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): April 21, 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 April 21, 2014, Sarepta Therapeutics, Inc. issued a press release announcing its plan to submit a New Drug Application to the U.S. Food and Drug Administration by year end 2014 for the approval of eteplirsen for the treatment of Duchenne muscular dystrophy. The press release making such announcement 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 April 21, 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: April 21, 2014

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated April 21, 2014

Exhibit 99.1

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Sarepta Therapeutics Announces Plans to Submit New Drug Application to FDA for Eteplirsen for the Treatment of Duchenne Muscular Dystrophy by Year End 2014

— FDA provides updated guidance on potential early approval pathway for eteplirsen;

— Agreement reached with the Agency on eteplirsen open-label confirmatory studies with enrollment of a broader base of DMD patients later this year;

— FDA provides initial guidance on development of follow-on DMD drug candidates;

— Company to hold teleconference at 8:00 a.m. EDT

CAMBRIDGE, Mass. – April 21, 2014 – Sarepta Therapeutics, Inc. (NASDAQ: SRPT), a developer of innovative RNA-based therapeutics, today announced it plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) by the end of 2014 for the approval of eteplirsen for the treatment of Duchenne muscular dystrophy (DMD). Eteplirsen is Sarepta's lead exon-skipping drug candidate in development for the treatment of patients with DMD who have a genotype amenable to skipping of exon 51.

The plan to submit an NDA for eteplirsen by the end of 2014 is based on a guidance letter from the Agency that proposed a strategy regarding the submission of an NDA for eteplirsen under a potential Accelerated Approval pathway and served as the final meeting minutes for four meetings that took place between November, 2013 and March, 2014. The Agency stated that "with additional data to support the efficacy and safety of eteplirsen for the treatment of DMD, an NDA should be fileable," and outlined examples of additional data and analysis that, if positive, will be important to enhance the acceptability of an NDA filing by addressing areas of ongoing concern in the existing dataset. Additionally, the Agency provided clear guidance on an open-label, historically controlled confirmatory study of eteplirsen, as well as initial guidance on a placebo-controlled study of one or more follow-on DMD drug candidates, which, like the open-label study, could also be considered an acceptable confirmatory study to verify the clinical benefit of eteplirsen in the event of an accelerated approval.

"As we announce our plan to submit an eteplirsen NDA by the end of 2014, we are very pleased with the detailed guidance that the FDA has provided us on a potential eteplirsen approval pathway and their support of a historically controlled eteplirsen confirmatory study," said Chris Garabedian, president and chief executive officer of Sarepta Therapeutics. "We also appreciate that the FDA shares our urgency in dosing a broader base of eteplirsen patients and has encouraged us to begin the clinical program with our follow-on exon-skipping drugs as soon as possible."

Based on the Agency's guidance, Sarepta plans to initiate several additional clinical studies with eteplirsen later this year in exon-51 amenable genotypes. These studies will include a clinical trial with predefined efficacy endpoints for ambulatory patients between the ages of 7 to 16 years who can walk a minimum distance, and two additional clinical trials that will evaluate safety and biomarkers in DMD patients younger than 7 years and DMD patients who have advanced in their disease progression to a point they cannot walk a minimum distance or have become non-ambulant. Additionally, Sarepta plans to initiate a placebo-controlled study with one or more of its follow-on DMD exon-skipping drug candidates by the end of the year.

"We are excited to have guidance from the FDA that allows us to move quickly into additional clinical trials with eteplirsen to confirm our current understanding of eteplirsen's safety profile, its effect on dystrophin production, and its impact on clinical outcomes in DMD patients," said Edward Kaye, M.D., senior vice president and chief medical officer of Sarepta Therapeutics. "We are particularly pleased that the FDA shares our interest in accelerating the clinical development of our follow-on exon-skipping drugs and we expect to initiate enrollment in this trial later this year."

Sarepta plans to immediately take steps to initiate the additional eteplirsen clinical studies with the goal of beginning dosing in the confirmatory study in the third quarter, with dosing in the additional trials (i.e., younger and more advanced DMD patients) to begin later this year. Once available, detailed study eligibility criteria and clinical site information will be posted on www.ClinicalTrials.gov and Let's Skip Ahead, an online resource center from Sarepta for the DMD community available at www.SkipAhead.com.

Excerpts from the FDA's letter on an NDA filing included:

"…with additional data to support the efficacy and safety of eteplirsen for the treatment of DMD, described below, an NDA should be fileable (assuming other aspects of the submitted application meet applicable standards). As we are sure you appreciate, however, our willingness to consider an application for filing cannot be taken to suggest the outcome of our review. We also note that if the application is filed, you should expect public discussion of the NDA at an Advisory Committee meeting."

The FDA outlined two potential pathways to accelerated approval:

"1. The clinical data from Study 201/202 [Phase IIb clinical trial program] on 6-minute walk could be considered a finding on an intermediate clinical endpoint that could have the potential to support accelerated approval."

Related to this first pathway to Accelerated Approval, the Agency stated that they have "significant concerns regarding our ability to draw valid conclusions based on the Study 201/202 data with respect to walking performance and other data," and identified areas relating to the interpretation of the existing data set that will be addressed as part of an NDA review once the NDA is filed.

"2. We have discussed the possibility of using a number of modalities to quantify dystrophin in muscle biopsies, and discussed how these biomarkers might be used as a surrogate endpoint(s) to support accelerated approval."

In evaluating this pathway, the FDA expressed concerns about methodological problems in the assessments of dystrophin and, "remain skeptical about the persuasiveness of the (dystrophin) data" and, as a result, the Agency is "uncertain whether the existing dystrophin biomarker data will be persuasive enough to serve as a surrogate endpoint that is reasonably likely to predict clinical benefit." However, the Agency further states that if they "were to find the biomarker data to be adequate upon detailed review, however, they would have the potential to support accelerated approval." To that end, the Agency proposed "a collaborative effort in which we will work to better understand the methods and analyses used for the existing biomarker data," and "also work together on methods for the collection of additional data that could be more reliable."

Furthermore, the Agency suggested that "another approach to demonstrating an effect of eteplirsen on dystrophin protein production would be to obtain a fourth muscle biopsy in patients who are continuing in Study 202," which could serve to enhance the acceptability of an NDA filing and accelerated approval.

Under either potential application of the Accelerated Approval pathway, the FDA's letter included comments expressing both a desire for more eteplirsen safety and efficacy data and a willingness to consider supplemental data in an NDA filing or during an NDA review (following the NDA filing) from the ongoing Study 202 and early safety and biomarker data from a confirmatory eteplirsen study. The Agency also encouraged Sarepta to collect safety and biomarker data with eteplirsen in a broader population of patients, including DMD patients who were younger, older and non-ambulant, and previously treated with drisapersen.

Additional excerpts from the FDA's letter on the eteplirsen and follow-on exon-skipping drug confirmatory studies:

"…any accelerated approval [of eteplirsen] would necessitate confirmatory studies to verify the clinical benefit. Confirmatory studies should be underway at the time of approval."

The FDA outlined two approaches for confirmatory trials and urged Sarepta to "initiate both of these trials as soon as possible."

"1. A historically-controlled trial might be acceptable to confirm clinical benefit following accelerated approval."

"2. A randomized, placebo-controlled trial of another PMO [phosphorodiamidate morpholino oligomer] with a similar mechanism of action, directed at a different exon (e.g., SRP-4053 or SRP-4045), with a demonstration of a correlation between dystrophin production and definitive clinical benefit on 6-minute walk or another measure, could provide confirmatory evidence of eteplirsen's clinical benefit if approval were based on a surrogate endpoint."

Conference Call Information

The conference call may be accessed by dialing 800.708.4539 for domestic callers and 847.619.6396 for international callers. The passcode for the call is 37151466. Please specify to the operator that you would like to join the "Sarepta Therapeutics Regulatory Update Call." The conference call will be webcast live under the investor relations section of Sarepta's website at www.sarepta.com. Please connect to Sarepta's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. An audio replay will be available through May 5, 2014 by calling 888.843.7419 or 630.652.3042 and entering access code 37151466.

About Duchenne Muscular Dystrophy

DMD is an X-linked rare degenerative neuromuscular disorder causing severe progressive muscle loss and premature death. DMD affects approximately one in every 3,500 boys born worldwide. A devastating and incurable muscle-wasting disease, DMD is associated with specific errors in the gene that codes for dystrophin, a protein that plays a key structural role in muscle fiber function. Progressive muscle weakness in the lower limbs spreads to the arms, neck and other areas. Eventually, increasing difficulty in breathing due to respiratory muscle dysfunction requires ventilation support, and cardiac dysfunction can lead to heart failure. The condition is universally fatal, and death usually occurs before the age of 30.

About Eteplirsen and Sarepta's Proprietary Exon-Skipping Platform Technology

Eteplirsen is Sarepta's lead drug candidate and is designed to address the underlying cause of DMD by enabling the production of a functional dystrophin protein. Data from clinical studies of eteplirsen in DMD patients have demonstrated a broadly favorable safety and tolerability profile and restoration of dystrophin protein expression.

Eteplirsen uses Sarepta's novel phosphorodiamidate morpholino oligomer (PMO)-based chemistry and proprietary exon-skipping technology to skip exon 51 of the dystrophin gene enabling the repair of specific genetic mutations that affect approximately 13 percent of the total DMD population. By skipping exon 51, eteplirsen may restore the gene's ability to make a shorter, but still functional, form of dystrophin from messenger RNA, or mRNA. Promoting the synthesis of a truncated dystrophin protein is intended to stabilize or significantly slow the disease process and prolong and improve the quality of life for patients with DMD.

Sarepta also has seven additional PMO-based exon-skipping drugs in earlier stages of development that are intended to treat other genetic sub-groups of DMD patients by skipping exons 53, 45, 50, 44, 52, 55 or 8. Overall, Sarepta's current pipeline of exon-skipping drug candidates has the potential to treat nearly half of all patients with DMD. In addition, the company is committed to exploring the potential of its technology in the future to address all patients with DMD who may be candidates for an exon skipping therapy, even those with rare genetic mutations.

About the Accelerated Approval Regulatory Pathway

To speed the development and availability of new medicines for serious and life-threatening diseases, the FDA has the authority to grant accelerated approval based on evidence that an investigational new drug provides a meaningful therapeutic benefit over existing treatments. The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (Section 901) reinforced the FDA's authority to grant marketing approval on the basis of adequate and well-controlled clinical trials that show the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The FDA typically requires a drug sponsor to conduct post-marketing studies to verify and describe the clinical benefit of a medicine approved under the Accelerated Approval pathway.

For more information, please see "Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses" (21 C.F.R. Part 314, Subpart H) available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=314&showFR=1&subpartNode=21%3A5.0.1.1.4.8 .

About Sarepta Therapeutics

Sarepta Therapeutics is focused on developing first-in-class RNA-based therapeutics to improve and save the lives of people affected by serious and life-threatening rare and infectious diseases. The Company's diverse pipeline includes its lead program eteplirsen, for Duchenne muscular dystrophy, as well as potential treatments for some of the world's most lethal infectious diseases. Sarepta aims to build a leading, independent biotech company dedicated to translating its RNA-based science into transformational therapeutics for patients who face significant unmet medical needs. For more information, please visit us at www.sarepta.com.

Looking Statements and Information

This press release contains forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "believes or belief," "anticipates," "plans," "expects," "will," "intends," "potential," "possible," "advance" and similar expressions. These forward-looking statements include statements about the timing of an NDA submission for eteplirsen in the treatment of DMD; the potential filing and acceptance of an NDA for eteplirsen by the FDA; the timing and submission of additional data, analysis and other information to the FDA necessary for the FDA to make regulatory determinations; the timing of and ability to initiate additional studies for eteplirsen and other follow-on exons; and the potential regulatory approval of eteplirsen on an accelerated pathway.

Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others: we may not be able to comply with all FDA requests; the FDA may determine that substantial additional data is required for accelerated or other approval of eteplirsen or that our NDA submission for eteplirsen does not qualify for filing, even with additional information; the results of our ongoing and new clinical trials may not be positive; there may be delays in timelines relating to an NDA submission, initiating clinical trials, or making a product commercially available for regulatory or internal reasons; we may not be able to manufacture sufficient supply for clinical trials or commercialization; and those identified under the heading "Risk Factors" in Sarepta's Annual Report on Form 10-K for the year ended December 31, 2013, and filed with the Securities and Exchange Commission, and Sarepta's other filings with the SEC.

Any of the foregoing risks could materially and adversely affect Sarepta's business, results of operations and the trading price of Sarepta's common stock. For a detailed description of risks and uncertainties Sarepta faces, you are encouraged to review the Company's filings with the Securities and Exchange Commission. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

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