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): July 2, 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 July 2, 2012, Protalix BioTherapeutics, Inc. issued a press release announcing that that new clinical data on taliglucerase alfa was presented at the 10th Annual European Working Group on Gaucher Disease Meeting that took place June 28-30 in Paris, France. 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 July 2, 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: July 2, 2012

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

Protalix BioTherapeutics Announces New Clinical Data on taliglucerase alfa Presented at the 10th Annual European Working Group on Gaucher Disease Meeting

CARMIEL, Israel, July 2, 2012 /GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX, TASE:PLX), announced today that new clinical data on taliglucerase alfa was presented at the 10th Annual European Working Group on Gaucher Disease Meeting that took place June 28-30 in Paris, France. Taliglucerase alfa is approved in the United States as an enzyme replacement therapy for the treatment of adults with type 1 Gaucher disease.

Laura van Dussen, M.D., of the Academic Medical Center, University of Amsterdam, presented long-term bone marrow responses in Gaucher patients from the Company's pivotal and extension trials. Bone marrow imaging can be used as an important indicator for determining bone risk potential for Gaucher patients. Bone marrow fat fractions of eight naïve patients from the pivotal and extension trials who were treated with taliglucerase alfa for at least 36 months, and 15 untreated Gaucher patients, were evaluated using Quantitative Chemical Shift Imaging (QCSI) MRI. At 36 months, the patients treated with taliglucerase alfa demonstrated a significant improvement in fat fraction from baseline (p-value = 0.012 after 36 months of follow-up). The range of absolute fat fraction values was between 0.19% and 0.42%, which corresponds to a mean change of 92% from baseline of fat fraction, after 36 months. In addition, there was a significant increase in bone marrow fat fractions of Gaucher patients treated with taliglucerase alfa when compared to untreated Gaucher patients (p-value = 0.004 after 36 months of follow-up). All patients treated with taliglucerase alfa demonstrated sustained improvements in all other disease parameters. The results demonstrate that treatment with taliglucerase alfa significantly increases lumbar spine fat fractions, thereby indicating clearance of Gaucher cells from the bone marrow, an important indication of overall bone disease status in Gaucher patients.

Professor Ari Zimran, M.D., Director of the Gaucher Clinic, Shaare Zedek Medical Center, Jerusalem, Israel, presented safety and efficacy data from the Company's study of taliglucerase alfa in pediatric patients with Gaucher disease. Eleven treatment-naive patients with symptoms and clinical manifestations of Gaucher disease between the ages of two and eighteen were enrolled in the trial. Patients were randomized to receive two different doses in a blinded manner; five patients were treated with a 60 U/kg dose and six patients were treated with a 30 U/kg dose. The primary endpoint of the study was change in hemoglobin concentration, and the secondary endpoints were change of spleen volume, liver volume, platelet count and chitotriosidase activity. Patients were enrolled in clinics in Israel, Paraguay, and South Africa.

After 12 months of treatment with taliglucerase alfa, changes in hemoglobin concentration were demonstrated by both dosage groups, with increases of 15.8% in the 60 U/kg group and of 13.8% in the 30 U/kg group. In addition, significant improvements were also seen in all secondary endpoints. Spleen volumes decreased by 41.1% in patients receiving 60 U/kg, and by 28.6% in patients receiving 30 U/kg of taliglucerase alfa. Similarly, liver volumes also decreased by 14.0% in the 60 U/kg group and 6.3% in the 30 U/kg group. Both treatment groups also demonstrated improvements in platelet counts with a 73.7% increase from baseline in the 60 U/kg group, and a 30.9% increase from baseline in the 30 U/kg group. Lastly, the chitotriosidase activity decreased from baseline, with a 66.0% reduction in patients receiving 60 U/kg and a 58.0% reduction in patients receiving 30 U/kg.

With respect to pediatric patients in this study, the majority of the treatment-related adverse events were mild or moderate in intensity, and transient in nature. One severe adverse event was assessed as treatment-related; gastroenteritis. The event was reported as serious due to the need for hospitalization for rehydration. This patient continues to receive taliglucerase alfa. In conclusion, the results of this study suggest that taliglucerase alfa has the potential to provide alternative therapy in pediatric patients with Gaucher Disease, as it is for adults.

Gregory Pastores, M.D., Professor of Neurology and Pediatrics and Director of the Neurogenetics Laboratory at New York University School of Medicine, presented the full results of all adult patients that participated in the Company's multi-center, open-label, nine month switchover trial of taliglucerase alfa for the treatment of Gaucher disease. In the switchover trial, patients with stable disease were switched from treatment via intravenous infusions of imiglucerase (Cerezyme (R)) to intravenous infusions of taliglucerase alfa every two weeks at an equivalent dose to the patient's previous imiglucerase dose. Twenty-six adult patients were enrolled in the switchover trial which was performed in centers throughout Europe, Israel, North America and Australia.

The results of the switchover trial demonstrate that over a nine-month treatment period of the study, patients remained stable with regard to the efficacy endpoints—spleen volume, liver volume, platelet count and hemoglobin concentration—after switching to taliglucerase alfa from imiglucerase. The safety analysis presented for the switchover trial demonstrates that taliglucerase alfa was well tolerated, and no drug related serious adverse events were reported. One patient developed neutralizing IgG antibodies that were determined to be positive in an in vitro assay, and were determined to be negative in a cell-based assay. Another patient experienced a hypersensitivity reaction, which was treated in a physician's office and resolved. The patient declined to continue infusions with premedication. This study demonstrates that taliglucerase alfa is an alternative treatment for adult patients with Gaucher disease.

Raul Chertkoff, M.D., the Company's Vice President of Medical Affairs, and Pamela Becker, M.D., Ph.D., Institute for Stem Cell and Regenerative Medicine, University of Washington, presented comparative data of taliglucerase alfa, imiglucerase, and velaglucerase alfa. Both analyses concluded that therapeutic responses are comparable between all three enzyme replacement options.

Additionally, Luc Bracoud of BioClinica Inc. discussed the importance of utilizing consistent MRI sequences when assessing longitudinal changes in spleen volume, in order to obtain optimal data in a clinical trial.

Additional information regarding the conference can be found at the official website for the meeting, http://www.ewggd-paris.com/.

Safety Information for ELELYSO™

As with any intravenous protein product, allergic reactions, some severe, were reported in the taliglucerase alfa clinical trials. A definition of anaphylaxis (as defined by Sampson et al 2006) was retrospectively applied to some of these reports. In patients who have experienced anaphylaxis during infusion with ELELYSO or with other ERT, caution should be exercised upon retreatment; appropriate medical support should be readily available.

Infusion reactions (including allergic reactions), defined as a reaction occurring within 24 hours of the infusion, were the most commonly observed reactions in patients treated with ELELYSO in clinical studies. The most commonly observed symptoms of infusion reactions were headache, chest pain or discomfort, asthenia, fatigue, urticaria, erythema, increased blood pressure, back pain and arthralgia, and flushing. Most of these reactions were mild and did not require treatment intervention.

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 Inc. 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: the risk that applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of a marketing application filed for the drug product, including the marketing applications filed for taliglucerase alfa; risks relating to the review process of the regulatory authorities that review our marketing applications, including the risk that the 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 U.S. Food and Drug Administration (FDA's), the European Medicine Agency (EMA's) or other foreign regulatory authorities' approval of any applications we file or refusals to approve such filings; risks relating to the completion of our clinical trials; and other factors described in our filings with the U.S. 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 or other marketing authorization application 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. 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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