

BIOMARIN PHARMACEUTICAL INC

Form 8-K

September 18, 2015

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): September 14, 2015

BioMarin Pharmaceutical Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

000-26727
(Commission
File Number)

68-0397820
(IRS Employer
Identification No.)

770 Lindero Street, San Rafael, California
(Address of principal executive offices)

94901
(Zip Code)

Registrant's telephone number, including area code: (415) 506-6700

(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.

As previously disclosed, BioMarin Pharmaceutical Inc. (BioMarin) received a paragraph IV notice letter, dated October 3, 2014, from Dr. Reddy s Laboratories, Inc. and Dr. Reddy s Laboratories, Ltd. (collectively, DRL), notifying BioMarin that DRL has filed an abbreviated new drug application (ANDA) seeking approval of a proposed generic version of Kuvan (sapropterin dihydrochloride) 100 mg oral tablets prior to the expiration of the BioMarin s patents listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). Additionally, BioMarin received a paragraph IV notice letter, dated January 22, 2015, from Par Pharmaceutical, Inc. (Par), notifying BioMarin that Par has filed an ANDA seeking approval of a proposed generic version of Kuvan (sapropterin dihydrochloride) 100 mg oral tablets prior to the expiration of BioMarin s patents listed in the Orange Book. Together with Merck & Cie (Merck), BioMarin filed lawsuits against both DRL and Par in the United States District Court for the District of New Jersey alleging patent infringement for BioMarin s patents relating to Kuvan, triggering the automatic 30 month stay on the approval of each ANDA. In response, DRL and Par have alleged, inter alia, that the asserted patents are not infringed and/or are invalid.

On September 14, 2015, BioMarin entered into a settlement agreement (Settlement Agreement) with DRL that resolves patent litigation with DRL in the United States described in the above paragraph related to BioMarin s Kuvan® (sapropterin dihydrochloride) 100mg oral tablets.

Under the terms of the Settlement Agreement, BioMarin will grant DRL a non-exclusive license to its patents related to Kuvan to allow DRL to market a generic version of sapropterin dihydrochloride 100mg tablets in the U.S. for the indications approved for Kuvan beginning at a confidential date in the future, but which is more than five years from today, or earlier under certain circumstances.

BioMarin will continue its suit against Par Pharmaceutical, Inc., which is not affected by this settlement.

On September 18, 2015, 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 filed as Exhibit 99.1 hereto and incorporated herein by reference.

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 September 18, 2015 |

SIGNATURE

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.

BioMarin Pharmaceutical Inc.,

a Delaware corporation

Date: September 18, 2015

By: /s/ G. Eric Davis
G. Eric Davis

Senior Vice President, General Counsel