offering expenses payable by Salarius. Salarius intends to use the net proceeds from the offering and ongoing non-dilutive financial support from the Cancer Prevention Institute of Texas (CPRIT) to fund the expansion of the Ewing sarcoma clinical trial and ongoing company operations.

Conference Call Information:

Salarius Pharmaceuticals will host a conference call and live audio webcast on Wednesday, November 11, 2020, at

4:30 p.m. ET, to discuss its corporate and financial results for the third quarter 2020. Interested participants and investors may access the conference call by dialing either:

- (833) 423-0481 (U.S.)
- (918) 922-2375 (international)
- Conference ID: 1277839

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 November 11, 2020.

About Salarius Pharmaceuticals

Salarius Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing cancer therapies for patients that need them the most. 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, 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 1/2 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 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 or follow the Company 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," "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: Salarius' growth strategy; the value of seclidemstat as a potential treatment for Ewing sarcoma and other cancers; the status and anticipated progress and milestones of Salarius' clinical trials in advanced solid tumors and Ewing sarcoma including statements related to when Salarius will reach the maximum tolerated dose in the Phase 1 portion of the study and when Salarius will begin the Phase 2 expansion portion of any study; the expansion of Salarius' clinical trials to include Ewing-related sarcomas; Salarius' belief as to being well-capitalized; statements related to Salarius' ability to obtain or the availability of any additional amount from the CPRIT award; the anticipated use of proceeds from Salarius' recent public offering to advance and expand the seclidemstat development pipeline; Salarius' goal to maximize the potential of seclidemstat; Salarius' developing seclidemstat for several cancers with high unmet medical need; and Salarius plans to announce two additional clinical trials. 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 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; Salarius' ability to project future capital needs and cash utilization and timing and accuracy thereof; the ability of Salarius to access the remaining funding available under the CPRIT grant; future clinical trial results and impact of results on Salarius; 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 Salarius' quarterly report on Form 10-Q for the quarter ended June 30, 2020 and in Salarius' 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.

Contact

Tiberend Strategic Advisors, Inc.
Maureen McEnroe, CFA/Miriam Miller (investors)
(212) 375-2664 / 2694
mmcenroe@tiberend.com
mmiller@tiberend.com
Johanna Bennett (media)
(212) 375-2686
jbennett@tiberend.com

SALARIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 9,557,813	$ 3,738,900
Grants receivable from CPRIT	3,212,678	—
Prepaid expenses and other current assets	1,148,667	955,899
Total current assets	13,919,158	4,694,799
Property and equipment, net	15,635	25,016
Goodwill	8,865,909	8.865.909
Other assets	262,509	308,674
Total assets	$ 23,063,211	$ 13,894,398
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,195,063	$ 1,790,966
Accrued expenses and other current liabilities	448,862	160,783
Note payable	761,096	502,332
Deferred revenue	—	541,701
Warrant liability	52,224	317,762
Total liabilities	2,457,245	3,313,544
Commitments and contingencies (Note 6)		
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; 19,821,716 and 4,519,533 shares issued at September 30, 2020 and December 31, 2019, and 19,818,912 and 4,511,174 shares outstanding at September 30, 2020 and December 31, 2019, respectively	1,981	451
Additional paid-in capital	38,265,391	22,657,103
Accumulated deficit	(17,661,406)	(12,076,700)
Total stockholders' equity	20,605,966	10,580,854
Total liabilities and stockholders' equity	$ 23,063,211	$ 13,894,398

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

	Three Months Ended September 30	
	2020	**2019**
Revenue:		
Grant revenue	$ 1,378,239	$ 874,949
Operating expenses:		
Research and development	1,803,682	1,140,909
General and administrative	1,333,062	3,494,205
Total operating expenses	3,136,744	4,635,114
Loss before other income (expense)	(1,758,505)	(3,760,165)
Change in fair value of warrant liability	45,103	1,130,848
Government grants and other income	—	—
Interest income (expense), net	(3,230)	(752)
Loss from continuing operations	**(1,716,632)**	**(2,630,069)**
Income from discontinued operations	—	2,348
Net loss	**$ (1,716,632)**	**$ (2,627,721)**
Loss per common share — basic and diluted	**$ (0.10)**	**$ (0.73)**
Weighted-average number of common shares outstanding — basic and diluted	17,968,664	3,605,913


Salarius
PHARMACEUTICALS
The Cancer Epigenetics Company