BIOMARIN PHARMACEUTICAL INC
Form 8-K
January 04, 2008

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 31, 2007

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 1.01 Entry into a Material Definitive Agreement.

Effective January 1, 2008, BioMarin Pharmaceutical Inc. (the Company) restructured its relationship (the Restructuring) with its joint venture partner, Genzyme Corporation (Genzyme) regarding the manufacturing, marketing and sale of Aldurazyme® (laronidase). As part of the Restructuring, the Company entered into a number of agreements (the Restructuring Agreements) with Genzyme and BioMarin/Genzyme LLC (the LLC), the joint venture entity owned fifty percent (50%) by Genzyme and fifty percent (50%) by the Company and its wholly-owned subsidiary, BioMarin Genetics, Inc. (together with the Company, the BioMarin Companies).

On December 31, 2007, the Company entered into a Manufacturing, Marketing and Sales Agreement (the MMS Agreement) with Genzyme and the LLC, effective as of January 1, 2008, pursuant to which the Company has agreed to assume the duties and obligations related to the manufacturing of Aldurazyme (including payment of expenses related thereto), while Genzyme has agreed to assume the duties and obligations related to the marketing, sales and distribution of Aldurazyme (including payment of expenses related thereto at a specified minimum level). Genzyme has the exclusive right to distribute, market and sell Aldurazyme globally and is required to purchase exclusively its requirements from the Company. The parties are subject to a non-competition restriction preventing them from participating in certain activities related to Aldurazyme and other pharmaceutical compositions of alpha-L-iduronidase (the Collaboration Products) for alpha-L-iduronidase deficiencies outside of the Restructuring Agreements. Pursuant to the MMS Agreement, Genzyme will record sales of Aldurazyme and is required to pay the Company on a quarterly basis a tiered payment ranging from approximately thirty-nine and a half percent (39.5%) to fifty percent (50%) on worldwide net product sales. Under the revised structure, payments are projected to result in both the Company and Genzyme receiving approximately the same profit as under the original joint venture structure.

The Company has also agreed to provide Genzyme with a limited number of vials of Aldurazyme for compassionate use and expanded access programs as well as a limited number of vials for in-country acceptance testing. The Company and Genzyme have agreed to cooperate with each other in the filing of any necessary regulatory documentation, with the Company being generally responsible for all such filings in the United States and Genzyme being generally responsible for all such filings outside of the United States. Each of the Company and Genzyme has agreed to indemnify the other party for its breach of the MMS Agreement, its negligence or willful misconduct in connection with performance of its obligations under the MMS Agreement and for certain product liability claims allocated to it under the MMS Agreement.

The term of the MMS Agreement is perpetual unless earlier terminated by Genzyme or the Company: (a) for certain material breaches of the other party; (b) for convenience (with one year prior written notice); (c) in the event the other party enters into a change of control transaction; or (d) in the event of the other party s bankruptcy. Upon termination for a material breach, the breaching party will transfer its interest in the LLC to the non-breaching party, and the non-breaching party will pay a specified buyout amount for the breaching party s interest in Aldurazyme and in the LLC (collectively, its Interest). Upon termination for convenience, the non-terminating party will have an option to purchase the terminating party s Interest at a specified buyout amount. If such option is not exercised, all rights in Aldurazyme will be sold and the LLC will be dissolved. Upon termination for a change of control, the terminating party will submit an offer for the non-terminating party s Interest, pursuant to the terms and conditions in the MMS Agreement. If the non-terminating party does not accept the offer, the non-terminating party is required to purchase the terminating party s Interest for the same price as the offer.

Effective January 1, 2008, the Company, Genzyme and the LLC also amended and restated their Collaboration Agreement (the Amended and Restated Collaboration Agreement), pursuant to which LLC will no longer engage in commercial activities related to Aldurazyme and will solely (1) hold the intellectual property relating to Aldurazyme and other Collaboration Products and license all such intellectual property on a royalty free basis to the Company and Genzyme to allow them to exercise their rights and perform their obligations under the Restructuring Agreements; and (2) engage in research and development activities that are mutually selected and funded by Genzyme and the Company. Pursuant to the Amended and Restated Collaboration Agreement, Genzyme and the Company license rights related to Aldurazyme to the LLC, and the LLC sublicenses these rights to Genzyme and the Company such that each may perform its obligations under the Restructuring Agreements. The Amended and Restated Collaboration Agreement will automatically terminate upon the effective date of the termination of the MMS Agreement and may not be terminated independently from the MMS Agreement.

Pursuant to a Members Agreement entered into by and among the BioMarin Companies, Genzyme and the LLC related to the Restructuring, the LLC distributed cash and inventory to the BioMarin Companies and cash, accounts receivable and certain other assets and liabilities to Genzyme, such that the fair value of the net assets distributed to the BioMarin Companies and to Genzyme was equivalent. The value of the assets will be determined after the year-end audit of the LLC.

The Company s press release issued on January 3, 2008 related to the foregoing transactions and agreements is attached hereto as Exhibit 99.1.

Item 9.01 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 January 3, 2008

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company 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: January 4, 2008

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

Vice President, General Counsel

EXHIBIT INDEX

Exhibit 99.1 Press Release of the Company dated January 3, 2008