

BIOMARIN PHARMACEUTICAL INC

Form 8-K

October 26, 2009

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 20, 2009

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.)

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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 1.01. Entry into a Material Definitive Agreement.

On October 20, 2009, BioMarin Pharmaceutical Inc. (BioMarin) entered into a stock purchase agreement with Huxley Pharmaceuticals, Inc. (Huxley) and the stockholders of Huxley to acquire all of the outstanding shares of capital stock of Huxley. Huxley has the rights to a proprietary form of 3,4-diaminopyridine (3,4-DAP), amifampridine phosphate, for the rare autoimmune disease Lambert Eaton Myasthenic Syndrome (LEMS). Last week, the Committee for Medicinal Products for Human Use of the European Medicines Evaluations Agency adopted a positive opinion recommending approval of amifampridine phosphate for LEMS. If approved by the European Commission, amifampridine phosphate will be the first approved treatment for LEMS, thereby conferring orphan drug protection and providing ten years of market exclusivity in Europe.

Under the terms of the stock purchase agreement, on October 23, 2009, BioMarin purchased all of the capital stock of Huxley for an upfront cash payment to the stockholders of Huxley of \$15.0 million and will pay an additional \$6.5 million to the Huxley stockholders upon final European Commission approval of amifampridine in LEMS, which is expected in late 2009 or early 2010. BioMarin will also pay Huxley stockholders \$1.0 million upon receipt of FDA orphan drug designation for amifampridine in LEMS, which is expected to be granted in the first quarter of 2010. Additionally, Huxley stockholders are eligible to receive up to approximately \$36.0 million in milestone payments if certain annual, cumulative sales and U.S. development milestones are met.

The foregoing description of the stock purchase agreement is qualified in its entirety by reference to the full text of the stock purchase agreement, a copy of which will be filed with the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

Forward-Looking Statement

This current report of Form 8-K contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: the expectations of the development and potential approval of Huxley's 3,4-Diaminopyridine product for the treatment of LEMS. 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 content and timing of decisions by the U.S. Food and Drug Administration, the European Commission and other regulatory authorities, particularly the pending decision by the European Commission on the Marketing Authorization Application for such product, our success in the commercialization of such product, if approved; results and timing of current and planned preclinical studies and clinical trials related to such product; our ability to successfully manufacture the product; 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 2008 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.

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: October 26, 2009

By: /s/ **JEAN-JACQUES BIENAIMÉ**
Jean-Jacques Bienaimé
Chief Executive Officer