BIOMARIN PHARMACEUTICAL INC
Form 8-K
April 13, 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): April 12, 2017

BioMarin Pharmaceutical Inc.

(Exact name of registrant as specified in its charter)

000-26727

(Commission File No.)

Delaware	**68-0397820**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

770 Lindaro Street, San Rafael, CA **94901**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code: (415) 506-6700

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 a Material Definitive Agreement.

On April 12, 2017, BioMarin Pharmaceutical Inc., a Delaware corporation (the Company), entered into a Settlement and License Agreement (the Settlement Agreement) with Merck & Cie (Merck) and Par Pharmaceutical, Inc. (Par) related to the ongoing patent infringement litigation (the Litigation) that the Company and Merck filed against Par in the U.S. District Court for the District of New Jersey (the District Court). As previously disclosed, in the Litigation, the Company and Merck allege that certain patents of the Company and Merck covering Kuvan® (sapropterin dihydrochloride) 100 mg oral tablets and powder for oral solution in 100 mg packets (the Kuvan Patents) are or will be infringed by the generic versions of Kuvan covered by the abbreviated new drug applications (ANDAs) filed by Par.

Under the Settlement Agreement, the Company and Merck have agreed to file a stipulation of dismissal of the Litigation with the District Court, Par has agreed to release the Company and Merck from all claims that Par has, may have had, might have asserted, may now have or assert, or may hereafter have or assert that are reasonably related to the Litigation, and the Company and Merck have agreed to release Par from all claims that the Company or Merck have, may have had, might have asserted, may now have or assert, or may hereafter have or assert that are reasonably related to the Litigation.

Pursuant to the Settlement Agreement, the Company and Merck have granted Par a fully paid up, royalty-free, non-exclusive license under the Kuvan Patents to make, have made, use, import, distribute, have distributed, sell and offer for sale a generic version of Kuvan in 100 mg oral tablet and powder for oral solution in 100 mg and 500 mg packet formulations in the United States and its territories, including the Commonwealth of Puerto Rico, upon the earlier of (i) April 1, 2021, if Par is not entitled to the 180-day first-filer exclusivity period described in 21 U.S.C. § 355(j)(5)(B)(iv) with respect to a generic equivalent of Kuvan (the Exclusivity Period), or (ii) October 1, 2020, if Par is entitled to the Exclusivity Period, or earlier under certain circumstances (the Generic Entry Date). Such circumstances include a final decision that the then-asserted and adjudicated claims of the Kuvan Patents are invalid, unenforceable or not infringed by a generic equivalent, or events related to the market entry of other generic versions of Kuvan. The Settlement Agreement will remain in effect until the expiration of the last to expire of the Kuvan Patents. The Settlement Agreement with Par does not resolve pending patent litigation brought by the Company against other parties who have submitted ANDAs to the U.S. Food and Drug Administration seeking marketing approval for generic versions of Kuvan.

In accordance with legal requirements, the parties have agreed to submit the Settlement Agreement to the U.S. Federal Trade Commission Bureau of Competition (FTC) and the Antitrust Division of the U.S. Department of Justice (DOJ) for review.

The foregoing description of the Settlement Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Settlement Agreement, which will be filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ending June 30, 2017.

Item 8.01 Other Events.

On April 13, 2017, the Company issued a press release pursuant to which it announced that it had entered into the Settlement Agreement. A copy of the press release is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 1.01 shall be deemed to be furnished, and not filed:

Exhibit No.	**Description**
99.1	Press release dated April 13, 2017

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements about: possible launch dates for generic versions of Kuvan in both the United States and the European Union, and ongoing litigation related to generic versions of Kuvan. These forward-looking statements are predictions and involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, but are not limited to, risks and uncertainties related to: the review of the settlement agreement with Par Pharmaceutical by the FTC and the DOJ; the outcome of current litigation with Dr. Reddy s Laboratories, possible future ANDA filings related to Kuvan tablets or Kuvan powder for oral solution; and those factors detailed in BioMarin s filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption Risk Factors and elsewhere in the Company s Securities and Exchange Commission (SEC) filings and reports (Commission File No. 001-26727), including the Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on February 27, 2017, and future filings and reports by the Company. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Current Report on Form 8-K as a result of new information, future events or changes in its expectations.

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.

Date: April 12, 2017

BIOMARIN PHARMACEUTICAL INC.

By: /s/ G. Eric Davis
G. Eric Davis
Executive Vice President, General Counsel

EXHIBIT INDEX

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