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 (State or other jurisdiction of incorporation) 001-14895 (Commission File Number) 93-0797222 (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

Exhibit Number Description

99.1 Press release dated October 4, 2016





Sarepta Therapeutics and Summit Enter Into Exclusive License and Collaboration Agreement for European Rights to Summit's Utrophin Modulator Pipeline for the Treatment of Duchenne Muscular Dystrophy

- Sarepta and Summit collaborate to advance the development of novel therapies for patients with Duchenne muscular dystrophy
- Summit receives \$40 million upfront, with potential future ezutromid-related milestone payments totalling up to \$522 million plus royalties
- Sarepta and Summit to share research and development costs
- · Sarepta also receives option for Latin American rights

Cambridge, MA, and Oxford, UK, 4 October 2016 – Sarepta Therapeutics (NASDAQ: SRPT) and Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM) today announced that they have entered into an exclusive license and collaboration agreement granting Sarepta rights in Europe, as well as in Turkey and the Commonwealth of Independent States ('the licensed territory'), to Summit's utrophin modulator pipeline, including its lead clinical candidate, ezutromid, for the treatment of Duchenne muscular dystrophy ('DMD'). As part of the agreement, Sarepta also obtains an option to license Latin American rights to Summit's utrophin modulator pipeline. Summit retains commercialization rights in all other countries.

Utrophin modulation is a potential disease-modifying treatment for all patients with the fatal muscle wasting disease DMD, regardless of their underlying dystrophin gene mutation. Ezutromid is currently in a Phase 2 proof of concept trial called PhaseOut DMD.

"This partnership with Summit Therapeutics furthers our commitment to invest in innovative approaches to treating Duchenne and supports our common goal of improving the lives of patients with DMD," said Edward Kaye, M.D., Sarepta's Chief Executive Officer. "Summit's utrophin modulation technology represents a potentially promising approach to treat DMD, which may complement our current approach of exon skipping therapy."

"Sarepta Therapeutics has paved the way in the development of disease-modifying therapies for DMD with the first FDA-approved drug in this disease area, making them a strong strategic partner to support our utrophin modulator pipeline," commented Glyn Edwards, Chief Executive Officer of Summit. "This agreement provides us with access to Sarepta's development, regulatory and commercialisation expertise for the continued advancement of our promising utrophin modulator pipeline. We look forward to this partnership and working together to bring great advances to patients and families living with DMD."

Under the terms of the agreement, Summit will receive an upfront fee of \$40 million. In addition, Summit will be eligible for future ezutromid related development, regulatory and sales milestone payments totalling up to \$522 million, including a \$22 million milestone upon the first dosing of the last patient in Summit's PhaseOut DMD trial, and escalating royalties ranging from a low to high teens percentage of net sales in the licensed territory. Summit will also be eligible to receive development and regulatory milestones related to its next-generation utrophin modulators. Sarepta and Summit will share specified utrophin modulator-related research and development costs at a 45%/55% split, respectively, beginning in 2018. If Sarepta elects to exercise its option for Latin American rights, Summit would be entitled to additional fees, milestones and royalties.

Sarepta and Summit will host an update call for the Duchenne community on Monday, October 10 at 12:00 EDT. Details of the call can be accessed by visiting http://www.parentprojectmd.org/communitycall.

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014 (MAR).





About Utrophin Modulation in DMD

DMD is a progressive muscle wasting disease that is caused by different genetic faults in the gene that encodes dystrophin, a protein that is essential for the healthy function of all muscles. There is currently no cure for DMD and life expectancy is into the late twenties. Utrophin protein is functionally and structurally similar to dystrophin. In preclinical studies, the continued expression of utrophin has a meaningful, positive effect on muscle performance. Summit believes that utrophin modulation has the potential to treat all patients with DMD, regardless of the underlying dystrophin gene mutation. Summit also believes that utrophin modulation could potentially be complementary to other therapeutic approaches for DMD. The Company's lead utrophin modulator, ezutromid, is an orally administered, small molecule. DMD is an orphan disease, and the US Food and Drug Administration ('FDA') and the European Medicines Agency have granted orphan drug status to ezutromid. Orphan drugs receive a number of benefits including additional regulatory support and a period of market exclusivity following approval. In addition, ezutromid has been granted Fast Track designation and Rare Pediatric Disease designation by the FDA.

About Summit Therapeutics

Summit is a biopharmaceutical company focused on the discovery, development and commercialisation of novel medicines for indications for which there are no existing or only inadequate therapies. Summit is conducting clinical programmes focused on the genetic disease Duchenne muscular dystrophy and the infectious disease *C. difficile* infection. Further information is available at www.summitplc.com and Summit can be followed on Twitter (@summitplc).

About Sarepta

Sarepta Therapeutics is a commercial-stage biopharmaceutical company focused on the discovery and development of unique RNA-targeted therapeutics for the treatment of rare neuromuscular diseases. The Company is primarily focused on rapidly advancing the development of its potentially disease-modifying DMD drug candidates, including EXONDYS 51, designed to skip exon 51 and approved under the accelerated approval pathway. For more information, please visit us at www.sarepta.com.

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Sarepta Forward-looking Statements

This press release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements about the terms of the license and collaboration agreement Sarepta has entered into with Summit (Oxford) LTD, including the rights, obligations and benefits of each party under the agreement such as Sarepta's commercialization rights for certain product candidates in specified territories and Sarepta's payments associated with those rights to Summit; the potential of ezutromid and utrophin modulation as a disease-modifying treatment for all patients with DMD regardless of their dystrophin gene mutation; the potential benefits to the parties and the DMD community resulting from the agreement; the partnership between the parties furthering their common goal of improving the lives of patients with DMD; the potential of utrophin modulation technology to complement Sarepta's current approach of exon skipping therapy; Summit's plans to access Sarepta's expertise for the continued advancement of their promising utrophin modulator pipeline and working together to bring great advances to patients and families living with DMD.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: the expected benefits and opportunities related to the license and collaboration and agreement may not be realized or may take longer to realize than expected due to challenges and uncertainties inherent in product research and development; the partnership between Sarepta and Summit may not result in any viable treatments suitable for clinical research or 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 or may never become commercialized products due to other various reasons including any potential future inability of the parties to fulfill their commitments and obligations under the agreement, including any inability by Sarepta to fulfill its financial commitments to Summit; and even if the agreement results in commercialized products the parties may not achieve any significant revenues from the sale of such products.

Any of the foregoing risks could 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 Sarepta's 2015 Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by Sarepta. 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.

Summit Forward-looking Statements

Any statements in this press release about Summit's future expectations, plans and prospects, including but not limited to, statements about the potential benefits and future operation of the collaboration with Sarepta Therapeutics, including any potential future payments thereunder, clinical and preclinical development of Summit's product candidates, the therapeutic potential of Summit's product candidates, and the timing of initiation, completion and availability of data from clinical trials, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a clinical trial will be predictive





of the final results of that trial or whether results of early clinical trials or preclinical studies will be indicative of the results of later clinical trials, expectations for regulatory approvals, availability of funding sufficient for Summit's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" section of filings that Summit makes with the Securities and Exchange Commission including Summit's Annual Report on Form 20-F for the fiscal year ended January 31, 2016. Accordingly readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent Summit's views only as of the date of this release and should not be relied upon as representing Summit's views as of any subsequent date. Summit specifically disclaims any obligation to update any forward-looking statements included in this press release.