**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): September 8, 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**<br>**Science Park, POB 455**<br>**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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 September 8, 2009, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that it has received notice from the U.S. Food and Drug Administration (FDA) that the FDA's Office of Orphan Products Development has granted orphan drug designation to prGCD, the Company's proprietary plant cell expressed recombinant form of glucocerebrosidase (GCD) for the treatment of 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 September 8, 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: September 8, 2009

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

**FDA Grants Protalix Orphan Drug Designation for prGCD**

CARMIEL, Israel, September 8, 2009 (Business Wire) — Protalix BioTherapeutics, Inc. (NYSE-Amex:PLX), announced today that it has received notice from the U.S. Food and Drug Administration (FDA) that the FDA's Office of Orphan Products Development has granted orphan drug designation to prGCD, the Company's proprietary plant cell expressed recombinant form of glucocerebrosidase (GCD) for the treatment of Gaucher disease. Gaucher disease is a lysosomal storage disorder resulting from a deficiency or mutation of the GCD enzyme that can cause damage to the liver, spleen, bone marrow and in some cases, the central nervous system.

The FDA grants orphan drug designation to drugs that may provide a significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer US patients per year. Orphan drug status grants a priority review, for a faster review time of the drug's New Drug Application (NDA) and qualifies the drug for possible funding and tax savings to support clinical trials and for other financial incentives. The sponsor company of a drug must continue to meet certain conditions established by the FDA to remain eligible for orphan drug status once granted.

"The FDA's orphan drug designation further strengthens our prGCD program for treating Gaucher disease by offering important clinical development and commercialization benefits," said Dr. David Aviezer, the Company's President and Chief Executive Officer.

prGCD is currently being evaluated for the treatment of Gaucher disease in a Phase III clinical trial which is scheduled to end this month. The Company plans to announce top-line results from the Phase III trial in October, and to complete filing of an NDA with the FDA before the end of the year. In addition, after the FDA's recent approval of the Company's treatment protocol for prGCD, the Company filed applications for medical Institutional Review Board (IRB) approvals in hospitals worldwide and expects to start treating patients under the extended access treatment protocol.

**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 (FDA) agreed on the final design of the pivotal Phase III clinical trial through the FDA's Special Protocol Assessment (SPA) process. In addition, Protalix has received Fast Track Designation from the FDA for prGCD and the FDA's Office of Orphan Products Development has granted orphan drug designation to prGCD. 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 phase III trial; delays in the FDA's or other health regulatory authorities' approval of any applications we file or refusals to approve such filings; prGCD's continuing to be eligible for expedited review under the fast track and orphan drug programs, if we file an NDA for prGCD; 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 our approved treatment protocol, prGCD might be provided only to a limited number of patients and only for a limited time, and the medical institutional review board of hospitals may not choose to start treating patients under our extended access treatment protocol in a timely manner, if at all. 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, the fast track approval, or the orphan

drug designation will not have any effect on the FDA's approval of any NDA we file 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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