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): August 17, 2009

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Florida	**001-33357**	**65-0643773**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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))

Item 8.01. Other Events

On August 17, 2009, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that that U.S. Food and Drug Administration (FDA) has approved the Company's treatment protocol for prGCD, for the use of prGCD in patients with Gaucher disease. The Company previously announced, on July 6, 2009, that the FDA approached the Company and asked it to consider submitting a treatment protocol for prGCD in order to address an expected shortage of the current enzyme replacement therapy approved for Gaucher disease. 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 August 17, 2009.

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: August 17, 2009

By: /s/ David Aviezer
Name: David Aviezer, Ph.D.
Title: President and Chief Executive Officer

U.S. Food and Drug Administration Approves Protalix's Treatment Protocol for prGCD

CARMIEL, Israel, August 17, 2009 (Business Wire) — Protalix BioTherapeutics, Inc. (NYSE-Amex:PLX), announced today that the U.S. Food and Drug Administration (FDA) has approved the Company's treatment protocol for prGCD, the Company's proprietary plant-cell expressed recombinant form of glucocerebrosidase (GCD) for the treatment of Gaucher disease. The treatment protocol allows physicians and other care-providers to treat patients of Gaucher disease with prGCD in the United States and additional countries world-wide while studies of prGCD continue as part of the Company's ongoing pivotal Phase III clinical trial. Prior to accepting the protocol, the FDA reviewed available data from the Company's on-going Phase III clinical development programs.

The treatment protocol is a multicenter, open-label trial designed to allow physicians and other care-providers to treat patients of Gaucher disease with prGCD during the expected shortage of Cerezyme® and thereafter. Cerezyme® is a mammalian cell expressed version of glucocerebrosidase and the only enzyme replacement therapy currently approved for Gaucher disease. The treatment protocol allows patients enrolled in the protocol to continue being treated with prGCD until its anticipated marketing approval from the FDA. The Company will provide the drug free of charge to patients enrolled in the protocol.

"We appreciate the guidance and vote of confidence provided by the FDA in establishing a treatment protocol for prGCD and are working closely with physicians and patient advocacy groups to allow Gaucher disease patients to gain access to our drug," commented Dr. David Aviezer, the Company's President and Chief Executive Officer. "We expect to conclude our phase III pivotal study next month and are looking forward to announcing top-line results from this study in October. We anticipate filing an NDA with the FDA by the end of this year."

About Protalix BioTherapeutics

Protalix is a biopharmaceutical company. Its goal is to become a fully integrated biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins to be 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 conducting a Phase III pivotal study for its lead product candidate, prGCD, to be used in enzyme replacement therapy for Gaucher disease, a rare and serious lysosomal storage disorder in humans with severe and debilitating symptoms. Protalix and the U.S. Food and Drug Administration agreed on the final design of the pivotal Phase III clinical trial through the FDA's Special Protocol Assessment (SPA) process. Protalix has completed enrollment for this study and is treating patients in the study in North America, South America, Israel, Europe and South Africa. The study is monitored by an independent

Data Monitoring Committee, including experts in the field, who monitor the on-going safety data, which has recently held their last scheduled meeting before the end of the trial. No serious adverse events have been reported in the study. Protalix is also advancing additional recombinant biopharmaceutical drug development programs.

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 preclinical development of our product candidates; the completion of clinical trials; the review process of the FDA, foreign regulatory bodies and other governmental regulation, including the FDA's review of any filings we make in connection with the treatment protocol; delays in the FDA's or other health regulatory authorities' approval of any applications we file or refusals to approve such filings; 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; the identification of lead compounds; the risk that we may fail to satisfy certain conditions relating to grants we have received from the Office of the Chief Scientist of Israel's Ministry of Industry and Trade which may lead to our being required to refund grants previously received together with interest and penalties; the risk that the Office of the Chief Scientist may not deliver to us all of the funds awarded to us; uncertainties related to the ability to attract and retain partners for our technologies and products under development; and other factors described in our filings with the Securities and Exchange Commission. Under the approved treatment protocol, prGCD might be provided only to a limited number of patients and only for a limited time. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials or in preliminary findings for such clinical trials. The FDA's approval of the treatment protocol for prGCD will not have any effect on the FDA's approval of any NDA we filed with respect to prGCD, if any, and the review by the FDA of any data from the Phase III clinical development programs in connection with the approval of the treatment protocol will not have any effect on the FDA's subsequent review of our complete Phase III clinical trial data in the future. The statements are valid only as of the date hereof and we disclaim any obligation to update this information.

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