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 6, 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** **(Address of principal executive offices)**	**20100** **(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 December 6, 2011, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that it received notification from the U.S. Food and Drug Administration (FDA) that the FDA has extended the Prescription Drug User Fee Act (PDUFA) goal date of the New Drug Application (NDA) for taliglucerase alfa to May 1, 2012, a three-month extension from the previous PDUFA date of February 1, 2012. 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 6, 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: December 6, 2011

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

FDA Extends taliglucerase alfa PDUFA Date to May 1, 2012

CARMIEL, Israel, December 6, 2011 /PR Newswire/Protalix BioTherapeutics, Inc. (NYSE-AMEX:PLX, TASE:PLX), announced today that it received notification from the U.S. Food and Drug Administration (FDA) that the FDA has extended the Prescription Drug User Fee Act (PDUFA) goal date of the New Drug Application (NDA) for taliglucerase alfa to May 1, 2012, a three-month extension from the previous PDUFA date of February 1, 2012. Taliglucerase alfa is the Company's proprietary plant cell expressed recombinant form of human Glucocerebrosidase (GCD), which is being developed for the treatment of Gaucher disease.

In November 2011, the Company submitted certain clinical information regarding taliglucerase alfa in response to an FDA request. This request related mainly to the presentation of select data provided in the NDA. As this information was requested and provided within 90 days of the February 1, 2012 PDUFA goal date, the agency has the option to extend the PDUFA goal date to provide adequate time for the FDA to complete their review. A three month extension cycle is the standard period granted. No additional data were requested by the FDA in the notification, nor was the Company notified of any specific deficiency in the taliglucerase alfa NDA.

"We believe we have addressed the FDA's request," said Dr. David Aviezer, Protalix's President and Chief Executive Officer. "We look forward to working closely with the agency as it continues its review."

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(TM). 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, the 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(TM)) 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 review process of the FDA, the European Medicines Agency (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; risks relating to 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 applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of an application we file for the drug product; risks relating to the completion of our clinical trials; 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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