

BIOMARIN PHARMACEUTICAL INC

Form 8-K

October 02, 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): October 1, 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)
770 Lindaro**

**68-0397820
(I.R.S. Employer**

Identification No.)

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San Rafael, CA 94901

(Address of Principal Executive Offices, Including Zip Code)

(415) 506-6700

(Registrant's Telephone Number, Including Area Code)

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))

Item 1.01 Entry into a Material Definitive Agreement

On October 1, 2015, BioMarin Pharmaceutical Inc., a Delaware corporation (the Company or BioMarin), entered into a Termination and Transition Agreement (the Kuvan Agreement) with Ares Trading, S.A., a corporation organized under the laws of Switzerland (Merck Serono), which will terminate the Development, License and Commercialization Agreement, dated May 13, 2005, as amended (the License Agreement), between BioMarin and Merck Serono, including the license granted in the License Agreement from BioMarin to Merck Serono related to the approved pharmaceutical product referred to as Kuvan. Also on October 1, 2015, BioMarin and Merck Serono entered into a Termination Agreement (the Pegvaliase Agreement), which will terminate the license granted in the License Agreement from BioMarin to Merck Serono related to the investigational medicinal product referred to as pegvaliase.

Pursuant to the Kuvan Agreement, BioMarin will pay Merck Serono 340,000,000, in cash, at the closing and up to a maximum of 60,000,000, in cash, if future sales milestones are met. Pursuant to the Pegvaliase Agreement, BioMarin will pay Merck Serono up to a maximum of 125,000,000, in cash, if future development milestones are met. Merck Serono has agreed to transfer certain inventory, regulatory materials and approvals, and intellectual property rights to BioMarin and perform certain transition services for BioMarin following the closing. Following the closing, BioMarin and Merck Serono will have no further rights or obligations under the License Agreement and BioMarin will have the exclusive right to exploit Kuvan and pegvaliase worldwide with the exception of Kuvan in Japan.

This closing of the Kuvan Agreement and the Pegvaliase Agreement are subject to customary representations and warranties, covenants and indemnification provisions and are expected to close in January 2016.

The foregoing is a summary description of the terms of the Kuvan Agreement and the Pegvaliase Agreement and does not purport to be complete, and it is qualified in its entirety by reference to the full text of the Kuvan Agreement and the Pegvaliase Agreement, which BioMarin intends to file as an exhibit to the Current Report on Form 8-K that will be filed when the Kuvan Agreement and the Pegvaliase Agreement close, with confidential terms redacted.

Item 1.02 Termination of a Material Definitive Agreement

The contents of Item 1.01 are incorporated by reference into this Item 1.02.

Item 7.01 Other Events

On October 1, 2015, the Company issued a press release regarding its entry into the Kuvan Agreement and the Pegvaliase Agreement. A copy of the Company's October 1, 2015, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall not be treated as filed for purposes of the Securities Exchange Act of 1934, as amended.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: the completion of the acquisition of the rights to Kuvan and pegvaliase from Merck Serono, the subsequent commercialization of Kuvan in the Merck Serono territories and the development and commercialization of pegvaliase. These forward-looking statements are predictions and involve risks and uncertainties such that actual results may differ materially from these statements. These risks and uncertainties include, among others: clearance of the transaction by relevant anti-trust authorities; our ability to transition commercial activities related to Kuvan and our subsequent success in executing those activities; actions by regulatory authorities, particularly with respect to the transfer of the Kuvan marketing authorizations and

the development of pegvaliase; the timing and results of ongoing and future clinical trials of pegvaliase; our ability to manufacture both Kuvan and pegvaliase in the quantity and configuration required for each jurisdiction and intended use; 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 in BioMarin's 2014 Annual Report on Form 10-K, and the factors contained in BioMarin's reports on Form 10-Q. Stockholders are urged not to place undue reliance on forward-looking statements, which speak only as of the date hereof. BioMarin is under no obligation, and expressly disclaims any obligation to update or alter any forward-looking statement, whether as a result of new information, future events or otherwise. For additional information, please visit www.BMRN.com. Information on BioMarin's website is not incorporated by reference into this press release.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| No. | Description |
|------------|---------------------------------------|
| 99.1 | Press Release, dated October 1, 2015. |

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.

BIOMARIN PHARMACEUTICAL INC.

Date: October 2, 2015

By: /s/ G. Eric Davis
G. Eric Davis
Senior Vice President, General Counsel & Secretary

EXHIBIT INDEX

No. Description

99.1 Press Release, dated October 1, 2015.