

BIOMARIN PHARMACEUTICAL INC
Form 8-K
December 13, 2007

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): December 13, 2007

BioMarin Pharmaceutical Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-26727
(Commission
File Number)

68-0397820
(IRS Employer
Identification No.)

105 Digital Drive, Novato, California
(Address of principal executive offices)

94949
(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.

On December 13, 2007, BioMarin Pharmaceutical Inc. (the Company) issued a press release regarding the granting of marketing approval for Kuvan (sapropterin dihydrochloride) by the U.S. Food and Drug Administration. The Company's press release issued on December 13, 2007 is attached hereto as Exhibit 99.1. On a conference call to be held on Thursday, December 13, 2007 at 5:00 p.m. ET, related to the press release, the Company will describe that BioMarin's list sale price for Kuvan is \$0.29 per mg, which BioMarin believes will result in an average annual cost of therapy of \$57,000 per patient, based on certain assumptions that will be discussed on the call. BioMarin expects 2008 Kuvan revenue to be in the range of \$35 million to \$70 million.

Some of the statements in this Current Report on Form 8-K are forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: the per patient pricing of its product Kuvan and the expected revenue from Kuvan. 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: the practices of physicians in using Kuvan; the actual response in patients using Kuvan in commercial distribution; the content and timing of decisions by the U.S. Food and Drug Administration, the European Medicines Agency and other regulatory authorities concerning Kuvan; results and timing of current and planned clinical trials of 6R-BH4 for other indications; 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 2006 Annual Report on Form 10-K, as amended, and the factors contained in BioMarin's reports on 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.

Item 9.01. Financial Statements, Pro Forma Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.
Not Applicable.

(b) Pro Forma Financial Information.
Not Applicable.

(c) Shell Company Transactions.
Not Applicable.

(d) Exhibits.

Exhibit 99.1 Press Release of the Company dated December 13, 2007.

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., a Delaware corporation
(Registrant)

Date: December 13, 2007

/s/ G. Eric Davis
G. Eric Davis
Vice President, General Counsel

EXHIBIT INDEX

Exhibit No.	Description
Exhibit 99.1	Press Release of the Registrant dated December 13, 2007.