Sarepta Therapeutics, Inc.
Form 8-K
January 15, 2016

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): January 15, 2016

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	

Suite 7

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))

Item 7.01 Regulation FD Disclosure.

On January 15, 2016, the U.S. Food and Drug Administration (the FDA) posted on its web site the FDA Briefing Information (the FDA Briefing Information) for the January 22, 2016 meeting of the Peripheral and Central Nervous System Drug Advisory Committee (the Advisory Committee Meeting) to review the New Drug Application filed by Sarepta Therapeutics, Inc. (the Company) for eteplirsen as a treatment for Duchenne muscular dystrophy. In addition to the FDA Briefing Information, the FDA also posted the Company s Briefing Information, which includes an addendum submitted by the Company with a comparison of 4 year ambulation data between study 202 subjects and an external control (collectively, the Sarepta Briefing Information), for the Advisory Committee Meeting on its web site. The Company is not responsible for the content of, nor the statements made in, the FDA Briefing Information.

The FDA Briefing Information and the Company Briefing Information posted by the FDA may be obtained by following this pathway to the FDA web site:
[http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAd

Committee/ucm478063.htm].

The information in this report furnished pursuant to Item 7.01 shall not be deemed filed for the purposes of Section 18 of the Securities and 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.

* * *

By filing this report and furnishing this information, the Company makes no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of the Company s filings with the SEC and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

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/ Edward Kaye
Edward Kaye
Interim Chief Executive Officer, Senior Vice President and Chief Medical Officer

Date: January 15, 2016