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): July 17, 2017

SAREPTA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-14895**	**93-0797222**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

215 First Street **Suite 415** **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 274-4000

Not applicable
(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:

☐ 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 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 1.01 Entry into Material Definitive Agreements.

License Agreement

On July 17, 2017, Sarepta Therapeutics, Inc. and Sarepta International C.V. (collectively, the "Company" or "Sarepta") and BioMarin Leiden Holding BV, BioMarin Nederlands BV and BioMarin Technologies BV (collectively, "BioMarin") executed a License Agreement (the "License Agreement"), pursuant to which BioMarin granted Sarepta a royalty-bearing, worldwide license under patent rights ("Licensed Patents") and know-how ("Licensed Know-How") controlled by BioMarin with respect to BioMarin's Duchenne muscular dystrophy ("DMD") program, which are potentially necessary or useful for the treatment of DMD, to practice and exploit the Licensed Patents and Licensed Know-How in all fields of use and for all purposes, including to develop and commercialize antisense oligonucleotide products that target one or more exons of the dystrophin gene to induce exon skipping, including eteplirsen (collectively, the "Products").

The license granted by BioMarin to Sarepta under the terms of the License Agreement is exclusive, even as to BioMarin, with respect to the Licensed Patents, and is non-exclusive with respect to Licensed Know-How. Under the License Agreement, BioMarin has the option to convert the exclusive license under the Licensed Patents into a co-exclusive license (co-exclusive with BioMarin) ("BioMarin Co-Exclusive Option").

Under the terms of the License Agreement, the Company is required to pay BioMarin an upfront payment of $15 million, and BioMarin will be eligible to receive up to $20 million from the Company per dystrophin gene exon (other than exon 51) targeted by one or more Products in specified regulatory milestones, as well as an additional $10 million milestone, payable following the regulatory approval of eteplirsen by the European Medicines Agency. BioMarin will also be eligible to receive $15 million from the Company upon the achievement of $650 million in sales, as well as royalties segmented by specified geographic markets, in some of jurisdictions dependent on an the existence of a patent, ranging from four (4) to eight (8) digit percentages of net sales on a product-by-product and country-by-country basis.

Milestone and royalty payments are payable with respect to eteplirsen (an exon 51 skipping Product), casimersen (an exon 45 skipping Product), golodirsen (an exon 53 skipping Product) and other Products. For eteplirsen, casimersen and golodirsen, the royalty term will expire upon the end of 2023 in the United States, upon September 30, 2024 in the European Union and no later than September 30, 2024 in other countries provided certain conditions are met. For Products other than exon 45 skipping Products, exon 51 skipping Products and exon 53 skipping Products, the royalty term will end on a country-by country basis upon expiration of granted Licensed Patents covering the applicable Product. The royalties for all Products are subject to reduction upon BioMarin's exercise of the BioMarin Co-Exclusive Option. All royalties are subject to further potential reductions, including for generic competition and, under specified conditions, for a specified portion of payments that the Company may become required to pay under third-party license agreements, subject to a maximum royalty reduction.

Unless earlier terminated, the License Agreement will expire upon the expiration of the last-to-expire royalty term. Either party may terminate the License Agreement in the event of the other party's uncured material breach. BioMarin may also terminate the License Agreement on a Licensed Patent-by-Licensed Patent basis under specified circumstances relating to patent challenges by the Company.

Settlement Agreement

On July 17, 2017, Sarepta, BioMarin, and The University of Western Australia on the one hand, and BioMarin on the other hand (collectively with the addition of Academisch Ziekenhuis Leiden ("AZL"), which has not yet executed the Settlement Agreement, the "Settlement Parties"), executed a Settlement Agreement pursuant to which all legal actions in the United States and certain legal actions in Europe (the "Actions") would be stopped or withdrawn as between the Settlement Parties. Specifically, the terms of the Settlement Agreement require that existing efforts pursuing ongoing litigation and opposition proceedings would be stopped as between the Settlement Parties and the Settlement Parties would cooperate to withdraw the Actions before the European Patent Office (except for actions involving third parties), the U.S. Patent and Trademark Office, the U.S. Court of Appeals for the Federal Circuit and the High Court

of Justice of England and Wales, except for the cross-appeal of the Interlocutory Decision of the Opposition Division dated April 15, 2013 of the European Patent Office of EP 1619249B1 ("EP '249 Appeal") in which Sarepta will withdraw its appeal and BioMarin/AZL will continue with its appeal with Sarepta having oversight of the continued appeal by BioMarin/AZL.

Additionally, under the terms of the Settlement Agreement, the Settlement Parties agree to release each other and the customers, end-users, agents, suppliers, distributors, resellers, contractors, consultants, services and partners of Sarepta or BioMarin (as applicable) from claims and damages related to (i) the patent rights controlled by the releasing party that are involved in the Actions, (ii) with respect to the Company and UWA, its patent rights related to the patent rights involved in the Actions, and (iii) with respect to BioMarin and AZL, all of the Licensed Patents and Licensed Know-How.

Under the terms of the Settlement Agreement, the Company will pay BioMarin an upfront payment of $20 million.

Conditions to Effectiveness of License and Settlement Agreements

The License and Settlement Agreements become effective if, within seven days of the execution date of the agreements, which is July 24, 2017 (the "Deadline"), AZL (i) executes the settlement agreement and (ii) simultaneously provides a written consent to BioMarin's execution of the License Agreement. If these conditions to effectiveness are not met by the Deadline, the Settlement Agreement and License Agreement become null and void.

The foregoing description of certain terms of the License Agreement and Settlement Agreement do not purport to be complete, is intended to be a summary of the material terms of such agreements and is qualified in its entirety by reference to complete text of each of the License Agreement and Settlement Agreement that Sarepta intends to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.

Item 8.01 Other Events.

On July 18, 2017, the Company issued a press release announcing the execution of the License and Settlement Agreements. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated July 18, 2017.

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.

Dated: July 18, 2017

SAREPTA THERAPEUTICS, INC.

By: /s/ Sandesh Mahatme
Name: Sandesh Mahatme
Title: Executive Vice President, Chief Financial Officer and Chief Business Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release, dated July 18, 2017.

Exhibit 99.1

Sarepta Therapeutics and BioMarin Pharmaceutical Inc. Announce Execution of a Global Settlement and a License Agreement Resolving Exon Skipping Patent Litigation

— Agreement terms resolve global patent proceedings regarding Sarepta's sale of EXONDYS 51® (eteplirsen) and future Duchenne muscular dystrophy (DMD) exon-skipping products —

CAMBRIDGE, Mass. and SAN RAFAEL, Calif., July 18, 2017 (GLOBE NEWSWIRE) — Sarepta Therapeutics, Inc. (NASDAQ:SRPT), a U.S. commercial-stage biopharmaceutical company focused on the discovery and development of unique RNA-targeted therapeutics for the treatment of rare neuromuscular diseases, and BioMarin Pharmaceutical Inc. (NASDAQ:BMRN), a leading biotechnology company in therapies for rare genetic diseases, announced today that Sarepta and BioMarin executed a license agreement that provides Sarepta Therapeutics with global exclusive rights to BioMarin's DMD patent estate for EXONDYS 51 and all future exon-skipping products. BioMarin retains the right to convert the license to a co-exclusive right in the event it decides to proceed with an exon-skipping therapy for DMD. In addition, Sarepta and BioMarin executed a settlement agreement, resolving the ongoing worldwide patent proceedings related to the use of EXONDYS 51 and all future exon-skipping products for the treatment of DMD. The effectiveness of the agreements is subject to closing conditions including execution of necessary approvals by Academisch Ziekenhuis Leiden (AZL) by July 24, 2017.

Under the terms of the license and settlement agreements, Sarepta will make a one-time payment of $35 million to BioMarin and certain additional regulatory and commercial milestone payments for exons 51, 45, 53 and possibly on future exon-skipping products.

In addition, Sarepta will pay royalties to BioMarin as follows:

- Exon-skipping compounds 51, 45, and 53 and possibly on future exon-skipping products: Sarepta will pay BioMarin 5 percent of net sales through the end of 2023 in the United States; and
- Exon-skipping compounds 51, 45, and 53 and possibly on future exon-skipping products: Sarepta will pay BioMarin 8 percent of net sales through September 30, 2024 in the European Union and in other countries where certain BioMarin / AZL patents exist.

“Upon their effectiveness, these global license and settlement agreements provide Sarepta worldwide freedom to operate for EXONDYS 51 and our future exon-skipping products,” said Douglas Ingram, Sarepta’s President and Chief Executive Officer. “The resolution of these legal matters provides us with more certainty to fully focus our resources and energy on our crucial mission of developing innovative medicines to improve the lives of those impacted by DMD around the world.”

“We are pleased to reach a global settlement and license agreement with Sarepta that fairly recognizes the important innovation by the Leiden University Medical Center and allows patients certainty that this issue will not create a barrier to access,” said G. Eric Davis, BioMarin’s Executive Vice President and General Counsel.

About EXONDYS 51

EXONDYS 51 uses Sarepta’s proprietary phosphorodiamidate morpholino oligomer (PMO) chemistry and exon-skipping technology to skip exon 51 of the dystrophin gene. EXONDYS 51 is designed to bind to exon 51 of dystrophin pre-mRNA, resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 51 skipping. Exon skipping is intended to allow for production of an internally truncated dystrophin protein. Data from clinical studies of EXONDYS 51 in a small number of DMD patients have demonstrated a consistent safety and tolerability profile. The pivotal trials were not designed to evaluate long-term safety and a clinical benefit of EXONDYS 51 has not been established.

Important Safety Information

Adverse reactions in DMD patients (N=8) treated with EXONDYS 51 30 or 50 mg/kg/week by intravenous (IV) infusion with an incidence of at least 25% more than placebo (N=4) (Study 1, 24 weeks) were (EXONDYS 51, placebo): balance disorder (38%, 0%), vomiting (38%, 0%) and contact dermatitis (25%, 0%). The most common adverse reactions were balance disorder and vomiting. Because of the small numbers of patients, these represent crude frequencies that may not reflect the frequencies observed in practice. The 50 mg/kg once weekly dosing regimen of EXONDYS 51 is not recommended.

In the 88 patients who received ³30 mg/kg/week of EXONDYS 51 for up to 208 weeks in clinical studies, the following events were reported in ³10% of patients and occurred more frequently than on the same dose in Study 1: vomiting, contusion, excoriation, arthralgia, rash, catheter site pain, and upper respiratory tract infection.

There have been reports of transient erythema, facial flushing, and elevated temperature occurring on the day of EXONDYS 51 infusion.

About Sarepta Therapeutics

Sarepta Therapeutics is a U.S. 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 Duchenne muscular dystrophy (DMD) drug candidates. For more information, please visit www.sarepta.com.

About BioMarin Pharmaceutical Inc.

BioMarin is a global biotechnology company that develops and commercializes innovative therapies for people with serious and life-threatening rare disorders. The company's portfolio consists of six commercialized products and multiple clinical and pre-clinical product candidates. For additional information, please visit www.biomarin.com. Information on BioMarin's website is not incorporated by reference into this press release.

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 license agreement providing Sarepta with global exclusive rights to BioMarin's DMD patent estate for EXONDYS 51 and all future exon-skipping products; the settlement agreement resolving the ongoing worldwide patent proceedings related to the use of EXONDYS 51 and all future exon-skipping products for the treatment of DMD; the payments and royalties that Sarepta will

be making as part of the settlement and license agreements; the settlement and license agreements providing for Sarepta's worldwide freedom to operate for EXONDYS 51 and Sarepta's future exon-skipping products; the settlement providing Sarepta with the certainty to fully focus its resources and energy on its crucial mission of developing innovative medicines to improve the lives of those impacted by DMD around the world; and the statement that the patent proceedings between the parties will not create for patients a barrier to access to the innovation by the Leiden University Medical Center.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: the settlement and license agreements may not become effective if their conditions to effectiveness are not met within the required deadline; the parties may not be able to fulfill their commitments and obligations under the settlement and license agreements; any future claims of infringement by other third parties; the expected benefits and opportunities related to the settlement and license agreements between the parties may not be realized or may take longer to realize than expected due to challenges and uncertainties regarding the sales of EXONDYS 51 and the research and development of future exon-skipping products; Sarepta may experience significant fluctuations in sales of EXONDYS 51 from period to period and, ultimately, Sarepta may never generate sufficient revenues from EXONDYS 51 to reach or maintain profitability or sustain its anticipated levels of operations; Sarepta may never receive regulatory approval to its future exon-skipping products due to a variety of reasons including that the results of additional research may not be consistent with past results or may not be positive or may otherwise fail to meet regulatory approval requirements for the safety and efficacy of product candidates; and even if Sarepta obtains regulatory approvals, it may not achieve any significant revenues from the sale of such products; Sarepta may not have worldwide freedom to operate for EXONDYS 51 and Sarepta's future exon-skipping products due to future proceedings brought by other parties.

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 2016 Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 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.

Internet Posting of Information

We routinely post information that may be important to investors in the 'For Investors' section of our website at www.sarepta.com. We encourage investors and potential investors to consult our website regularly for important information about us.

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