BIOMARIN PHARMACEUTICAL INC
Form 8-K
June 01, 2006

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): June 1, 2006

BioMarin Pharmaceutical Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26727**	**68-0397820**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

105 Digital Drive, Novato, California	**94949**
(Address of principal executive offices)	**(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 8.01. Other Events.

BioMarin Pharmaceutical Inc. (the Company) today announced that the U.S. Food and Drug Administration (FDA) has granted marketing approval for Orapred ODT (prednisolone sodium phosphate orally disintegrating tablets), the first orally disintegrating tablet form of prednisolone available in the United States.

On March 15, 2006, the Company and BioMarin and Alliant Pharmaceuticals, Inc., a privately held pediatrics-focused specialty pharmaceutical company located in Alpharetta, Georgia entered into a North American licensing and acquisition agreement relating to the Orapred product line. Pursuant to the agreement, Alliant will pay The Company $7.5 million upon FDA approval of Orapred ODT, $4 million upon commercial launch and $4 million upon the first anniversary of approval. Additionally, Alliant will pay the Company royalties ranging from 25 percent to 30 percent on net sales of Orapred ODT, net of the royalties owed to a third party for use of their proprietary, taste-masking oral disintegrating tablet technology used in Orapred ODT.

Orapred is the leading brand of liquid prednisolone sodium phosphate used to treat exacerbations of asthma and other inflammatory diseases and conditions in children. In 2003, approximately 2.4 million prescriptions of Orapred were written in the United States, representing greater than 50 percent market share, and net product sales of approximately $49 million.

Forward-Looking Statement

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 sales and marketing expectations of Orapred; the continued development and commercialization of Orapred, including Orapred ODT; and actions by regulatory authorities, including actions related to Orapred ODT. 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: Alliant s success in the commercialization of Orapred; the content and timing of decisions by the U.S. Food and Drug Administration concerning Orapred ODT; the market for each of these products and particularly Orapred ODT; actual sales of Orapred; 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 2005 Annual Report on Form 10-K, as amended, and the factors contained in BioMarin s reports on Form 10-Q and Form 8-K. 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.

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: June 1, 2006

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

Vice President, Corporate Counsel