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): June 22, 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 7.01. Regulation FD Disclosure

On June 22, 2012, Protalix BioTherapeutics, Inc. (the “Company”) issued a press release announcing that the Company has scheduled a conference call and webcast for Friday, June 22 at 9:00 AM EDT to review the European Medicines Agency (EMA)’s Committee for Medicinal Products for Human Use ("CHMP") opinion for taliglucerase alfa (ELELYSO™), an enzyme replacement therapy for the treatment of Gaucher disease. A copy of the press release is furnished as Exhibit 99.1.

The information contained in Item 7.01 of this report and in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events

On June 22, 2012, the Company issued a press release announcing that the CHMP has issued an Opinion recommending against the marketing authorization of taliglucerase alfa (ELELYSO™). A copy of the press release is filed as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated June 22, 2012.
99.2 Press release dated June 22, 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: June 22, 2012

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

Protalix BioTherapeutics to Review CHMP Opinion for ELELYSO™
Conference Call and Webcast Scheduled for Friday, June 22 at 9:00 AM EDT

CARMIEL, Israel, June 22, 2012/GlobeNewswire/Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX, TASE:PLX), announced today the Company has scheduled a conference call and webcast for Friday, June 22, 2012 at 9:00 AM EDT to review the Committee for Medicinal Products for Human Use's (CHMP) opinion for taliglucerase alfa (ELELYSO™), an enzyme replacement therapy for the treatment of Gaucher disease.

To participate in the conference call, please dial +1 (877) 868-1833 (toll free from the U.S. and Canada), or +1 (914) 495-8604 (for international callers); Conference ID 93586245. Investors may also access a live audio webcast of this conference call at www.protalix.com on the event calendar page. A replay of this conference call and webcast will be available approximately two hours after the conclusion of the call and will remain available for 14 days. The audio replay can be accessed by dialing +1 (855) 859-2056 (toll free from the U.S. and Canada), or +1 (404) 537-3406 (for international callers) and entering Conference ID 93586245.

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(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), was approved for marketing by the U.S. Food and Drug Administration on May 1, 2012 and is partnered with Pfizer for worldwide development and commercialization, excluding Israel, where Protalix retains full rights. Marketing applications for taliglucerase alfa have been filed in additional territories as well. 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(R)) 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 delays in the European Medicines Agency's (EMA) or other foreign regulatory authorities' approval of any applications we file or refusals to approve such filings, including the filings made regarding 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; and other factors described in our filings with the Securities and Exchange Commission. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information.

Investor Contact

Marcy Nanus
The Trout Group, LLC
646-378-2927
mnanus@troutgroup.com

Media Contact

Jennifer Conrad or Kari Watson
MacDougall Biomedical Communications
781-235-3060
jconrad@macbiocom.com
kwatson@macbiocom.com

Exhibit 99.2

For Immediate Release:

June 22, 2012

Pfizer Contacts:

Joan Campion (Media - US)
212-733-2798
Joan.Campion@Pfizer.com

Andrew Widger (Media – EU)
+44-1737-330909
Andrew.Widger@Pfizer.com

Suzanne Harnett (Investors)
212-733-8009
Suzanne.Harnett@Pfizer.com

Protalix Contacts:

Jennifer Conrad (Media)
MacDougall Biomedical Communications
781-235-3060
jconrad@macbiocom.com

Marcy Nanus (Investors)
The Trout Group, LLC
646-378-2927
Mnanus@troutgroup.com

EMA Adopts Opinion on Taliglucerase Alfa Marketing Authorization Application

NEW YORK and CARMIEL, Israel, June 22, 2012 – Pfizer Inc. (NYSE:PFE) and Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX, TASE:PLX) today announced that the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) has adopted an Opinion recommending against the Marketing Authorization of taliglucerase alfa, an enzyme replacement therapy (ERT) for the treatment of Gaucher disease. As part of its Opinion, the CHMP gave a positive risk-benefit assessment for taliglucerase alfa 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 Committee could not recommend Marketing Authorization due to Shire's velaglucerase alfa, which received prior Marketing Authorization with orphan drug designation for the same condition. Therefore, Shire's treatment has orphan market exclusivity in the European Union (EU) for ten years from the time of its authorization in August 2010. Pfizer pursued a request for derogation from Shire's orphan market exclusivity based on a number of factors. This request, however, was denied.

"While we are disappointed by the CHMP's recommendation, we are encouraged that the Committee gave a positive risk-benefit assessment. The recommendation was based solely on orphan market exclusivity and not the safety and efficacy profile of taliglucerase alfa," said Diem Nguyen, General Manager Biosimilars "Pfizer will continue to work with relevant stakeholders to determine the appropriate next steps."

Pfizer and Protalix are dedicated to the treatment of Gaucher disease worldwide and continue to move forward with other global regulatory filings for taliglucerase alfa. Taliglucerase alfa (ELELYSO™) was approved by the U.S. Food and Drug Administration on May 1, 2012 for the long term enzyme replacement therapy (ERT) of adults with a confirmed diagnosis of Type 1 Gaucher disease.

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 on May 1, 2012. Additional marketing applications for taliglucerase alfa have been filed in other countries.
This release contains forward-looking statements about ELELYSO that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties related to the timing of a commercial launch and market acceptance in the United States; decisions by regulatory authorities in other countries regarding whether and when to approve drug applications that have been or may be filed for ELELYSO as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of June 22, 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.

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.

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. 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.

# # #