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): February 13, 2013

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 February 13, 2013, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that new clinical data on ELELYSO™ (taliglucerase alfa) will be presented at the 9th Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2013 being held February 13-15 in Orlando, Florida. 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 February 13, 2013

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: February 13, 2013

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

Protalix Announces New Clinical Data on ELELYSO™ to be Presented at the WORLD Symposium 2013

CARMIEL, Israel, February 13, 2013/GlobeNewswire/Protalix BioTherapeutics, Inc. (NYSE MKT:PLX, TASE:PLX), announced today that new clinical data on ELELYSO™ (taliglucerase alfa) will be presented at the 9th Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2013 being held February 13-15 in Orlando, Florida. ELELYSO, the Company's first commercial product, is the first FDA-approved plant cell-based enzyme replacement therapy for Gaucher disease.

“The data to be presented at the conference further reinforce the use of ELELYSO as a treatment option for Gaucher patients, including naïve Gaucher patients, and patients who were previously treated with imiglucerase (Cerezyme®),” stated Professor Ari Zimran, M.D., Director of the Gaucher Clinic in Shaare Zedek Medical Center, Jerusalem, Israel and lead clinical investigator. “With the approval of ELELYSO in Israel, I am pleased to be able to provide a new treatment option to my patients.”

Gregory Pastores, M.D., Professor of Neurology and Pediatrics and Director of the Neurogenetics Laboratory at the New York University School of Medicine, is presenting long-term data from the Company’s multi-center, open-label switchover extension trial of ELELYSO for the treatment of Gaucher disease. The Company's original switchover trial was a nine-month trial in which patients with stable disease were switched from treatment via intravenous infusions of imiglucerase (Cerezyme®) to intravenous infusions of ELELYSO every two weeks at an equivalent dose to the patient's previous imiglucerase dose. Patients who participated in the switchover trial were given the option to continue treatment with ELELYSO in the Company's switchover extension trial.

Twenty-five adult patients completed the switchover trial, of which 19 elected to continue treatment with ELELYSO through the long-term extension trial. Five of the six patients who did not enroll in the extension trial continued nonetheless to receive ELELYSO through the Company's various compassionate use programs. One patient was unable to comply with the study protocol and therefore was not eligible to participate in the extension trial.

A 24 month interim analysis of the switchover trial demonstrates that all patients remained stable with regard to all key disease parameters, spleen volume, liver volume, platelet count and hemoglobin concentration, as well as the chitotriosidase activity biomarker after switching to ELELYSO from imiglucerase. The safety analysis presented for the 24-month switchover treatment duration demonstrates that ELELYSO 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. Four of the 19 patients enrolled in the extension trial discontinued treatment; one switched to the ELELYSO compassionate use program, one enrolled in another clinical trial, one was unable to comply with the study protocol and one was not pleased with that individual’s personal results. In conclusion, the data demonstrates that ELELYSO has a well-established safety profile and is an effective alternative treatment for adult Gaucher patients treated previously with Cerezyme.

These results will also be presented during the poster sessions, which will take place on Wednesday, February 13 from 4:30-6:30 PM ET and on Thursday, February 14 from 4:30-6:00 PM ET.

Professor Ari Zimran is presenting a poster describing long-term safety and efficacy data from the Company's double-blind, follow-on extension study of ELELYSO for the treatment of Gaucher disease in adult naïve patients. Eligible patients who completed treatment in the Company's pivotal nine-month phase III clinical trial were offered the opportunity to participate in the extension study and continue to receive ELELYSO at the same dose they received in the pivotal trial for an additional 30 months in a blinded manner. Accordingly, the extension trial included two treatment groups; one treated with a 60 U/kg dose and the other with a 30 U/kg dose. The primary endpoint of the extension trial was the percent change from baseline in spleen volume. Major secondary endpoints included percentage change from baseline in hemoglobin concentration, liver volume, platelet count and chitotriosidase activity. Twenty-six patients enrolled in the extension trial which was performed in centers throughout Europe, Israel, North America, South America and South Africa.

At thirty-six months of treatment, both the primary and major secondary efficacy endpoints were achieved. Mean spleen volume decreased 62% and 47% in each of the 60 U/kg dose and 30 U/kg dose groups, respectively; mean hemoglobin concentration increased by 3 g/dL, from 11.0 g/dL to 14.0 g/dL, in the 60 U/kg dose group and by 1.9 g/dL, from 12.4 g/dL to 14.3 g/dL, in the 30 U/kg dose group; mean liver volume decreased 19% and 21% in each of the 60 U/kg dose and 30 U/kg dose groups, respectively; mean platelet counts increased by 62,972 /mm^3, from 73,055 to 136,027 /mm^3, in the 60 U/kg dose group and by 29,783 /mm^3, from 64,900 to 94,683/mm^3, in the 30 U/kg dose group; and mean chitotriosidase activity decreased 83.0% and 73.5% for each of the 60 U/kg dose and 30 U/kg dose groups, respectively.

The safety analysis presented for both treatment groups demonstrates that ELELYSO was well tolerated, and no drug related serious adverse events were reported. Two participants 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. In addition, one patient in the 60 U/kg dose group experienced a hypersensitivity reaction during month 10 of treatment. Treatment of this patient with ELELYSO has been continued with premedication for an additional 44 months without any treatment related adverse events reported. Three of the 26 participants enrolled in the extension trial discontinued treatment; one switched into the ELELYSO compassionate use program, one was unable to comply with study protocol and one had a skin reaction during month 15.

The long-term safety and efficacy results from the naïve adult patient extension study demonstrate that ELELYSO has a well-established safety profile and is an effective long-term treatment for Gaucher disease.

Professor Zimran will also present a poster entitled “A Multicenter, Double-Blind, Randomized Safety and Efficacy Study of Two Dose Levels of Taliglucerase Alfa in Pediatric Patients with Gaucher Disease.” These data were first announced by the Company at the 10th Annual European Working Group on Gaucher Disease Meeting in June 2012.

Copies of the posters are being posted on the investor relations page of the Company's website, www.protalix.com. The content of the Company's website is not intended to be incorporated by reference into this press release or in any report or document we file.

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 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®. 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 (FDA) 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 is partnered with Pfizer Inc. for worldwide development and commercialization, excluding Israel, where Protalix retains full rights. 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: failure or delay in the commencement or completion of our clinical trials which may be caused by several factors, including: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; inability to monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; a lack of sufficient funding to finance the clinical trials; the risk that the results of our clinical trials will not support our claims of safety or efficacy; that taliglucerase alfa will not have the desired effects or includes undesirable side effects or other unexpected characteristics; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; risks relating to the review process of the FDA and other foreign 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, or other foreign regulatory authorities' approval of any applications we file or refusals to approve such filings; 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. 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. 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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