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): November 1, 2012

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 November 1, 2012, Protalix BioTherapeutics, Inc. and Pfizer Inc. issued a press release announcing that the European Commission (EC) has issued a Commission Decision refusing the Marketing Authorization for taliglucerase alfa, an enzyme replacement therapy (ERT) for the treatment of Gaucher disease. A copy of the press release is filed as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated November 1, 2012.

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: November 1, 2012

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

Exhibit 99.1

For Immediate Release:

November 1, 2012

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European Commission Issues Decision on Taliglucerase Alfa Marketing Authorization Application

NEW YORK and CARMIEL, Israel, November 1 – Pfizer Inc. (NYSE:PFE) and Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX, TASE:PLX) today announced that the European Commission (EC) has issued a Commission Decision refusing the Marketing Authorization for taliglucerase alfa, an enzyme replacement therapy (ERT) for the treatment of Gaucher disease. The EC has endorsed the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) recommendation not to issue a Marketing Authorization for taliglucerase alfa in the European Union. The CHMP recommendation was not related to the safety, quality or efficacy of taliglucerase alfa, but solely to the specific requirements of the European Union (EU) Orphan Drug Regulation.

As first disclosed on June 22, 2012, the CHMP issued its Opinion on taliglucerase alfa and gave a positive risk-benefit assessment concluding that the benefits of the medicine outweighed its risks in the treatment of Type 1 Gaucher disease. Despite the positive risk-benefit assessment, the CHMP could not recommend Marketing Authorization due to the fact that Shire plc (Shire)'s velaglucerase alfa had received prior Marketing Authorization with orphan drug designation for the same condition. Therefore, Shire's treatment has orphan market exclusivity in the EU for a ten-year period commencing on its authorization in August 2010. Pfizer pursued a request for derogation from Shire's orphan market exclusivity based on a number of factors but the request was denied.

"We are disappointed by the EC's decision on taliglucerase alfa and believe it is important, given the history of past shortages, for the Gaucher disease community in the EU to have a third treatment option available," said Diem Nguyen, General Manager, Pfizer Biosimilars. "We will continue to work closely with our partner, Protalix, to make taliglucerase alfa available to the Gaucher disease community in other countries."

Pfizer and Protalix are dedicated to the treatment of Gaucher disease and continue to move forward with regulatory filings in other countries for taliglucerase alfa. Taliglucerase alfa (ELELYSO™) was approved by the U.S. Food and Drug Administration in May 2012 for the long-term enzyme replacement therapy (ERT) of adults with a confirmed diagnosis of Type 1 Gaucher disease and was approved by Israel's Ministry of Health in September 2012.

On November 30, 2009, Pfizer and Protalix BioTherapeutics, Inc. entered into an agreement to develop and commercialize taliglucerase alfa. Under the terms of the agreement, Pfizer received exclusive worldwide licensing rights for the commercialization of taliglucerase alfa, while Protalix retained the exclusive commercialization rights in Israel.

Pfizer Inc.: Working together for a healthier world™
At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments visit www.pfizer.com.

Protalix BioTherapeutics, Inc.
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(R). Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first approved product manufactured by ProCellEx, ELELYSO™ (taliglucerase alfa), an enzyme replacement therapy for the treatment of Gaucher disease, was approved for marketing by the U.S. Food and Drug Administration in May 2012 and by Israel's Ministry of Health in September 2012. Additional marketing applications for taliglucerase alfa have been filed in other countries.

Protalix Forward Looking Statement Disclaimer
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. Forward-looking statements involve substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties related to the timing of a commercial launch in Israel; decisions by regulatory authorities in various countries regarding whether and when to approve drug applications that have been or may be filed for taliglucerase alfa in such countries as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; risks related to the European Commission's decisions not to grant a market authorization for taliglucerase alfa; and risks related to competitive developments. The statements in this release are valid only as of the date hereof and Protalix disclaims any obligation to update this information. These and other risks and uncertainties are detailed under the heading "Risk Factors" in Protalix's Annual Report on Form 10-K for the year ended December 31, 2011 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of November 1, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking statements about taliglucerase alfa (trade name ELELYSO in the United States) that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, decisions by regulatory authorities in various countries regarding whether and when to approve drug applications that have been or may be filed for taliglucerase alfa in such countries as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments. A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q and Form 8-K.

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