BIOMARIN PHARMACEUTICAL INC
Form 8-K
January 08, 2009

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): January 4, 2009

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.

On January 4, 2009, BioMarin CF Limited (BioMarin CF), a wholly-owned subsidiary of BioMarin Pharmaceutical Inc. (the Company), entered into a development and commercialization agreement (the Development Agreement) with La Jolla Pharmaceutical Company (La Jolla) granting BioMarin CF a co-exclusive license to develop, use, offer for sale, sell, import, export, market, distribute and promote Riquent in the Territory in any and all fields, and to manufacture Riquent anywhere in the world, provided that, if Riquent is made outside of the Territory, it will only be sold in the Territory pursuant to the terms of the Development Agreement. The Territory includes all countries of the world except the Asia-Pacific Territory (the Asia-Pacific Territory is defined to include all countries of East Asia, Southeast Asia, South Asia, Australia, New Zealand, and other countries of Oceania). Riquent is comprised of a lupus disease specific epitope attached to a carrier platform and is being researched for the treatment of systemic lupus erythematosus.

Under the Development Agreement, BioMarin CF has agreed not to exercise its rights or license unless and until BioMarin CF has effected its full commitment to the development and commercialization of Riquent in the Territory (the Full Participation Point) except that until the Full Participation Point is effected, BioMarin CF shall be able to exercise such rights as are necessary for manufacturing Riquent.

Under the Development Agreement, BioMarin CF and La Jolla will jointly commercialize Riquent in the United States and La Jolla retains the right to deploy a portion of the total number of sales representatives and line marketing personnel for Riquent in the United States. In other countries in the Territory, BioMarin CF shall be exclusively responsible for the commercialization of Riquent. Notwithstanding the foregoing, prior to BioMarin CF effecting the Full Participation Point, La Jolla shall conduct all commercialization activities with respect to Riquent for all or any portion of the Territory at its own expense and the costs of performing all development and regulatory activities with respect to Riquent prior to the Full Participation Point shall be at La Jolla s sole expense.

After BioMarin CF effects the Full Participation Point, BioMarin CF and La Jolla shall share equally all losses and profits related to development, commercialization, regulatory and manufacturing activities with respect to Riquent within the Territory. After effecting the Full Participation Point, BioMarin CF shall have the right to grant sublicenses to develop, use, offer for sale, sell, import, export, market, distribute and promote Riquent in the Territory to any of its affiliates or to any third party in any country of the Territory; provided, however, that any sublicense to a third party that includes the right to substantially all of the sale, marketing and distribution of Riquent in any Major Market Country (defined as the United States, France, Germany, Italy, Spain and the United Kingdom) shall be subject to La Jolla s prior written consent.

Both BioMarin CF and La Jolla shall use commercially reasonable efforts to prevent Riquent from being sold outside its respective territory (BioMarin CF s respective territory is the Territory and La Jolla s respective territory is the Asia-Pacific Territory) and neither BioMarin CF nor La Jolla shall directly or indirectly conduct clinical trials, testing or other development activities with respect to Riquent in the other party s territory.

In the event that La Jolla desires to enter into a license with a third party with respect to Riquent for all or any portion of the Asia-Pacific Territory BioMarin CF, has a right of first refusal with respect to any such proposed license.

BioMarin CF and La Jolla will establish a joint steering committee, which is responsible for overseeing, reviewing and coordinating the activities of the parties under the Development Agreement.

To obtain the foregoing rights, BioMarin CF has agreed to pay La Jolla specified amounts based upon the results of the ASPEN study at each of the first interim, second interim and final results. In connection with BioMarin CF s entering into the Development Agreement, BioMarin CF has agreed to pay to La Jolla a $7.5 million upfront fee by January 19, 2009 and the Company has agreed to purchase (pursuant to a securities purchase agreement described more fully below) $7.5 million worth of the La Jolla s Series B Convertible Preferred Stock (the Series B Preferred Stock) on January 20, 2009.

In order to maintain its license, BioMarin CF is required to pay $15.0 million to La Jolla upon the occurrence of the first interim efficacy analysis and a non-futile determination. However, if the occurrence of the first interim efficacy analysis is accompanied by a p-value achievement, BioMarin CF must effect the Full Participation Point by paying to La Jolla $47.5 million (up to $7.5 million of which can be paid, at BioMarin CF s option, as an equity purchase of La Jolla s Series B Preferred Stock).

If BioMarin CF maintains its right to effect the Full Participation Point following the first interim efficacy analysis, then upon the occurrence of the second interim efficacy analysis and a non-futile determination, BioMarin CF is required to pay La Jolla either $22.5 million to maintain its license (up to $5.0 million of which can paid, at BioMarin CF s option, as an equity purchase of Series B Preferred Stock) or $15.0 million to effect the Full Participation Point (up to $5.0 million of which can be paid, at BioMarin CF s option, as an equity purchase of the Series B Preferred Stock). If the occurrence of the second interim efficacy analysis is accompanied by a p-value achievement, BioMarin CF is required to pay to La Jolla $55.0 million (up to $10.0 million of which can be paid, at BioMarin CF s option, as an equity purchase of the Series B Preferred Stock) and effect the Full Participation Point.

If BioMarin CF voluntarily elected to effect the Full Participation Point in connection with the second interim efficacy analysis, upon receipt of the 128 flare topline data (the final results) accompanied by a p-value achievement, BioMarin CF is required to pay La Jolla $30.0 million. If BioMarin CF maintained its right to effect the Full Participation Point after the occurrence of the first and second interim efficacy analyses, then upon receipt of the 128 flare topline data accompanied by a p-value achievement, BioMarin CF is required to pay La Jolla $55.0 million (up to $15.0 million of which can be paid, at BioMarin CF s option, as an equity purchase of the Series B Preferred Stock) and effect the Full Participation Point.

If the first interim efficacy analysis or the second interim efficacy analysis is accompanied by a futile determination or if, based on receipt of the 128 flare topline data, the phase III trial does not reach p-value achievement, then BioMarin CF may choose to either terminate the Development Agreement effective immediately or effect the Full Participation Point on a modified basis. Under such modified basis, each of BioMarin CF and La Jolla would be responsible for 50% of the development costs up to a maximum of $2.0 million each in any one month until La Jolla s receipt of approval of a new drug application from the FDA and $15.0 million each in the aggregate. Any expenditure in excess of these amounts would require the prior written consent of both parties. Further, in this circumstance and in lieu of certain other payments, in order to participate fully and exercise the rights and licenses granted by La Jolla, BioMarin CF must make an additional payment of $55.0 million (up to $15.0 million of which can be paid, at BioMarin CF s option, as an equity purchase of the Series B Preferred Stock) following FDA approval of Riquent.

The Development Agreement also provides that, upon La Jolla s receipt of approval of a new drug application for Riquent from the FDA, BioMarin CF is required to pay up to $45.0 million to La Jolla. Upon approval of an application to market and sell Riquent either within the European Union or in all the European Major Market Countries, BioMarin CF is required to pay $10.0 million to La Jolla.

In addition, BioMarin CF is required to pay La Jolla several one time sales milestone payments that start once Riquent s net sales in any calendar year in the Territory reach $250.0 million. The final milestone is achieved on net sales in any calendar year in the Territory reaching $1.0 billion. If all such payments are triggered the total amount of all such payments is $181.0 million.

Unless terminated as described below, the Development Agreement continues for the commercial life of Riquent (and other follow-on products). As outlined in the Development Agreement, commercial life continues until there are no further sales of any product and no further development activities with respect to any product within the Territory and thereafter until disposition, redeployment or shutdown of all operations and assets related to the products.

The Development Agreement provides that either party may terminate the Development Agreement based upon a material breach by the other party that is not cured within the applicable cure period, with such termination effective upon expiration of such cure period. Either party may also terminate the Development Agreement if the other party becomes unable to pay its debts as they mature, applies for a receivership, is dissolved or liquidated in part or full or in the event of proceedings for the appointment of a receiver, trustee, liquidator or custodian of the other party or of all or a substantial part of the property thereof, or an involuntary case or other proceedings seeking liquidation, reorganization or other relief with respect to the other party or the debts thereof under any bankruptcy, insolvency or other similar law now or hereafter in effect, which is not dismissed within a specified period, with such termination effective immediately.

If La Jolla terminates the Development Agreement due to an uncured material breach by BioMarin CF, then La Jolla shall have the right to purchase (the Purchase Right) all right, title and interest of BioMarin CF under the Development Agreement in and to Riquent. If net sales of Riquent in the Territory in any two consecutive quarters have not reached an aggregate of $75.0 million, the purchase price shall be a single royalty rate that is reasonable under the circumstances. Otherwise, the purchase price shall be 80% of the fair market value.

If BioMarin CF terminates the Development Agreement due to an uncured material breach by La Jolla, BioMarin CF has the right to sell (the Sale Right) to La Jolla all right, title and interest of BioMarin CF under the Development Agreement in and to Riquent. The sale price shall be equal to the higher of the fair market value (as determined by an investment banking firm) or three times all payments made by BioMarin CF to La Jolla under the Development Agreement up to the earlier of (1) the date BioMarin CF notifies La Jolla of the termination of the Development Agreement due to a material breach by La Jolla, or (2) the date that BioMarin CF makes the milestone payment related to approval of the new drug application from the FDA. Notwithstanding the foregoing, if La Jolla obtains the approval of its stockholders to grant a purchase right to BioMarin CF prior to BioMarin CF s exercise of the Sale Right, then BioMarin s Sale Right will be eliminated and BioMarin CF will only have the right to purchase all of La Jolla s right, title and interest under the Development Agreement in and to Riquent in the same manner as La Jolla s Purchase Right. Moreover, at any stockholders meeting of La Jolla at which La Jolla proposes to seek approval of a purchase right for BioMarin CF, BioMarin CF has agreed to vote any voting securities then held by it on the record date applicable to such specific vote in favor of such proposal.

The Development Agreement terminates automatically if: (i) BioMarin CF does not make payments under certain circumstances as set forth in the Development Agreement, or (ii) BioMarin CF does not effect the Full Participation Point pursuant to the terms set forth in the Development Agreement.

Before BioMarin CF effects the Full Participation Point, it has the right to terminate the Development Agreement for convenience upon thirty days written notice to La Jolla. After BioMarin CF effects the Full Participation Point, it has the right to terminate the Development Agreement for convenience upon one hundred and eighty days written notice to La Jolla.

In connection with the Development Agreement, the Company entered into a securities purchase agreement, dated as of January 4, 2009 (the Purchase Agreement) with La Jolla. The Purchase Agreement provides that La Jolla shall issue to the Company 3,391,035 shares of Series B Preferred Stock at a price per share of $2.21171, for an aggregate purchase price of $7.5 million. The purchase and sale of these shares of Series B Preferred Stock is expected to occur on January 20, 2009. The Series B Preferred Stock is initially convertible at a rate of one to three (*i.e.*, three shares of Common Stock for every one share of Series B Preferred Stock).

Further, if BioMarin CF elects to satisfy a portion of certain of its milestone payments by making an equity investment in La Jolla as described above, La Jolla shall issue up to $20.0 million worth of Series B Preferred Stock at a price per common share equivalent equal to the greater of (a) one hundred ten percent (110%) of the average closing price of La Jolla s Common Stock for the ten trading days commencing five trading days immediately prior to La Jolla s public announcement of the event triggering the milestone payment, and (b) $0.73724. The initial purchase of Series B Preferred Stock will be Series B-1 Convertible Preferred Stock and subsequent issuances will be either Series B-2 or B-3 Convertible Preferred Stock. Each series of Series B Preferred Stock will be *pari passu* with each other series. Each series of the Series B Preferred Stock is non-voting, convertible into La Jolla s Common Stock at any time at the Company s election and has a liquidation preference on a liquidation of La Jolla equal to the initial purchase price, subject to adjustment.

Under the Purchase Agreement, the Company was granted certain registration rights with respect to the shares of Common Stock issuable upon conversion of the Series B Preferred Stock, including the right to demand registration of such shares of Common Stock and the right to register such shares of Common Stock under a registration statement relating to an offering of any of La Jolla s securities for its own account or the account of securities holders other than the Company exercising their demand registration rights.

La Jolla has waived the application of its shareholders rights plan to the purchase by the Company of securities pursuant to the Purchase Agreement. Finally, under the Purchase Agreement, the Company has the right to participate in future sales or issuances of Common Stock, or other securities or rights convertible into Common Stock, by La Jolla, subject to certain exceptions.

The foregoing descriptions of the Development Agreement and the Purchase Agreement are qualified in their entirety by reference to the full text of Development Agreement and the Purchase Agreement, copies of which will be filed with the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

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: January 7, 2009

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