

BIOMARIN PHARMACEUTICAL INC  
Form 8-K  
June 25, 2001

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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): June 25, 2001 (June 25, 2001)

BioMarin Pharmaceutical Inc.  
(Exact name of registrant as specified in its charter)

|   |                             |                                      |
|---|-----------------------------|--------------------------------------|
| Delaware  | 000-26727                   | 68-0397820                           |
| (State or other jurisdiction of<br>incorporation) | (Commission<br>File Number) | (IRS Employer<br>Identification No.) |

371 Bel Marin Keys Boulevard, Suite 94949  
210 (Zip Code)  
Novato, California  
(Address of principal executive  
offices)  
(415) 884-6700

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(Registrant's telephone number, including area  
code)

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Item 5.                   Other Events

Filing of Clinical Trial Exemption To Conduct Clinical Trial of Vibriolysin Topical

On June 25, 2001, we announced the filing of a Clinical Trial Exemption application with the Medicines Control Agency in the United Kingdom for permission to conduct a human clinical trial of Vibriolysin Topical in patients with serious burns. Vibriolysin Topical has displayed promising efficacy in numerous preclinical studies related to the debridement (cleaning) of dead tissue resulting from serious burns. Pending approval of the Clinical Trial Exemption by the Medicines Control Agency, the Company anticipates initiating a clinical trial of Vibriolysin Topical in the United Kingdom. If the application is approved, Vibriolysin Topical will represent our third enzyme-based product to be tested in humans.

Treatment of an acute burn injury requires the removal of dead tissue to enable healing. Depending on the depth and location of the wound, debridement may be attempted by topical drug treatment or manual methods that have been devised to reduce the blood loss and pain inherent in surgery. Vibriolysin Topical's propensity for selectively breaking down dead tissue without digesting healthy tissue, as observed in preclinical studies, suggests that Vibriolysin Topical may offer physicians treating burns a safe and effective alternative to surgery and other less effective topical drugs for the debridement of burn wounds.

This foregoing information contains forward-looking statements about our business prospects and products, including Vibriolysin Topical. 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 progress of our product programs, the results of current and proposed clinical trials, actions of regulatory authorities, including the Medicines Control Agency's actions on the Clinical Trial Exemption application, and those factors detailed in our other filings with the Securities and Exchange Commission such as 10Q, 10K and 8K reports.

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Stockholders are urged not to place undo reliance on forward-looking statements, which speak only as of the date hereof. We are under no obligation, and expressly disclaim any obligation, to update or alter any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 7. Financial Statements and Exhibits

None.

SIGNATURES

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.

By: /s/ Fredric D. Price

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Fredric D. Price  
Chief Executive Officer and  
Chairman of the Board

Date: June 25, 2001

Exhibit Index

None.