

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): **July 13, 2007**

**Protalix BioTherapeutics, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Florida**  
(State or Other Jurisdiction of Incorporation)

**000-27836**  
(Commission File Number)

**65-0643773**  
(IRS Employer Identification No.)

**2 Snunit Street Science Park POB 455 Carmiel, Israel**  
(Address of Principal Executive Offices)

**21000**  
(Zip Code)

**+972-4-988-9488**  
(Registrant's Telephone Number, Including Area Code)

(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 July 13, 2007, Protalix BioTherapeutics, Inc. (the “Company”) issued a press release announcing that it had reached an agreement with the United States Food and Drug Administration on the design of the Company’s phase III clinical trial of prGCD for the treatment of Gaucher disease, through the FDA’s special protocol assessment (SPA) process. The press release is attached hereto as Exhibit 99.1.

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

99.1 Press release dated July 13, 2007.

**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: July 13, 2007

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

**Protalix BioTherapeutics, Inc. Receives Special Protocol Assessment Approval from  
FDA for its Phase III Clinical Study of prGCD**

*Company Expects to Begin Enrolling Gaucher Disease Patients for Phase III Clinical Trials  
of prGCD in Third Quarter of 2007*

Carmiel, Israel – July 13, 2007 - Protalix BioTherapeutics, Inc. (AMEX: PLX) today announced that it has reached an agreement with the United States Food and Drug Administration on the final design of its pivotal phase III clinical trial for its lead product candidate, prGCD, through the FDA's Special Protocol Assessment (SPA) process. The Company expects to initiate enrollment of patients for its phase III clinical trials during the third quarter of 2007.

prGCD is a proprietary plant cell expressed recombinant form of human Glucocerebrosidase (GCD), for the treatment of Gaucher disease, a lysosomal storage disorder in humans.

The phase III clinical trial will take place in leading medical centers in the United States, Israel, where approval from the Israeli Ministry of Health has been received, and other locations worldwide. The clinical trial will initially consist of male and female adult patients with Gaucher disease.

**About Protalix BioTherapeutics, Inc.**

Protalix is a clinical stage 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™ presents a proprietary method for the expression of recombinant proteins that Protalix believes is safe and scalable and will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins. Protalix has recently announced that it has received written notice from the United States Food and Drug Administration that it may initiate a phase III clinical trial in the United States of its lead product candidate, prGCD, for its enzyme replacement therapy for Gaucher disease, a lysosomal storage disorder in humans. 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 such a material difference include, among others, the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; delays in our preparation and filing of applications for regulatory approval; delays in the approval or potential rejection of any applications we file with the FDA, or other health regulatory authorities; any lack of progress of our research and development (including the results of clinical trials being conducted by us); obtaining on a timely basis sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional financings required to fund our research programs; our ability to establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationships with collaborators, distributors and partners; potential product liability risks and risks of securing adequate levels of product liability and clinical trial insurance coverage; the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, couriers, collaborative partners, licensees, and clinical trial sites; and other factors described in our filings with the Securities and Exchange Commission. The statements are valid only as of the date hereof and we disclaim any obligation to update this information.

**For additional information, contact:**

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AMEX IR Alliance for Protalix:

Lee Roth / David Burke

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