Sarepta Therapeutics, Inc.
Form 8-K
July 18, 2017

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

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