

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): April 18, 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 21000

(Address of principal executive offices) (Zip Code)

(Former Name or Former Address, if Changed Since Last Report)

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

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 April 18, 2007, Protalix BioTherapeutics, Inc. (the "Company") issued a press
release announcing that had 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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated April 18, 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: April 18, 2007

By: /s/ David Aviezer

Name: David Aviezer, Ph.D.

Title: President and
Chief Executive Officer

Protalix BioTherapeutics, Inc. Receives Approval
from the FDA to Initiate a Phase III Clinical Trial of prGCD

Phase III clinical trial may commence shortly

Carmiel, Israel - April 18, 2007 - Protalix BioTherapeutics, Inc. (AMEX: PLX) today announced that it has received written notice from the United States Food and Drug Administration (FDA) that it may initiate a Phase III clinical trial in the United States of its lead product candidate, prGCD, a proprietary plant cell expressed recombinant form of human Glucocerebrosidase (GCD), for the treatment of Gaucher Disease, a lysosomal storage disorder in humans.

The FDA has allowed the Company to directly initiate Phase III based upon the results of the Company's pre clinical and Phase I clinical trials of prGCD. The Company presented the completed data from its Phase I clinical trial at the European Working Group of Gaucher Disease (WEGGD) in Cambridge, United Kingdom in July 2006.

The Company hopes to commence the Phase III clinical trial shortly. The trial will take place in centers in the United States, Israel, where approval from the Israeli Ministry of Health has been received, and other locations worldwide. The study will initially consist of male and female adult patients with Gaucher Disease.

David Aviezer, Ph.D., President and Chief Executive Officer of Protalix BioTherapeutics, commented, "The receipt of the FDA's approval to initiate a Phase III clinical trial of prGCD represents an important milestone in the development of this product, and we are excited about the progress we have made thus far. Following the success of our Phase I trial and our promising pre clinical and biochemical data, we believe that we will continue to see positive results from our patients in Phase III."

Dr. Aviezer continued, "We remain deeply committed to the development of a treatment for Gaucher Disease and are excited by the opportunity to commence the Phase III trial and working with the medical experts and patient community."

About Protalix BioTherapeutics, Inc.

Protalix's proprietary technology is based on its plant cell culture and bioreactor system, which provides an effective and scaleable cell system for industrial production of recombinant biopharmaceuticals. Protalix is pursuing advanced clinical studies for its enzyme therapy for Gaucher Disease and intends to advance additional recombinant biopharmaceutical drug development programs. The Company believes its plant-based expression has significant advantages over more traditional mammalian and bacterial expression technology with respect to patient safety, cost and scalability.

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; 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 our subsidiary, our manufacturing facilities, collaborative partners, licensees, and clinical trial sites; and other factors described in our filings with the Securities and Exchange Commission. The statements are accurate only as of the date hereof and we disclaim any obligation to update this information, except as required by law.

For additional information, contact:

Protalix Investor relations: investors@protalix.com
++972-4-988-9488

AMEX IR Alliance for Protalix:

Lee Roth / David Burke
212-896-1209 / 212-896-1258
lroth@kcsa.com / dburke@kcsa.com