
**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): February 2, 2010 (February 2, 2010)

Protalix BioTherapeutics, Inc.
(Exact name of registrant as specified in its charter)

Florida
(State or other jurisdiction
of incorporation)

000-33357
(Commission File Number)

65-0643773
(IRS Employer
Identification No.)

**2 Snunit Street
Science Park, POB 455
Carmiel, Israel**
(Address of principal executive offices)

20100
(Zip Code)

Registrant's telephone number, including area code +972-4-988-9488

(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))
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Item 8.01. Other Events

On February 2, 2010, Protalix BioTherapeutics, Inc. (the “Company”) issued a press release announcing that, in connection with the New Drug Application (“NDA”) filed by the Company in December 2009 for taliglucerase alfa for the treatment of Gaucher disease, the U.S. Food and Drug Administration has requested additional data regarding the Chemistry, Manufacturing and Controls (CMC) section of the NDA. No additional Clinical or Preclinical information was requested. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits**(d) Exhibits**

99.1 Press release dated February 2, 2010.

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.

PROTALIX BIOTHERAPEUTICS, INC.

Date: February 2, 2010

By: /s/ David Aviezer

Name: David Aviezer, Ph.D.

Title: President and Chief Executive Officer

**Protalix Announces NDA Submission Update for taliglucerase alfa
for the Treatment of Gaucher Disease**

CARMIEL, Israel, February 2, 2010 — Protalix BioTherapeutics, Inc. (NYSE- Amex: PLX) announced today that, in connection with the New Drug Application (NDA) filed by the Company in December 2009 for taliglucerase alfa for the treatment of Gaucher disease, the U.S. Food and Drug Administration (FDA) has requested additional data regarding the Chemistry, Manufacturing and Controls (CMC) section of the NDA. No additional Clinical or Preclinical information was requested. The request focused primarily on validation of the manufacturing process in the Company's upgraded manufacturing facility. A validation plan for the Company's manufacturing process of taliglucerase alfa has already been established and reviewed by the FDA. The Company is working diligently to provide the requested data to the FDA and anticipates submitting the requested data during the second quarter of 2010.

Based on the FDA's request as part of its rolling review of the NDA, the Prescription Drug User Fee Act (PDUFA) action date for taliglucerase alfa is expected to be issued following submission of the additional requested CMC data.

Taliglucerase alfa will continue being provided to Gaucher patients in the United States under an Expanded Access protocol, as well as to patients in the European Union, Israel and other countries under Named Patient provisions.

About Gaucher disease

Gaucher disease, an inherited condition, is the most prevalent lysosomal storage disorder, with an incidence of about 1 in 20,000 live births. People with Gaucher disease do not have enough of an enzyme, β -glucosidase (glucocerebrosidase), that breaks down a certain type of fat molecule. As a result, lipid engorged cells (called Gaucher cells) amass in different parts of the body, primarily the spleen, liver and bone marrow. Accumulation of Gaucher cells may cause spleen and liver enlargement, anemia, excessive bleeding and bruising, bone disease and a number of other signs and symptoms.

About Protalix

Protalix is a biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins expressed through its proprietary plant cell based expression system. Protalix's ProCellEx(TM) presents a proprietary method for the expression of recombinant proteins that Protalix believes will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins in an environment free of mammalian components and viruses. Protalix is also advancing additional recombinant biopharmaceutical drug development programs. Taliglucerase alfa is an enzyme replacement therapy in development under a Special Protocol Assessment with the FDA for Gaucher disease. In August 2009, the FDA granted orphan drug status and fast track designation to taliglucerase alfa for the treatment of Gaucher disease and Protalix filed a rolling NDA submission with the

FDA in December 2009. In November 2009, Protalix granted Pfizer Inc. exclusive, worldwide rights to develop and commercialize taliglucerase alfa for the treatment of Gaucher disease, except in Israel. Protalix retained the right to commercialize taliglucerase alfa in Israel.

Safe Harbor Statement:

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause material differences include, among others, risks relating to: the successful completion of our clinical trials; the review process of the FDA, the EMEA, other foreign regulatory bodies and other governmental regulatory bodies, including the FDA's and the EMEA's review of any filings we make in connection with the treatment protocol for taliglucerase alfa; delays in the FDA's, the EMEA's or other health regulatory authorities' approval of any applications we file or refusals to approve such filings, including the NDA we filed with the FDA or taliglucerase alfa for the treatment of Gaucher disease; refusals by such regulatory authorities to approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product; and other factors described in our filings with the Securities and Exchange Commission. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA, EMEA or any other foreign regulatory authority may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain approval from the FDA, EMEA or any other foreign regulatory authority of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information.

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