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): August 28, 2014

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 August 28, 2014, Protalix BioTherapeutics, Inc. (the "Company") and Pfizer Inc. ("Pfizer") issued a joint press release announcing that the U.S. Food and Drug Administration (FDA) approved ELELYSO™ (taliglucerase alfa) for injection for pediatric patients. ELELYSO is therefore now indicated for long-term enzyme replacement therapy (ERT) for adult and pediatric patients with a confirmed diagnosis of Type 1 Gaucher disease. Also on August 28, 2014, the Company issued a second press release announcing that the Company will host a conference call on Wednesday, September 3, 2014 at 8:30am ET to discuss the approval of ELELYSO for pediatric patients described herein. In addition, the Company's management will provide an update on the additional ongoing clinical programs, PRX-112 and PRX-102, and hold a Q&A session. Copies of the press releases are attached hereto as Exhibits 99.1 and 99.2.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated August 28, 2014.
99.2 Press release dated August 28, 2014.

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: August 28, 2014

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

Exhibit 99.1

For immediate release:
August 28, 2014

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Pfizer And Protalix BioTherapeutics Announce FDA Approval Of Pediatric Indication For ELELYSO™ (taliglucerase alfa) For Injection, For Intravenous Use For The Treatment Of Type 1 Gaucher Disease

NEW YORK, N.Y., & CARMIEL, Israel, August 28 – Pfizer Inc. (NYSE:PFE) and Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX, TASE:PLX) announced today that the U.S. Food and Drug Administration (FDA) approved ELELYSO™ (taliglucerase alfa) for injection for pediatric patients. ELELYSO is therefore now indicated for long-term enzyme replacement therapy (ERT) for adult and pediatric patients with a confirmed diagnosis of Type 1 Gaucher disease.

"The approval of ELELYSO to treat pediatric patients with Type 1 Gaucher disease provides physicians another treatment option for this rare and potentially debilitating disease," said Rory O'Connor, Senior Vice President, Global Medical Affairs, Global Innovative Pharma Business, Pfizer Inc. "This pediatric indication, along with the recent announcement that ELELYSO received kosher certification by the Orthodox Union (OU), reinforces the ongoing commitment of Pfizer to addressing the needs of the Gaucher community."

The safety and efficacy of ELELYSO were assessed in fourteen pediatric patients with Type 1 Gaucher disease in two clinical trials. The first trial consisted of nine patients in a 12-month, multi-center, double-blind, randomized study in treatment-naïve patients aged two to 13 years. At the end of the 12-month study, therapeutic efficacy of ELELYSO was demonstrated, as measured by a decrease in spleen and liver volume and an increase in platelet count. A second trial consisted of 5 pediatric patients aged 6 to 16 years who were switched from imiglucerase to ELELYSO. The trial was a 9-month, multi-center, open-label, single-arm study in patients who had been receiving treatment with imiglucerase at dosages ranging from 9.5 units/kg to 60 units/kg every other week for a minimum of 2 years. ELELYSO was administered for 9 months at the same dose as each patient's previous imiglucerase dose. If needed, adjustment of dosage was allowed during the study in order to maintain stability of clinical parameters. Mean spleen and liver volume, platelet count and hemoglobin value remained stable through 9 months of ELELYSO treatment.

The recommended dosage of ELELSYO for treatment-naïve adult and pediatric patients four years of age and older is 60 units per kg of body weight administered every other week as a 60 to 120 minute intravenous infusion.

Patients previously treated on a stable dosage of imiglucerase are recommended to begin treatment with ELELYSO at that same dosage when they switch from imiglucerase to ELELYSO. Dosage adjustments can be made based on achievement and maintenance of each patient's therapeutic goals.

Serious hypersensitivity reactions, including anaphylaxis, have occurred in some patients treated with ELELYSO. The most common adverse reactions for ELELYSO in clinical trials were itching, flushing, headache, joint pain, pain in extremity, abdominal pain, vomiting, fatigue, back pain, dizziness, nausea and rash. Vomiting occurred more often in pediatric patients than adults.

“While Type 1 Gaucher disease can manifest in childhood or adulthood, the disease more often presents during childhood,” said Paige Kaplan, MB, BCh, Section of Biochemical Genetics (Metabolic Diseases), Children's Hospital of Philadelphia. “It is important that children with this disease have access to a range of FDA-approved treatment options that are effective.”

As part of its ongoing commitment to helping address the unmet medical needs of people with rare diseases, Pfizer also offers a specialized support program -- called Gaucher Personal Support (GPS) -- for people living with Gaucher disease. Pfizer GPS is a one-stop resource for personalized patient support and specialty pharmacy services for patients and healthcare professionals. Pfizer GPS employs a dedicated and caring team of healthcare specialists who are available to help patients with Gaucher disease and their caregivers with reimbursement assistance, coordinating and locating infusion services and ongoing pharmacy support. Using Pfizer GPS, patients and healthcare professionals can access all support services 24/7 using one toll-free phone number, 1-855-ELELYSO (1-855-353-5976).

ELELYSO for injection is supplied as 200 units per vial and is available by prescription only.

For more information about Gaucher disease, please visit www.ELELYSO.com.

INDICATION

ELELYSO™ is indicated for long-term enzyme replacement therapy (ERT) for adult and pediatric patients with a confirmed diagnosis of Type 1 Gaucher disease.

IMPORTANT SAFETY INFORMATION

Serious hypersensitivity reactions including anaphylaxis have occurred in some patients treated with ELELYSO (taliglucerase alfa) for injection, for intravenous use. When treated with ELELYSO your doctor should monitor you before and after infusion for reactions.

Medical support should be readily available when ELELYSO is given. Discontinue ELELYSO immediately if you show signs or symptoms of anaphylaxis during infusion and get immediate medical care. Signs and symptoms of anaphylaxis included hives, low blood pressure, flushing, wheezing, chest tightness, nausea, vomiting and dizziness.

Signs and symptoms of hypersensitivity included itching, swelling under the skin, flushing, redness, rash, nausea, vomiting, cough, chest tightness and throat irritation. These reactions occurred up to 3 hours after the start of infusion

Management of hypersensitivity reactions is based on the severity of the reaction. Your doctor may manage the reactions by slowing or temporarily stopping the infusion, and/or treating with medications such as an antihistamine, a fever reducer and/or corticosteroids for mild reactions. Treatment with antihistamines and/or corticosteroids prior to infusion with ELELYSO may prevent these reactions from reoccurring. If severe hypersensitivity reactions occur, immediately stop the infusion of ELELYSO and get immediate medical care.

You should be carefully re-evaluated for treatment with ELELYSO if serious or hypersensitivity reactions including anaphylaxis occur.

The most common adverse reactions for ELELYSO are itching, flushing, headache, joint pain, pain in extremity, abdominal pain, vomiting, fatigue, back pain, dizziness, nausea and rash. Vomiting occurred more often in children than adults.

The recommended dosage of ELELYSO for adults and children who are 4 years of age and older and not taking another ERT is 60 units per kg of body weight given every other week as a 60 to 120 minute intravenous infusion.

As with all therapeutic proteins, including (enzyme replacement therapy) ERTs, there is a possibility of developing antibodies to ELELYSO. The relationship between developing antibodies and hypersensitivity reactions is not clear. Your doctor should monitor you for antibodies to ELELYSO if you have developed antibodies or if you have experienced hypersensitivity reactions to ELELYSO or other ERTs.

If you are pregnant, or plan to become pregnant, you should talk to your doctor about potential benefits and risks.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For full prescribing information click here.

The health information contained herein is provided for educational purposes only and is not intended to replace discussions with a health care provider. All decisions regarding patient care must be made with a health care provider, considering the unique characteristics of the patient. This product information is intended only for residents of the United States.

About Gaucher Disease

Gaucher disease is an inherited lysosomal storage disorder in humans that affects an estimated 10,000 people worldwide and can cause severe and debilitating symptoms, including: enlargement of the liver and spleen, various forms of bone disease, easy bruising, and anemia (a low number of red blood cells).

Gaucher disease consists of varying degrees of severity; it has been sub-divided into three subtypes - Types 1, 2, and 3 - according to the presence or absence of neurological involvement. Type 1, the most common, is found at a higher frequency among individuals who are of Ashkenazi Jewish ancestry.

Pfizer and Rare Diseases

Rare diseases are among the most serious of all illnesses and impact millions of patients worldwide, representing an opportunity to apply our knowledge and expertise to help make a significant impact in addressing unmet medical needs. The Pfizer focus on rare diseases builds on more than a decade of experience and a global portfolio of 22 medicines approved worldwide that treat rare diseases in the areas of hematology, neuroscience, inherited metabolic disorders, pulmonology, and oncology.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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 one of the world's premier innovative biopharmaceutical companies, we 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, please visit us at 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®. Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (FDA) in May 2012, by Israel's Ministry of Health in September 2012, by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013, by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in April 2013, by the Australian Therapeutic Goods Administration (TGA) in May 2014 and by the regulatory authorities of other countries. Marketing applications for taliglucerase alfa have been filed in additional territories as well. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of taliglucerase alfa, excluding Israel and Brazil, where Protalix retains full rights. Protalix's development pipeline 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-112, an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel®) for the treatment of certain immune and inflammatory diseases, such as rheumatoid arthritis, Crohn's disease, colitis, psoriasis and other autoimmune and inflammatory disorders; PRX-110 for the treatment of Cystic Fibrosis; and others.

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 terms "anticipate," "believe," "estimate," "expect," "plan" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. 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 preclinical studies and clinical trials which may be caused by several factors, including: risks related to the commercialization efforts for taliglucerase alfa in the United States, Israel, Brazil and other countries in which it is approved for sale; risks relating to the review process of other foreign regulatory and other governmental bodies; risks relating to delays in other foreign regulatory authorities' approval of any applications filed for taliglucerase alfa or refusals to approve such filings, as well as the decisions of such regulatory authorities regarding labeling and other matters that could affect the availability of taliglucerase alfa or its commercial potential; the risk that applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of an application filed for the drug product; the dependence on performance by third party providers of services and supplies relating to the commercialization of taliglucerase alfa; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; and other factors described in our filings with the U.S. Securities and Exchange Commission. These forward-looking statements are based on current information that may change and you are cautioned not to place undue reliance on these forward-looking statements. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information. All forward-looking statements are qualified in their entirety by this cautionary statement.

Pfizer Disclosure Notice

The information contained in this release is as of August 28, 2014. 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 information about ELELYSO ™ (taliglucerase alfa) and about an indication in the U.S. for ELELYSO for the long-term treatment of pediatric patients with a confirmed diagnosis of Type 1 Gaucher disease, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties regarding the commercial success of ELELYSO and the indication for pediatric use in the U.S.; whether and when applications will be filed for ELELYSO in other jurisdictions and whether and when regulatory authorities in other jurisdictions will approve applications for ELELYSO, as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of ELELYSO; 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, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

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Protalix Announces Conference Call to Discuss ELELYSO Pediatric Approval and Provide Updates on Additional Programs

Conference call to be held on Wednesday, September 3, 2014 at 8:30am ET

CARMIEL, Israel, August 28, 2014 /GlobeNewswire/Protalix BioTherapeutics, Inc. (NYSE MKT:PLX, TASE:PLX), announced today that it will host a conference call on Wednesday, September 3, 2014 at 8:30am ET to discuss the recent approval of ELELYSO for pediatric patients as jointly announced with Pfizer on August 28, 2014. In addition, the Company's management will also provide an update on the additional ongoing clinical programs, PRX-112 and PRX-102, and hold a Q&A session.

The conference call can be accessed by dialing (855) 241-1923 (US callers) or (267) 751-3603 (International callers). An audio webcast will be accessible via the Event Calendar section of the Protalix website, www.protalix.com.

A webcast replay will remain available for 60 days in the Event Calendar section of the Protalix website.

About Protalix BioTherapeutics, Inc.

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Forward Looking Statements

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