

Sarepta Therapeutics, Inc.
Form 8-K
May 03, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): May 3, 2018

Sarepta Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-14895
(Commission

File Number)
215 First Street

Suite 415

93-0797222
(IRS Employer

Identification No.)

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Cambridge, MA 02142

(Address of principal executive offices, including zip code)

(617) 274-4000

(Registrant's telephone number, including area code)

(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))

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.

On May 3, 2018, Sarepta Therapeutics, Inc. issued a press release announcing, among other things, that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has rendered a negative trend vote following an oral explanation of the Company's Marketing Authorization Application (MAA) for eteplirsen. The Company plans to seek a re-examination and request that a Scientific Advisory Group (SAG) be convened to provide expert guidance and insight into different neuromuscular issues, including the validity of the external controls used and the importance of significantly slowing pulmonary decline in patients with Duchenne muscular dystrophy. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference, including the cautionary statement on forward-looking statements included in the press release regarding the Company's plan to seek a re-examination and request that a SAG be convened.

At the oral explanation, the Company presented and had a Q&A session with CHMP members per standard meeting protocol. A copy of the presentation is furnished as Exhibit 99.2 and is incorporated herein by reference.

The information in this report furnished pursuant to Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed filed for the 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. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

Number	Description
99.1	<u>Press release dated May 3, 2018.</u>
99.2	<u>Oral Explanation Presentation Slides</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.

Sarepta Therapeutics, Inc.

By: /s/ Douglas S. Ingram
Douglas S. Ingram

President and Chief Executive Officer

Date: May 3, 2018