

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 10, 2022

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 March 10, 2022, Salarius Pharmaceuticals, Inc. (the “Company”) reported financial results for the three and twelve months ended December 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) 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 March 10, 2022</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: March 10, 2022

SALARIUS PHARMACEUTICALS, INC.

By: /s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer



Salarius Pharmaceuticals Reports Business Highlights with Fourth Quarter and Full-Year 2021 Financial Results

Strategic acquisition of SP-3164, a targeted protein degrader in development for hematologic and solid tumors, adds to pipeline of cancer therapies

Clinical development of seclidemstat is continuing with updates from two Phase 1/2 clinical trials in sarcoma and hematologic cancer patients anticipated in 2022

Conference Call and Live Audio Webcast Scheduled for Today, March 10, 2022, 5:00 p.m. ET

HOUSTON, March 10, 2022 (GLOBE NEWSWIRE) – Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biopharmaceutical company developing cancer therapies for patients in need of new treatment options, today reported important corporate events and its financial results for the full year and the fourth quarter ended December 31, 2021.

“We believe the progress made by Salarius Pharmaceuticals during 2021 and the early weeks of 2022 has once again been remarkable, including the Company’s recent expansion into the field of targeted protein degradation (TPD),” stated David Arthur, CEO of Salarius Pharmaceuticals. “TPD is a fast-growing field of cancer drug development with commercial market potential estimated in billions of dollars and enticing significant investment from some of the world’s largest pharmaceutical companies. TPD has the ability to develop drugs for historically undruggable cancer-promoting targets and our new TPD development program, built around the portfolio of assets acquired by Salarius in January 2022, is led by the product candidate SP-3164. Salarius now boasts a multipronged pipeline built around two exciting approaches to cancer drug development – protein inhibition and targeted protein degradation.”

Financial Highlights:

- Cash and cash equivalents total \$29.2 million on December 31, 2021, with an estimated runway into 2023
- For the three-month and 12-month periods ended December 31, 2021, net loss per common share, basic and diluted, of \$0.09 and \$0.31, respectively, compared to \$0.10 and \$0.50, respectively, for the same periods in 2020

Recent Business and Corporate Highlights:

- Acquisition of TPD assets from DeuteRx LLC in January 2022 expands Salarius’ oncology pipeline into a fast-growing area of drug research focused on pursuing historically undruggable cancer-promoting targets with estimated multi-billion-dollar commercial market potential
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- Acquisition included the drug candidate SP-3164, additional targeted protein degrader programs, and a related intellectual property (IP) portfolio that includes issued composition of matter patents
- SP-3164 is an orally administered cereblon-binding targeted protein degrader developed as a next-generation version of the widely studied molecular glue, avadomide (CC-122) with the potential for an improved efficacy and safety profile
 - SP-3164 leverages the data from 10 clinical trials investigating avadomide in more than 400 patients
 - Preclinical data suggests the potential for SP-3164 to be more efficacious than avadomide
 - Salarium will continue collaborating with DeuteRx scientists to complete Investigational New Drug (IND) enabling studies for SP-3164
 - First clinical trial expected in 2023
- Consideration consists of cash and stock, with an upfront payment of \$1.5 million in cash and 1 million shares of restricted stock; future payments linked to clinical, regulatory, and commercial milestones, and net sales royalties
- Salarium continues to advance clinical development of seclidemstat; data updates expected in 2022 from two Phase 1/2 clinical trials
 - Sarcoma trial investigating seclidemstat in combination with chemotherapy agents topotecan and cyclophosphamide (TC), in patients with relapsed/refractory Ewing sarcoma advanced to second lead-in safety dosing cohort treating patients with seclidemstat at 900 mg BID
 - Sarcoma trial investigating seclidemstat as a single-agent therapy in Myxoid Liposarcoma and other FET-rearranged sarcomas continues enrollment
 - Enrollment continues in investigator-initiated trial (IIT) at MD Anderson Cancer Center exploring seclidemstat in combination with azacytidine as a treatment for hematologic cancers; updates on biomarkers including immature cells (blasts) and drug activity measures expected during 2022
 - Research underway to identify new indications for seclidemstat in established large markets

Mr. Arthur concluded, “2022 is a year of significant optimism at Salarium given the potential value-building opportunities and milestones on the horizon. Salarium is moving to rapidly advance the development of SP-3164 with plans to file an IND and initiate our first clinical trial for that program in 2023. Building on our optimism around SP-3164 and based on the abundance of preclinical and clinical data collected around its predecessor, avadomide, it is our belief that SP-3164 will establish a superior safety profile with the potential to be more effective. Additionally, we continue advancing the clinical exploration of seclidemstat, our oral, reversible LSD1 inhibitor and Salarium’s most advanced investigational cancer drug candidate. We look forward to providing data updates in the coming months.”



Three-Month and 12-Month Financial Results:

For the three-month period ended December 31, 2021, Salarius' reported net loss was \$4.1 million, or \$0.09 per basic and diluted share, compared to a net loss of \$1.8 million, or \$0.10 per basic and diluted share for the same period in 2020. The loss for the three-month period ended December 31, 2021, increased by \$2.3 million compared to the same time span last year, primarily because the Company had higher overall costs and no grant revenue in the current period.

For the 12-month period ended December 31, 2021, Salarius' reported net loss was \$12.8 million, or \$0.31 per basic and diluted share, compared to a net loss of \$7.4 million, or \$0.50 per basic and diluted share for the same period in 2020. The loss for the 12-month period ended December 31, 2021, increased by \$5.4 million compared to the loss from operations for the same period last year, resulting from increased charges related to R&D personnel and higher clinical trial costs more than offsetting lower drug development costs.

Net cash used for operating activities during the 12-month period ended December 31, 2021, totaled \$10.2 million, essentially the same as approximately \$10.3 million in the prior year. During 2021, the Company collected approximately \$4.1 million on its outstanding grant receivable compared to \$0.8 million in the prior year.

As of December 31, 2021, total cash, cash equivalents, and restricted cash were \$29.2 million, compared to \$11.1 million at year-end 2020. The increase in cash was primarily driven by the sale of equity securities during the first quarter of 2021. Current cash and cash equivalents are expected to fund our current planned operations into 2023.

Conference Call Information:

Salarius Pharmaceuticals will host a conference call and live audio webcast on Thursday, March 10, 2022, at 5:00 p.m. ET, to discuss its corporate and financial results for the fourth quarter and full-year 2021. Interested participants and investors may access the conference call by dialing either:

(833) 423-0481 (U.S.)

(918) 922-2375 (International)

Conference ID: 7375449

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 6:00 p.m. ET on March 10, 2022.

About Salarius Pharmaceuticals



Salarius Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing cancer therapies for patients in need of new treatment options. Salarius' product portfolio includes seclidemstat, which is being studied as a potential treatment for pediatric cancers, sarcomas, and other cancers with limited treatment options, and SP-3164, an oral small molecule protein degrader. 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, initiated by MD Anderson Cancer Center. 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 information that includes or is based upon "forward-looking statements" within the meaning of the Securities Litigation Reform Act of 1995. Forward-looking statements provide our expectations or forecasts regarding future events. You can identify these statements by the fact they do not relate strictly to historical or current facts. They may use words such as "anticipate," "believe," "designed to," "estimate," "expect," "look forward," "plan," "suggests," "underway," "will," and other terms of similar meaning in connection with a discussion of future operating or financial performance. In particular, forward-looking statements include statements relating to intended future actions; the potential size of the commercial market for our drug candidates; the functionality and capabilities of our drug candidates; our ability to expand our pipeline into new areas of drug research; the efficacy and/or safety of our drug candidates; the continuation or advancement of new and existing clinical trials; timing of updates from our clinical trials and other activities; plans to file INDs or other regulatory filings; and ability of cash and cash equivalents to fund our operations into the future. Any or all of our forward-looking statements here and elsewhere may turn out to be wrong. They can be affected by inaccurate assumptions or by known or unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements and from expected or historical results. Many such factors will be important in determining our actual future results. Consequently, no forward-looking statement can be guaranteed. In particular, you should read those risks described under the heading "Risk Factors" in our Securities and Exchange Commission filings, including in our annual and quarterly reports. We undertake no obligation to correct or update any forward-looking statements, whether as a result of new information, future developments, or otherwise, except to the extent required by applicable law. These forward-looking statements (except as may be otherwise noted) speak only as of the date of this press release. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. You are advised to consult any further disclosures we make on related subjects in our reports to the SEC.



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



	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 29,214,380	\$ 11,118,614
Grants receivable from CPRIT	—	3,855,996
Prepaid expenses and other current assets	949,215	822,050
Total current assets	30,163,595	15,796,660
Grants receivable from CPRIT	1,610,490	—
Property and equipment, net	7,880	22,639
Goodwill	8,865,909	8,865,909
Other assets	185,994	247,113
Total assets	<u>\$ 40,833,868</u>	<u>\$ 24,932,321</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,543,096	\$ 1,853,756
Accrued expenses and other current liabilities	553,269	383,138
Note payable	—	477,028
Warrant liability	14,518	59,211
Total liabilities	<u>\$ 2,110,883</u>	<u>\$ 2,773,133</u>
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; none issued or outstanding	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 45,241,808 and 23,810,541 shares issued at December 31, 2021 and December 31, 2020, and 45,241,808 and 23,808,546 shares outstanding at December 31, 2021 and December 31, 2020, respectively	4,524	2,381
Additional paid-in capital	70,915,653	41,585,761
Accumulated deficit	(32,197,192)	(19,428,954)
Total stockholders' equity	<u>38,722,985</u>	<u>22,159,188</u>
Total liabilities and stockholders' equity	<u>\$ 40,833,868</u>	<u>\$ 24,932,321</u>

**SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS**



	Three Months Ended 31-Dec		Twelve Months Ended 31-Dec	
	2021	2020	2021	2020
Revenue:				
Grant revenue	\$ -	\$ 1,478,922	\$ 1,840,216	\$ 5,233,301
Operating expenses:				
Research and development	2,695,633	2,023,478	8,548,520	6,913,853
General and administrative	1,449,227	1,212,772	6,104,631	6,105,793
Total operating expenses	4,144,860	3,236,250	14,653,151	13,019,646
Loss before other income (expense)	(4,144,860)	(1,757,328)	(12,812,935)	(7,786,345)
Change in fair value of warrant liability	39,488	(6,987)	44,693	258,551
Government grants and other income(expense)	499	(3,233)	4	175,540
Net loss	\$(4,104,873)	\$(1,767,548)	\$(12,768,238)	\$(7,352,254)
Fair value increase related to warrant modification	-	(396,407)	-	(396,407)
Loss attributed to common stockholders	\$(4,104,873)	\$(2,163,955)	\$(12,768,238)	\$(7,748,661)
Loss per common share — basic and diluted	\$ (0.09)	\$ (0.10)	\$ (0.31)	\$ (0.50)
Weighted-average number of common shares outstanding — basic and diluted	45,228,405	20,784,788	41,365,955	15,578,611