BIOMARIN PHARMACEUTICAL INC
Form 8-K
October 10, 2001

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 10, 2001

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.) |

| 371 Bel Marin Keys Boulevard, Suite 210, Novato, California | 94949 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (415) 884-6700

Not Applicable
(Former name or former address, if changed since last report)

Item 5. Other Events.

On October 10, 2001, the Registrant announced that it has reached a definitive agreement with IBEX Technologies Inc. ("IBEX") to acquire the rights to all IBEX pharmaceutical assets. IBEX's portfolio of enzyme therapeutics will complement the Registrant's existing pipeline of products for serious, life-threatening diseases and conditions.

Under the terms of the two asset purchase agreements which govern the transactions, the Registrant will acquire IBEX's pharmaceutical assets for approximately US$10.5 million, with all but approximately US$2.0 million payable in shares of the Registrant's common stock. The Registrant will also make contingent payments of up to US$9.5 million to IBEX shareholders upon U.S. FDA approval of products acquired from IBEX.

The boards of directors of the Registrant and IBEX have approved the transactions, which is subject to customary closing conditions. The transactions

are expected to close in the fourth quarter of this year.

The Registrant's press release on the transactions is attached hereto as Exhibit 99.1.

Item 7. Financial Statements, Pro Forma Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

Not Applicable.

(b) Pro Forma Financial Information.

Not Applicable.

(c) Exhibits.

Exhibit 99.1 Press Release of the Registrant dated October 10, 2001

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 10, 2001

By: /s/ Fredric D. Price_____
Fredric D. Price
Chairman and Chief Executive Officer

EXHIBIT INDEX

| Exhibit No. | Description |
|---|---|
| Exhibit 99.1 | Press Release of the Registrant dated October 10, 2001 |

Exhibit 99.1

Press Release

Contacts:

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Director
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BioMarin To Acquire Enzyme Products From IBEX Technologies

Neutralase(TM) to Enter Phase III Clinical Program for Coronary Artery Bypass Graft;Phenylase in Preclinical Development for Phenylketonuria

Conference Call and Webcast to be Held Today at 4:15 PM EDT (2215 CET)

Novato, California, October 10, 2001 - BioMarin Pharmaceutical Inc. (Nasdaq and SWX New Market: BMRN) today announced that it has reached a definitive agreement with IBEX Technologies Inc. (Toronto Stock Exchange: IBT) to acquire the rights to all IBEX pharmaceutical assets. IBEX's portfolio of enzyme therapeutics will complement BioMarin's existing pipeline of products for serious, life-threatening diseases and conditions.

New Product Additions to the BioMarin Pipeline

IBEX's lead product, NeutralaseTM, is an injectable heparinase that reverses the anticoagulation of blood by heparin and other new heparin-like anticoagulants. Neutralase is a carbohydrate-modifying enzyme that cleaves heparin, a glycosaminoglycan (GAG), in a manner similar to the activity of BioMarin's two enzyme replacement therapies: AldurazymeTM for the treatment of MPS I and rhASB for the treatment of MPS VI. Based on positive safety and efficacy data from IBEX's clinical trials of Neutralase, BioMarin plans to initiate a Phase III trial of Neutralase in Coronary Artery Bypass Graft (CABG) surgery in 2002.

In addition, IBEX has an early development stage program for Phenylase, an orally active enzyme with the potential to treat Phenylketonuria (PKU), a genetic disease caused by an enzyme deficiency that can lead to progressive, severe, and irreversible mental retardation.

Terms of the Agreement

Under the terms of the agreement, BioMarin will acquire IBEX's pharmaceutical assets for US$10.5 million, with all but US$2 million payable in shares of BioMarin common stock.

BioMarin will also make contingent payments of up to US$9.5 million to IBEX upon U.S. FDA approval of products acquired from IBEX.

The boards of directors of BioMarin and IBEX have approved the transaction, which is subject to customary closing conditions. The transaction is expected to close in the fourth quarter of this year. Leerink Swann & Co. acted as financial advisor to BioMarin with regard to this transaction.

Fredric D. Price, BioMarin's Chairman and Chief Executive Officer said, "Neutralase and Phenylase represent novel approaches to solving

medically-important problems that affect hundreds of thousands of patients in North America and Europe. The acquisition of these promising compounds further expands BioMarin's portfolio of treatments developed through our enzyme and carbohydrate chemistry expertise.

"Neutralase is a unique late-stage product with the potential to significantly reduce the serious problems associated with heparin reversal. With the addition of Neutralase, BioMarin will have five drug candidates in clinical trials next year: Aldurazyme, rhASB, Vibriolysin, Neutralase, and a fifth product that will advance from our internal development pipeline."

Robert Heft, Ph.D., Co-founder, President, and Chief Operating Officer of IBEX, added, "BioMarin's expertise in enzyme research, production, quality control and assurance, process development, and clinical trials management will greatly enhance the ability to effectively advance Neutralase and Phenylase through their next stages of development. I am looking forward to assuming my new position as Vice President, Product Development at BioMarin and contributing, with my team here in Montreal, to BioMarin's success."

Background on Neutralase and Phenylase Markets

There are approximately 300,000 CABG procedures and 725,000 angioplasties each year in the United States that could potentially benefit from heparin reversal. Estimates for the European markets are projected to be as large as those in the U.S. In addition, preclinical studies have shown that Neutralase may be effective as a reversal agent for the low molecular weight heparins (LMWHs) that are used in many surgeries such as hip and knee replacements as well as for a new class of drugs, pentasaccharides, that are also being developed for these indications.

Currently, protamine is the only product available for the reversal of heparin anticoagulation. Protamine has been known to cause significant problems during the reversal of heparin anticoagulation, but it has continued to be used in the absence of an appropriate alternative. According to numerous published articles, risks associated with protamine usage include: sudden decreases in blood pressure, depression of heart function, pulmonary hypertension, acute allergic reactions, complement activation, and strokes. IBEX's clinical trials have demonstrated that Neutralase adequately reverses heparin anticoagulation and improves blood pressure characteristics when compared to protamine. Additional data suggest that Neutralase may address other serious problems that have been linked to protamine usage as well.

Jeffrey Borer, M.D., Chief, Division of Cardiovascular Pathophysiology, Weill Medical College of Cornell University, noted, "Protamine complications during heart surgery are well known, but currently there are no other heparin antidotes. In clinical testing during open heart surgery, Neutralase has demonstrated the potential of being an effective alternative to protamine without its unwanted hemodynamic complications."

Jean-Francois Tanguay, M.D., Montreal Heart Institute, and principal investigator for IBEX's Phase II trial of Neutralase in angioplasty, commented, "Heparin reversal following angioplasty is uncommon because of the lack of a suitable drug. Initial clinical evaluation in patients undergoing angioplasty demonstrated that Neutralase has the ability to significantly reduce the time to sheath removal and the time required for safe patient ambulation."

PKU affects approximately 50,000 patients in North America and Europe. There are no drugs currently approved for treatment of PKU, and patients are required to adhere to strict, protein avoiding diets. The special formulas and foods are estimated to cost more than $5,000 per patient per year over normal food requirements. Many patients over five to ten years of age have difficulty

maintaining this dietary regimen, and their elevated phenylalanine levels lead to a variety of problems with brain function. Phenylase is an oral enzyme therapy that has the potential to reduce phenylalanine levels while allowing a less restricted, more palatable diet.

Charles R. Scriver, M.D., Alva Professor of Human Genetics, McGill University, said, "Up to now, treatment of thousands of PKU patients has been accomplished by changing lifestyle, diet and the intake of protein and phenylalanine. Almost fifty years of dietary treatment reveal how arduous and difficult it is. Oral enzyme substitution therapy with Phenylase has been demonstrated in a PKU animal model. It is time to move Phenylase forward so that it can be studied and used in the human patient."

BioMarin will host a conference call and webcast to discuss this acquisition today at 4:15 PM EDT (2215 CET). This event can be accessed on the BioMarin website at: http://investor.biomarinpharm.com.

Date: Wednesday, October 10, 2001

Time: 4:15 PM EDT (2215 CET)

U.S. & Canada Toll-free Dial in #: 1-800-997-8642

International Dial in #: 1-973-694-6836

Replay Toll-free Dial in #: 1-800-428-6051

Replay International Dial in #: 1-973-709-2089

Replay Code #: 212381

Questions and Answers Related to the Transaction

In order to provide comprehensive information to all investors regarding this transaction, BioMarin is taking this opportunity to present questions and answers related to this transaction on the accompanying pages.

BioMarin specializes in the development and commercialization of therapeutic enzyme products to treat serious, life-threatening diseases and conditions.

IBEX is a biopharmaceutical company developing enzyme-based therapeutics for a variety of applications, particularly cardiovascular disease and diseases of genetic origin.

This press release contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., and the acquisition of the assets to be acquired from IBEX and the products of IBEX. These forward-looking statements are predictions and involve risks and uncertainties such that actual results may differ materially from these statements. Results may differ materially depending on the completion of the acquisition, progress of BioMarin's product programs, including the ability to integrate the programs being acquired from IBEX, the actual results of the current and proposed clinical trials, actions of regulatory authorities, future availability of capital, future actions in the pharmaceutical market and developments by competitors, and those factors detailed in BioMarin's filings with the Securities and Exchange Commission such

as 10Q, 10K and 8K reports. Stockholders are urged not to place undo 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.

The securities to be issued in connection with this acquisition have not been registered under the Securities Act of 1933, as amended, or state securities laws and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements. The Company has agreed to use its best efforts to register all of the common stock relating to this transaction with the SEC following the closing of this acquisition.