

**UNITED STATES
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): September 10, 2025

SOLENO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36593
(Commission
File No.)

77-0523891
(IRS Employer
Identification Number)

**100 Marine Parkway, Suite 400
Redwood City, CA 94065**
(Address of principal executive offices)

(650) 213-8444
(Registrant's telephone number, including area code)

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:

- 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 symbols	Name of each exchange on which registered
Common Stock, \$0.001 par value	SLNO	NASDAQ

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 7.01 Regulation FD Disclosure

Soleno Therapeutics, Inc. is aware that a serious adverse event has been reported in the U.S. Food and Drug Administration's (FDA) Adverse Event Reporting System (FAERS) regarding a patient who is deceased. The treating physician has reported the case as not related to treatment with VYKAT™ XR and Soleno's assessment is the same.

This patient was a 17-year-old male with a history of co-morbidities, including lymphedema, superficial thrombophlebitis (treated and followed by a vascular surgery team), and obesity (326 lbs.) who died from an apparent pulmonary embolus.

VYKAT XR has a proven safety and efficacy profile and was approved by the FDA following a rigorous clinical program. Like any medication, VYKAT XR should be administered in accordance with its FDA-approved label, which describes anticipated side effects. Soleno Therapeutics is committed to reporting all adverse events experienced by individuals who have taken VYKAT XR in accordance with applicable law. Prader Willi Syndrome is a disease where patients have significant comorbidities and have a markedly reduced life expectancy due to reasons that can include cardiac or respiratory events as well as others such as pulmonary embolism. The mean age of death reported from a 40-year mortality study in the U.S. was 29.5 ± 15 years (range: 2 months—67 years). Going forward, Soleno does not intend to specifically comment on adverse events cases (including deaths) unless directly related to VYKAT XR use and unexpected per the U.S. Prescribing Information.

The existence of a report in the FAERS database does not establish causation. The FDA's website makes this clear: "For any given report, there is no certainty that a suspected drug caused the event. While consumers and healthcare professionals are encouraged to report adverse events, the event may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons." Additionally, the FDA states "Submission of a report does not mean that the information included in it has been medically confirmed nor it is an admission from the reporter that the drug caused or contributed the event."

The information under this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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.

SOLENO THERAPEUTICS, INC.

Date: September 10, 2025

By: /s/ Anish Bhatnagar
Anish Bhatnagar
Chief Executive Officer