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): December 9, 2009 (December 9, 2009)

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Florida	**000-33357**	**65-0643773**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2 Snunit Street **Science Park, POB 455** **Carmiel, Israel**	**20100**
(Address of principal executive offices)	**(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 Ruled-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 December 9, 2009, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing the completion of its New Drug Application (NDA) submission with the U.S. Food and Drug Administration (FDA) for taliglucerase alfa, a plant-cell expressed form of glucocerebrosidase (GCD) for the potential treatment of Gaucher's disease.

The Company also announced the filing of its proposed pediatric investigation plan to the pediatric committee of the European Medicines Agency (EMEA) for a clinical study in patients between the ages of two and 18. This event triggers a milestone payment to the Company of $5 million from Pfizer Inc. ("Pfizer"), in accordance with the terms and conditions of the Exclusive License and Supply Agreement, dated November 30, 2009, between the Pfizer and the Company.

In addition, the Company announced that it would be presenting the full Phase III trial results that were submitted to the FDA in the Company's NDA filing at the Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2010, February 10-12, 2010, in Miami, Florida.

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 December 9, 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: December 9, 2009

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

Protalix Completes NDA Submission for taliglucerase alfa for the Treatment of Gaucher's Disease

CARMIEL, Israel—(BUSINESS WIRE)—Protalix Biotherapeutics, Inc. (NYSE-Amex: PLX) today announced the completion of its New Drug Application (NDA) submission with the U.S. Food and Drug Administration (FDA) for taliglucerase alfa, a plant-cell expressed form of glucocerebrosidase (GCD) for the potential treatment of Gaucher's disease.

On December 1, 2009, Pfizer and Protalix entered into an agreement to develop and commercialize taliglucerase alfa for the treatment of Gaucher's disease. The agreement gives Pfizer exclusive worldwide licensing rights to commercialize taliglucerase alfa while Protalix retains commercialization rights in Israel.

"With this submission, Protalix and Pfizer take a significant step forward in making a cost-effective treatment alternative available for Gaucher's disease patients," said Dr. David Aviezer, president and CEO of Protalix. "Our global plans include submitting additional regulatory applications for taliglucerase alfa in the near term."

David Simmons, president and general manager of Pfizer's Established Products Business Unit, stated, "Pfizer has assembled a team of experts with significant orphan and genetic disease experience dedicated to working with the worldwide Gaucher's disease community. Upon the receipt of regulatory approvals, we are poised to quickly make taliglucerase alfa available to patients suffering with Gaucher's disease who are in need of new treatment options."

In addition, Protalix today announced the filing of its proposed pediatric investigation plan to the pediatric committee of the EMEA for a clinical study in patients between the ages of 2 and 18. This event triggers a milestone payment of $5 million by Pfizer to Protalix according to the agreement between the parties. The terms of the agreement calls for $55 million to be paid by Pfizer to Protalix in connection with certain regulatory milestones.

Taliglucerase alfa has been granted orphan product designation and fast track development status by FDA. Taliglucerase alfa is currently being provided to Gaucher's patients in the U.S. under an expanded access protocol, as well as to patients in the European Union under a compassionate use protocol.

On December 2, 2009, Protalix held a medical meeting with the principal investigators involved with the Company's taliglucerase alfa clinical trial program. At the event, the Company shared the full Phase III trial results that were submitted to FDA in the Company's NDA filing. These data will be presented at the Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2010, February 10-12, in Miami, Florida.

About Gaucher's disease

Gaucher's 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's 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™ 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 FDA for Gaucher's disease.

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 regulatory bodies, 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. 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 may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain FDA approval 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. Under our approved treatment protocol, UPLYSO might be provided only to a limited number of patients and only for a limited time. The FDA's

approval of the treatment protocol or the fast track designation will not have any effect on the FDA's approval of any NDA we file with respect to UPLYSO, if any, and the review by the FDA of any data from our 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 in this release are valid only as of the date hereof and we disclaim any obligation to update this information.

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