Sarepta Therapeutics, Inc.
Form 8-K
October 04, 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): October 3, 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 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 1.01 Entry into a Material Definitive Agreement.
License and Collaboration Agreement

On October 3, 2016, Sarepta Therapeutics, Inc. (the Company or Sarepta) entered into an exclusive Collaboration and License Agreement (the Collaboration Agreement) with Summit (Oxford) Ltd, a company organized and existing under the laws of England and Wales (Summit), pursuant to which Summit granted the Company the exclusive right to commercialize products in Summit s utrophin modulator pipeline in the European Union, Switzerland, Norway, Iceland, Turkey and the Commonwealth of Independent States (the Licensed Territory). Such products include Summit s lead product candidate, ezutromid, for the treatment of Duchenne muscular dystrophy (DMD) and its second generation and future generation small molecule utrophin modulators (collectively, the Licensed Products). Summit also granted the Company an option to expand the Licensed Territory to include Latin America. Summit retains commercialization rights in the rest of the world.

Financial Obligations

Under the terms of the Collaboration Agreement, the Company will pay an upfront payment of $40.0 million to Summit within 10 days of entry into the Collaboration Agreement. In addition, Summit will be eligible to receive up to $42.0 million from the Company in specified development milestones for ezutromid, including a $22.0 million milestone, payable on or after April 1, 2017, following the first dosing of the last patient in the Summit s ongoing Phase 2 clinical trial of ezutromid, which is referred to as PhaseOut DMD, and up to $150.0 million from the Company in specified regulatory milestones related to ezutromid in the Licensed Territory. Summit will also be eligible to receive up to $65.0 million in specified development milestones and up to $225.0 million in specified regulatory milestones from the Company for its second generation and future generation small molecule utrophin modulators in the Licensed Territory.

In addition, Summit will also be eligible to receive up to $330.0 million from the Company in specified sales milestones on a product-by-product basis, as well as tiered, escalating royalties ranging from a low to high teens percentage of net sales on a product-by-product basis in the Licensed Territory. The royalties are subject to potential reductions, including for a specified portion of royalty payments that the Company may become required to pay under any third-party license agreements, subject to a maximum royalty reduction.

Research and Development

Under the Collaboration Agreement, the Company and Summit have agreed to collaborate on the research and development of the Licensed Products pursuant to a joint development plan through a joint steering committee comprised of an equal number of representatives from each of the Company and the Summit. The Company has the final decision making authority with respect to commercialization decisions of the Licensed Products in the Licensed Territory. If the joint steering committee elects not to pursue development of a second generation (or future generation) small molecule utrophin modulator candidate, then Summit may engage, under certain circumstances, in the development of such candidate for commercialization outside of the Licensed Territory and outside of the Collaboration Agreement, subject to the Company s option, exercisable at the Company s discretion and only available to the Company under certain specified circumstances, to bring such candidate under the Collaboration Agreement.

Under the Collaboration Agreement, Summit will be solely responsible for all research and development costs for the Licensed Products until December 31, 2017. Thereafter, Summit will be responsible for 55.0% of the budgeted research and development costs related to the Licensed Products in the Licensed Territory, and the Company will be responsible for 45.0% of such costs. Any costs in excess of 110.0% of the budgeted amount are borne by the party that incurred such costs. Summit is also obligated to spend a specified minimum amount on the research and development of certain Licensed Products prior to the end of 2019.

Manufacture and Supply of Licensed Products

Summit has agreed to use commercially reasonable efforts to supply to the Company active pharmaceutical ingredient, finished drug product and placebo for the Company to conduct research, development and commercialization activities for the Licensed Products in accordance with the Collaboration Agreement. The Company also will have the right to establish back up and second source suppliers under certain circumstances.

Intellectual Property

Under the terms of the Collaboration Agreement, each party will own the entire right, title and interest in and to all know-how and patent rights first made or invented solely by the employees or consultants of such party in the course of the collaboration, and all such know-how and patent rights will be included in the licenses granted to the other party under the Collaboration Agreement. The parties will jointly own all rights, title and interests in and to all know-how and patent rights first made or invented jointly by employees or consultants of the parties in the course of the collaboration.

Latin America Option

Under the Collaboration Agreement, the Company has an exclusive option (the Latin America Option) to expand the Licensed Territory to include specified countries in South and Central America (the Option Territory). The Company may exercise the Latin America Option at any time prior to the date that is three months following the first receipt of regulatory approval for a Licensed Product in the United States or the European Union. The Company is required to pay Summit up to $17 million for the exercise of the Latin America Option and achievement of certain regulatory milestones. If Sarepta exercises the Latin America Option, it will be solely responsible for all research, development and commercialization costs of the Licensed Products that are specific to the Option Territory. Sarepta is also required to pay Summit up to $82.5 million in specified sales milestones on a product-by-product basis in the Option Territory as well as royalties at the same rates as elsewhere in the Licensed Territory.

Commercialization

Under the Collaboration Agreement, the Company will be solely responsible for all commercialization activities and associated costs, relating to Licensed Products in the Licensed Territories. Sarepta has agreed to use commercially reasonable efforts to commercialize Licensed Products in specified countries within the Licensed Territories and, if the Latin America Option is exercised, to use commercially reasonable efforts to commercialize Licensed Products in certain specified countries within the Option Territory.

Termination

Unless earlier terminated, the Collaboration Agreement will expire on a Licensed Product-by-Licensed Product and country-by-country basis upon the expiration of the royalty term in such country for such Licensed Product. The Collaboration Agreement may be terminated by the Company upon six months prior written notice in its entirety or on a Licensed Product-by-Licensed Product and country-by-country basis. Either party may, subject to a cure period, terminate the Collaboration Agreement in the event of the other party s uncured material breach. The Company may

also terminate the Collaboration Agreement under specified circumstances relating to the safety or regulatory approvability of ezutromid.

Except with respect to a second generation (or future generation) small molecule utrophin modulator candidate that the joint steering committee elects not to pursue, as described above, during the term of the Collaboration

Agreement the parties are prohibited from commercializing small molecule utrophin modulators anywhere in the world outside of the collaboration. Such exclusivity commitment may survive for one year following termination with respect to one party depending upon the circumstances of termination.

Standstill

The Collaboration Agreement also contains a standstill provision pursuant to which, among other things, each party has agreed that, for a period from the execution of the Collaboration Agreement until the date that regulatory approval is first received for a Licensed Product, subject to certain exceptions, or unless invited in writing by the other party to do so, neither party nor its respective affiliates will, directly or indirectly: (i) effect or seek, offer or propose to effect, or cause or participate in any acquisition of securities or assets of the other party; any tender or exchange offer, merger, consolidation or other business combination involving the other party; any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the other party; or any solicitation of proxies or consents to vote any voting securities of the other party, or in any way advise or, assist any other person in doing so; (ii) form, join or in any way participate in a group with respect to any securities of the other party; (iii) act in concert with any person in relation to voting securities of the other party; (iv) otherwise act to seek to control or influence the management, board of directors or policies of the other party; (v) take any action reasonably expected to force the other party to make a public announcement regarding any such matters; or (iv) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing.

The foregoing description of certain terms of the Collaboration Agreement does not purport to be complete, is intended to be a summary of the material terms of the agreement and is qualified in its entirety by reference to the Collaboration Agreement Sarepta intends to file as an exhibit to its next quarterly report filing on form 10-Q. A copy of the press release announcing the Collaboration Agreement is included as Exhibit 99.1 hereto and is incorporated herein by reference, including the cautionary statement on forward-looking statements included in the press release regarding the Collaboration Agreement.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits.

Exhibit Number	**Description**
99.1	Press release dated October 4, 2016

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 M. Kaye, M.D.
Edward M. Kaye, M.D.
President, Chief Executive Officer and

Chief Medical Officer

Date: October 4, 2016

EXHIBIT INDEX

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