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): July 21, 2025

Sarepta Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-14895**	**93-0797222**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
215 First Street **Cambridge, Massachusetts** **(Address of Principal Executive Offices)**		**02142** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 274-4000

(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:

☐ 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, $0.0001 par value per share	SRPT	Nasdaq Global Select 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 July 21, 2025, the Company announced that the U.S. Food and Drug Administration ("FDA") has placed a clinical hold on the Company's investigational gene therapy clinical trials for limb girdle muscular dystrophy ("LGMD"). The hold includes the Company's LGMD clinical trials related to its product candidates SRP-9003 (LGMD2E/R4/bidridistrogene xeboparvovec), SRP-9004 (LGMD2D/patidistrogene bexoparvovec), SRP-6004 (LGMD2B/R2), and SRP-9005 (LGMD2C/R5 g-sarcoglycan).

The Company previously announced on July 16, 2025 that it had paused each of the LGMD programs mentioned above as part of a strategic restructuring process, with the exception of SRP-9003. On December 18, 2024, the Company announced completion of enrollment and dosing in SRP-9003-301, the Phase 3 clinical trial of SRP-9003. The Company intends to seek to discuss with FDA the potential pathway to submit a Biologics License Application to FDA seeking accelerated approval for SRP-9003 after the clinical hold is lifted.

Also on July 21, 2025, the Company announced that FDA has revoked the platform technology designation for the Company's AAVrh74 platform technology previously granted on June 2, 2025.

Forward Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Any statements contained in this report that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "expects," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements regarding the Company's intentions related to SRP-9003.

These forward-looking statements involve risks and uncertainties, many of which are beyond the Company's control. Actual results could materially differ from those stated or implied by these forward-looking statements as a result of such risks and uncertainties. Known risk factors include the following: clinical development is lengthy and uncertain and clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which could have a material adverse impact on our business; because we are developing product candidates for the treatment of certain diseases in which there is little clinical experience and we are using new endpoints or methodologies, there is increased risk that the FDA, the European Medicines Agency or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze, and, accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent full or accelerated regulatory approval; and those risks identified under the heading "Risk Factors" in Sarepta's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC), as well as other SEC filings made by the Company which you are encouraged to review.

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 thereunto duly authorized.

Sarepta Therapeutics, Inc.

Date: July 21, 2025

By: /s/ Douglas S. Ingram
Douglas S. Ingram
Chief Executive Officer