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BIOMARIN PHARMACEUTICAL INC

Form 8-K

January 15, 2002

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 14, 2002

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 January 14, 2002, BioMarin Pharmaceutical Inc. (the "Registrant") announced that it has reached a definitive agreement to acquire Synapse Technologies Inc. ("Synapse"). The Registrant intends to use Synapse's proprietary technology to deliver therapeutic enzymes and other drugs across the blood-brain barrier by means of traditional intravenous injections.

Under the terms of the agreement, the Registrant will purchase all of the outstanding shares of Synapse for approximately US\$10.18 million by exchanging 885,275 shares of the Registrant's common stock at a value of US\$11.50 per share. The Registrant will also make contingent payments post-closing to Synapse stockholders in either cash or the Registrant's stock of

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up to approximately US\$5.10 million upon reaching certain development milestones.

The boards of directors of the Registrant and Synapse have approved the transaction, which is subject to approval of the shareholders of Synapse, approval of the Supreme Court of British Columbia after a hearing on the fairness of the terms and conditions of the acquisition, and customary closing conditions. The transaction is expected to close in the first quarter of 2002.

The Registrant's press release issued on January 14, 2002 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 January 14, 2002

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 14, 2002

By: /s/ Fredric D. Price

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Fredric D. Price  
Chairman and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
Exhibit 99.1	Press Release of the Registrant dated January 14, 2002

Exhibit 99.1

Press Release

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SOURCE: BioMarin Pharmaceutical Inc.

BioMarin to Acquire Developer of Unique Brain Delivery Technology  
Technology Pioneered by Synapse Transports Enzymes Across the Blood-Brain  
Barrier via Traditional IV Injection Conference Call and Webcast to be Held  
Today at 4:15 PM ET (2215 CET)

NOVATO, Calif., Jan. 14 /PRNewswire/ -- BioMarin Pharmaceutical Inc. (Nasdaq and Swiss SWX New Market: BMRN) today announced that it has reached a definitive agreement to acquire Synapse Technologies Inc., a privately held biopharmaceutical company based in Vancouver, British Columbia. BioMarin intends to use Synapse's proprietary technology to deliver therapeutic enzymes and other drugs across the blood- brain barrier by means of traditional intravenous injections. BioMarin will evaluate opportunities in lysosomal storage disorders using the Synapse technology to deliver enzyme replacement therapies to brain cells in order to treat the neurological effects of these genetic diseases.

### Terms of the Agreement

Under the terms of the agreement, BioMarin will purchase 100% of the outstanding shares of Synapse for approximately US\$10.18 million by exchanging 885,275 shares of BioMarin common stock at a value of US\$11.50 per share. BioMarin will also make contingent payments post-closing to Synapse stockholders in either cash or BioMarin stock of up to approximately US\$5.1 million upon reaching certain development milestones.

The boards of directors of BioMarin and Synapse have approved the transaction, which is subject to approval of the shareholders of Synapse, approval of the Supreme Court of British Columbia after a hearing on the fairness of the terms and conditions of the acquisition, and customary closing conditions. The transaction is expected to close in the first quarter of 2002.

Fredric D. Price, BioMarin's Chairman and Chief Executive Officer, said, "At present, intravenously administered biotechnology-based protein drugs

(including enzymes, hormones, and peptides) and certain small molecule drugs (including many anti-cancer agents) cannot penetrate the blood-brain barrier, the body's natural brain defense mechanism. If Synapse's brain delivery technology demonstrates safety and efficacy in human clinical trials, it will enable BioMarin to develop enzyme replacement therapies for the currently untreatable central nervous system effects of many lysosomal storage disorders.

"The acquisition of Synapse, along with the recent addition of Neutralase (TM) and Phenylase to our pipeline, enhances our enzyme technology base and opens up larger patient market opportunities for BioMarin. Equally important, this technology supports our strategic focus of developing novel enzyme therapies for significant, unmet medical needs."

Z. Sam Ruttonsha, President and Chief Executive Officer of Synapse, added, "This transaction provides an endorsement of our technology, which was originally developed by Dr. Wilfred Jefferies at the University of British Columbia, and subsequently has been financed, in part, by several leading Canadian venture capital firms. Now with the addition of BioMarin's development capabilities, we envision more rapid progress towards the commercialization of this technology."

Brain Delivery: A Significant Unmet Medical Need

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The blood-brain barrier is the brain's first line of defense against potentially harmful compounds and pathogens. It is also the major obstacle to developing drugs for the brain. Synapse's research involves the proprietary use of a natural human blood protein known as p97 that is being developed to transport both large and small molecule drugs as "payloads" across the blood-brain barrier and into brain cells. BioMarin is developing enzyme replacement therapies for lysosomal storage disorders and intends to use p97 to transport therapeutic enzymes across the blood-brain barrier into the brain for the treatment of the central nervous system effects -- such as delayed mental development -- that are associated with many lysosomal storage disorders.

Synapse has conducted preclinical studies using intravenously administered p97-enzyme conjugates that have demonstrated successful delivery of enzymes to the brain. Most importantly, the experiments have shown that these p97-enzyme conjugates remain active in brain tissue and appear within the brain cells in as little as 15 minutes after intravenous administration.

In addition, Synapse has demonstrated in animal models that it can deliver therapeutic doses of doxorubicin, an approved small molecule cancer drug that currently does not penetrate the blood-brain barrier on its own, to the brain using the p97 delivery system. Richard Beliveau, Ph.D., Professor at the University of Quebec at Montreal and Director of the Laboratory of Molecular Medicine, Ste. Justine Hospital in Montreal, Quebec, Canada, said, "Since every brain cell is within a few microns of a blood capillary, the most effective way of achieving uniform drug

distribution throughout the brain is via the brain's extensive vasculature. Therefore, the most efficient and convenient means of achieving brain delivery of enzymes and other drugs would be via the traditional intravenous injection into the bloodstream. Synapse's work is promising and, if confirmed in human clinical trials, could lead to a breakthrough in the treatment of central nervous system disorders."

Christopher M. Starr, Ph.D., BioMarin's co-founder and Senior Vice President, Research and Development, said, "While BioMarin's primary focus for p97 will be on treating the neurological problems associated with many lysosomal storage disorders, we also recognize that this technology platform may offer BioMarin additional business opportunities in the delivery of small molecule, hormone and peptide therapeutics across the blood-brain barrier. Our intention is to invest in these kinds of small molecule programs only to the extent that we can demonstrate proof of principle that we can deliver such compounds to the brain. After that time, we would then seek to form partnerships with other companies that would assume further development and commercialization responsibilities."

Synapse's employees will remain in Vancouver under the direction of Reinhard Gabathuler, Ph.D., who is currently Vice President, Research at Synapse and who will become BioMarin's Vice President, Brain Research.

Dr. Gabathuler added, "The expertise of BioMarin in enzyme replacement therapies is a near perfect fit with Synapse's brain delivery technology. Our collaborative efforts in the past few months have been fruitful and we look forward to building on this work and contributing to the future success of BioMarin." Additional information on the Synapse p97 brain delivery technology can be found on the BioMarin website by visiting:

[www.biomarinpharm.com/BM\\_ClinicalAndDevelopmentPrograms\\_BrainResearch.html](http://www.biomarinpharm.com/BM_ClinicalAndDevelopmentPrograms_BrainResearch.html)  
BioMarin will host a conference call and webcast to discuss this acquisition today at 4:15 PM EST (2215 CET). This event can be accessed on the BioMarin

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website at: <http://investor.biomarinpharm.com>.

Date: January 14th, 2002  
Time: 4:15 PM ET (2215 CET)  
U.S. & Canada Toll-free Dial in #: 1-800-360-9865  
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 #: 225408

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

Synapse Technologies Inc. is a biotechnology company specializing in the research and development of new technologies for therapeutic drug delivery to the brain across the blood-brain barrier and the identification of new drug targets in neurodegenerative diseases.

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 Synapse and the technologies of Synapse. 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 technologies being acquired from Synapse, 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 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.

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