Sarepta Therapeutics, Inc.
Form 8-K
October 27, 2014

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): October 27, 2014

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 415

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 8.01 Other Events.

On October 27, 2014, Sarepta Therapeutics, Inc. (the Company) issued a press release announcing that it has received additional guidance from the U.S. Food and Drug Administration (the FDA) regarding the information to be provided as part of the Company s planned submission of a New Drug Application (NDA) for the approval of eteplirsen for the treatment of Duchenne muscular dystrophy. In its correspondence with the Company, the FDA requested certain additional data as part of the NDA submission and indicated that further discussion would be needed to determine the information required to constitute a complete submission.

The Company further announced that based on the FDA s requests for additional data and further discussion, it plans to submit its NDA mid-year 2015. The press release making such announcements is attached to this filing as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press release dated October 27, 2014

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/ Christopher Garabedian
Christopher Garabedian
President and Chief Executive Officer

Date: October 27, 2014

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated October 27, 2014.