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): November 10, 2022

SALARIUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36812**	**46-5087339**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

2450 Holcombe Blvd.
Suite X
Houston, TX **77021**

(Address of principal executive offices) **(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 November 10, 2022, Salarius Pharmaceuticals, Inc. (the "Company") reported financial results for the three and nine months ended September 30, 2022 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 hereto) 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	Press Release Announcing Financial Results, dated November 10, 2022
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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.

SALARIUS PHARMACEUTICALS, INC.

Date: November 10, 2022

By: /s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer

Salarius Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Business Update

HOUSTON (November 10, 2022) – Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage biopharmaceutical company using protein inhibition and protein degradation to develop cancer therapies for patients in need of new treatment options, today reported financial results for the three and nine months ended September 30, 2022 and provided a business update. Highlights of the third quarter of 2022 and recent weeks include:

Financial Highlights

- Cash and cash equivalents were $16.8 million as of September 30, 2022, compared with $29.2 million as of December 31, 2021
- Net loss for the third quarter of 2022 was $14.4 million, or $6.41 per share, which included a loss on goodwill impairment of $8.9 million, or an impairment of $3.94 per share, compared with net loss for the third quarter of 2021 of $3.7 million, or $2.09 per share
- Higher operating expenses reflect initial SP-3164 costs as the company makes progress toward important near-term milestones
- Regained compliance with Nasdaq's minimum-bid requirement following a reverse stock split

SP-3164 (Targeted Protein Degrader) Highlights

- Advanced plans for filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in the first half of 2023 after completing the pre-IND meeting process
- Presented favorable preclinical results at the 5th Annual Targeted Protein Degrader Summit showing:
    - Potent cereblon binding, efficient degradation of select proteins and induction of cell death in both lymphoma and multiple myeloma cell lines
    - Significant increase in tumor growth inhibition compared with lenalidomide (Revlimid®) and pomalidomide (Pomalyst®) in multiple myeloma animal models
- Announced acceptance of an abstract for presentation at the American Society of Hematology (ASH) Annual Meeting showing SP-3164 has:
    - Attractive therapeutic properties compared with avadomide and lenalidomide (Revlimid®)
    - Potential to be administered at lower doses in clinic and provide a more flexible dosing regimen compared with avadomide
    - Increased and rapid protein (IKZF1) degradation compared with lenalidomide (Revlimid®) and avadomide
    - Significantly increased tumor growth inhibition as a monotherapy compared with lenalidomide (Revlimid®) in an established lymphoma mouse model

"The third quarter and recent weeks were productive yet challenging for Salarius. SP-3164, our promising targeted protein degrader or molecular glue, has been generating exciting preclinical data and commensurate interest within the scientific community. Next month at the 64th ASH annual meeting, one of blood cancer's most prestigious events of the year, Dr. Daniela Santiesteban, our director of targeted protein degradation development, will deliver a poster presentation providing an update on additional SP-3164 research data that we believe continue to support our excitement surrounding SP-3164. We remain focused on SP-3164 IND-enabling studies and are on track to submit the IND in the first half of 2023 and to begin clinical trials shortly thereafter," said David Arthur, CEO of Salarius.

Seclidemstat (Targeted Protein Inhibitor) Highlights

- Announced acceptance of an abstract for a presentation at ASH by collaborators at the University of Texas MD Anderson Cancer Center showing that in six patients with myelodysplastic syndrome or chronic myelomonocytic leukemia, the combination of

seclidemstat with azacitidine appeared safe at current dose levels and showed initial signs of potential activity
    - Response to therapy was observed in two patients including one patient with a complete marrow response and another patient with a complete marrow response plus hematologic improvement who transitioned to allogeneic stem-cell transplantation, which is generally considered as a potential curative treatment
- On October 18, 2022, enrollment of new patients in the Salarius-sponsored seclidemstat sarcoma clinical trial and the MD Anderson investigator-initiated hematologic clinical trial was voluntarily paused due to a suspected unexpected serious adverse reaction (SUSAR); patients currently enrolled in both studies are able to continue treatment after consulting with their physician
    - The U.S. Food and Drug Administration (FDA) subsequently agreed with Salarius' approach and placed the sarcoma trial on partial clinical hold; Salarius is working with the FDA to further analyze the available data with the goal of understanding how best to proceed and restart enrollment
- Salarius plans to report interim results from the Phase 1/2 study of seclidemstat in Ewing sarcoma and FET-rearranged sarcomas before the end of the year

Mr. Arthur continued, "Independent investigators at MD Anderson also had an abstract accepted for presentation at the upcoming ASH meeting and exhibition, focused on seclidemstat. The abstract concludes that in the six hematologic or blood cancer patients for whom data was available, the combination of seclidemstat with azacitidine seems safe at the current dose levels and shows signs of potential activity. Further enrollment and follow-up will continue to explore this combination. We believe this interim data is an encouraging development for these patients in need of new treatment options and we are looking forward to an additional data update next month."

Mr. Arthur concluded, "Although recent months were punctuated by highs and lows, we remain optimistic about the company's prospects. We are delighted to be part of the protein degradation sector of drug development, an exciting opportunity driven by the commercial success of first-generation molecular glues that together had 2021 global sales of more than $16 billion. We also remain excited about seclidemstat and look forward to reporting interim clinical data that could signal the potential for new treatment options. We are looking forward to the additional updates on both programs later this year."

Third Quarter Financial Results

Net loss for the third quarter of 2022 was $14.4 million, or $6.41 per share, compared with a net loss of $3.7 million, or $2.09 per share, for the third quarter of 2021. The increase in net loss was due to higher operating expenses, including development spending on SP-3164, which was acquired in January 2022. Net loss for the third quarter of 2022 included a non-cash charge of $8.9 million for impairment of goodwill related to the 2019 reverse merger with Flex Pharma, Inc.

Net cash used for operating activities during the third quarter of 2022 was $5.7 million, compared with $1.6 million during the same quarter last year.

Nine Month Financial Results

Net loss for the first nine months of 2022 was $25.2 million, or $12.13 per share, compared with a net loss of $8.7 million, or $5.41 per share, for the first nine months of 2021. The increase in net loss was primarily due to a $8.9 million one-time nonrecurring non-cash charge for impairment of goodwill, higher research and development expenses primarily resulting from the acquisition and development of SP-3164, higher seclidemstat development costs and higher general and administrative expenses. The 2021 period included grant revenue of $1.8 million, with no such revenue in 2022.

Net cash used in operating activities for the first nine months of 2022 was $12.9 million, compared with $7.5 million for the prior-year period. The increase was primarily due to higher research and development expenses.

As of September 30, 2022, Salarius had cash, cash equivalents and restricted cash of $16.8 million, compared with $29.2 million as of December 31, 2021. Current cash and cash equivalents are expected to fund the company's planned operations into the second half of 2023.

About Salarius Pharmaceuticals
Salarius Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing therapies for patients with cancer in need of new treatment options. Salarius' product portfolio includes seclidemstat, the company's lead candidate, 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 certain additional sarcomas that share a similar biology. Seclidemstat has received fast track, orphan drug and rare pediatric disease designations 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 an investigator-initiated Phase 1/2 clinical study in hematologic cancers at MD Anderson Cancer Center. Salarius has received financial support from the National Pediatric Cancer Foundation to advance the Ewing program and was a recipient of a Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). SP-3164 is currently in IND-enabling studies and anticipated to enter the clinic in 2023. For more information, please visit salariuspharma.com or follow Salarius on Twitter and LinkedIn.

Forward-Looking Statements
This announcement and the referenced presentation contain "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 presentation are forward-looking statements. These forward-looking statements may be identified by terms such as "will," "future," "believe," "developing," "expect," "may," "progress," "potential," "could," "look forward," "might," "should," and similar terms or expressions or the negative thereof. Examples of such statements include, but are not limited to, statements relating to the following: our future development plans for our product candidates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations with respect to the release of data from our clinical trials and the expected timing thereof; the potential for our product candidates to achieve success in clinical trials; and our expected financial condition, including the anticipation duration of cash runways and timing regarding needs for additional capital; and the impact that the addition of new clinical sites will have on the development of our product candidates. We 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: resolution of the FDA's partial clinical hold on the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas following the SUSAR; our ability to resume enrollment in the clinical trial following its review of the available data surrounding the SUSAR; anticipated pre-clinical studies and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested product candidate; we may elect to change our strategy regarding our product candidates and clinical development activities; we may not receive the necessary regulatory approvals for the clinical development of our products; economic and market conditions may worsen; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt our clinical development programs; and other risks described in our filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as revised or supplemented by its Quarterly Reports on Form 10-Q and other documents filed with the SEC. The forward-looking statements contained in this announcement and the referenced presentation speak only as of the date of this announcement and the referenced

presentation and are based on management's assumptions and estimates as of such date. We disclaim 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:

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SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	9/30/2022	12/31/2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 16,820,220	$ 29,214,380
Prepaid expenses and other current assets	1,145,812	949,215
Total current assets	17,966,032	30,163,595
Grants receivable from CPRIT	1,610,490	1,610,490
Other assets	146,461	193,874
Goodwill	—	8,865,909
Total assets	$ 19,722,983	$ 40,833,868
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,716,580	$ 1,543,096
Accrued expenses and other current liabilities	1,393,867	567,787
Total liabilities	3,110,447	2,110,883
Commitments and contingencies (Note 5)		
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; 2,249,371 and 1,809,593 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	224	181
Additional paid-in capital	74,046,524	70,919,996
Accumulated deficit	(57,434,212)	(32,197,192)
Total stockholders' equity	16,612,536	38,722,985
Total liabilities and stockholders' equity	$ 19,722,983	$ 40,833,868

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30		Nine Months Ended September 30	
	2022	**2021**	**2022**	**2021**
Revenue:				
Grant revenue	$ —	$ —	$ —	$ 1,840,216
Operating expenses:				
Research and development	3,790,123	2,015,930	11,151,170	5,852,887
General and administrative	1,832,032	1,730,730	5,346,181	4,655,404
Loss on impairment of goodwill	8,865,909	—	8,865,909	—
Total operating expenses	14,488,064	3,746,660	25,363,260	10,508,291
Loss before other income (expense)	(14,488,064)	(3,746,660)	(25,363,260)	(8,668,075)
Change in fair value of warrant liability	335	9,073	12,570	5,205
Interest income (expense), net	78,272	487	113,670	(495)
Loss from continuing operations	**(14,409,457)**	**(3,737,100)**	**(25,237,020)**	**(8,663,365)**
Net loss	**$ (14,409,457)**	**$ (3,737,100)**	**$ (25,237,020)**	**$ (8,663,365)**
Loss per common share — basic and diluted	**$ (6.41)**	**$ (2.09)**	**$ (12.13)**	**$ (5.41)**
Weighted-average number of common shares outstanding — basic and diluted	2,247,753	1,792,190	2,081,023	1,602,565

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