Sarepta Therapeutics, Inc.
Form 8-K
February 14, 2019

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): February 14, 2019

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 Instructions 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 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 February 14, 2019, Sarepta Therapeutics, Inc. (the "Company") announced that the United States Food and Drug Administration ("FDA"), Division of Neurology, has accepted the Company's New Drug Application seeking accelerated approval for golodirsen (SRP-4053) and provided a regulatory action date of August 19, 2019. The FDA has also granted Priority Review Status for golodirsen.

This Current Report on Form 8-K contains certain forward-looking statements. All statements other than historical or current facts are forward-looking statements, including, without limitation, the statement regarding the expected regulatory action date of August 19, 2019. These forward-looking statements involve risks and uncertainties, many of which are beyond the Company's control. Known risk factors include, among others: the Company may not be able to complete clinical trials required by the FDA for approval of golodirsen; priority review status for golodirsen may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that golodirsen will receive marketing approval; golodirsen may not result in a viable treatment suitable for commercialization due to a variety of reasons including the results of future research may not be consistent with past positive results or may fail to meet regulatory approval requirements for the safety and efficacy of product candidates; and even if golodirsen results in a commercialized product, the Company may not achieve any significant revenues from the sale of such product; and the Company may not be able to execute on its business plans, including meeting its expected or planned regulatory milestones and timelines, clinical development plans, and bringing its products to U.S. and ex-U.S. markets for various reasons including possible limitations of company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner, and regulatory, court or agency decisions, such as decisions by the United States Patent and Trademark Office with respect to patents that cover the Company's product candidates. The Company does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

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: February 14, 2019