

# 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 1, 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 8.01 Other Events.**

On October 18, 2022, Salarius Pharmaceuticals announced that per protocol design, it voluntarily paused new patient enrollment in the Company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas. At the time, Salarius also announced that the company's independent Safety Review Committee for the clinical trial determined that patients currently receiving seclidemstat treatment could continue treatment after consulting with their physician.

During a conference call with the US Food and Drug Administration (FDA) on Tuesday, November 1, 2022, the FDA informed Salarius that the agency agreed with the voluntary enrollment pause and, as an administrative action, the FDA provided verbal notification that the Ewing sarcoma and FET-rearranged sarcoma trial was on partial clinical hold. While on partial clinical hold, FDA informed Salarius that the pause in patient enrollment shall remain in place and patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. FDA's clinical hold procedures provide Salarius with an administrative process to work with the FDA to analyze the available data, adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment.

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**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 3, 2022

By:

/s/ Mark J. Rosenblum

Mark J. Rosenblum  
Chief Financial Officer