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 1, 2011

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**	**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 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 1, 2011, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that it has submitted its reply to the Complete Response Letter issued in February 2011 by the U.S. Food and Drug Administration after its review of the Company's New Drug Application (NDA) for taliglucerase alfa for the treatment of Gaucher disease. The reply includes top-line results from the Company's switchover trial. 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 1, 2011

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 1, 2011

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

Exhibit 99.1

Protalix Submits Reply to FDA Complete Response Letter for Taliglucerase Alfa and Reports Top-Line Results from the Company's Switchover Trial

CARMIEL, Israel, August 1, 2011 /PR Newswire/Protalix BioTherapeutics, Inc. (NYSE-AMEX:PLX, TASE:PLX), announced today that it has submitted its reply to the Complete Response Letter issued in February 2011 by the U.S. Food and Drug Administration (FDA) after its review of the Company's New Drug Application (NDA) for taliglucerase alfa. Taliglucerase alfa, the Company's proprietary plant-cell expressed form of glucocerebrosidase (GCD), is in development for the treatment of Gaucher disease.

"We believe we have adequately addressed the requests that were outlined by the FDA in their Complete Response Letter," said Dr. David Aviezer, President and CEO of Protalix. "We will continue to work closely with the FDA as it moves forward with the NDA review."

On November 30, 2009, Pfizer and Protalix BioTherapeutics, Inc. entered into an agreement to develop and commercialize taliglucerase alfa.

The Company's submission addresses the issues identified by the FDA in the Complete Response Letter, including the request for clinical data from the Company's switchover trial and long-term extension trial, and additional information relating to chemistry, manufacturing and controls (CMC).

Data from all twenty six adult patients enrolled in the Company's switchover trial of patients switched from Cerezyme® to taliglucerase alfa over the nine-month period, were included in the submission. The data supports the efficacy and safety data package showing that patients can be switched from imiglucerase (Cerezyme®) to taliglucerase alfa. One patient experienced a hypersensitivity reaction. The efficacy data demonstrates that mean hemoglobin and platelet count, spleen volume and liver volume remained stable. Patients enrolled in the trial were switched from imiglucerase (doses ranging from around 10-60 U/kg every other week) to an equivalent dose using the same number of units of taliglucerase alfa.

The submission also included data from treatment naïve patients who completed the Company's pivotal Phase III trial and have continued to receive taliglucerase alfa for over 24 months in the Company's blinded long-term extension trial. These patients continued to show an improvement in efficacy and the drug was safe and well tolerated. Furthermore, those patients who were followed specifically for their bone parameters using Quantitative Chemical Shift Imaging (QCSI) MRI continued to show bone marrow improvement over time. Detailed data from the Company's switchover trial and long-term extension trial will be presented at upcoming medical meetings.

Regarding CMC, Protalix submitted further analyses and modifications of analyses previously submitted to the FDA to address their questions raised with regard to testing specifications and assay validation.

The Company expects the FDA to provide an updated Prescription Drug User Fee Act (PDUFA) target action date within weeks, which is consistent with FDA guidelines.

About Protalix

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell based expression system, ProCellEx™. Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner in an environment free of mammalian components and viruses. Protalix's lead compound, taliglucerase alfa, an enzyme replacement therapy for the treatment of Gaucher disease, completed Phase III development. To date, marketing applications have been submitted for taliglucerase alfa in the United States, European Union, Brazil, Israel and Australia. Protalix's development pipeline also includes the following product candidates: PRX-102, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; PRX-105, a pegylated recombinant human acetylcholinesterase in development for several therapeutic and prophylactic indications, a biodefense program and an organophosphate-based pesticide treatment program; an orally-delivered glucocerebrosidase enzyme that is naturally encased in carrot cells, also for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel™) for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing, spondylitis, psoriatic arthritis and plaque psoriasis; and others.

Forward Looking Statements

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. The terms "anticipate," "believe," "estimate," "expect" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. 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 completion of our clinical trials; the review process of the FDA, the EMA, other foreign regulatory bodies and other governmental regulatory bodies, including the risk that regulatory authorities may find that the data from our clinical trials and other studies is insufficient for regulatory approval; delays in the FDA's, the EMA's or other foreign regulatory authorities' approval of any applications we file or refusals to approve such filings, including the NDA we filed with the FDA for taliglucerase alfa for the treatment of Gaucher disease; the risk that the FDA may find the information we provided in our reply to the Complete Response Letter from the FDA is in sufficient for regulatory approval; the risk that our facilities may fail to remain complaint with GMP (Good Manufacturing Practices); 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; 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 from clinical trials of drug products, the FDA, EMA or any other foreign regulatory authority may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain approval from the FDA, EMA or any other foreign regulatory authority of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operations by reducing our potential marketable products and our ability to generate corresponding product revenues. 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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