# 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 11, 2012

# Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Florida (State or other jurisdiction of incorporation)

001-33357 (Commission File Number) 65-0643773 (IRS Employer Identification No.)

2 Snunit Street
Science Park, POB 455
Carmiel, Israel
(Address of principal executive offices)

20100

(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 June 11, 2012, Protalix BioTherapeutics, Inc. issued a press release announcing that it has received a \$25 million milestone payment from Pfizer Inc. as part of the companies' global commercial agreement for ELELYSO<sup>TM</sup> (taliglucerase alfa). The payment was triggered by the U.S. Food and Drug Administration's approval of ELELYSO for the treatment of type 1 Gaucher disease on May 1, 2012. A copy of the press release is attached hereto as Exhibit 99.1.

# Item 9.01. Financial Statements and Exhibits

# (d) Exhibits

99.1 Press release dated June 11, 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 11, 2012 By: /s/ David Aviezer

Name: David Aviezer, Ph.D. Title: President and

Chief Executive Officer

#### Protalix Receives a \$25 Million Milestone Payment for U.S. Approval of ELELYSO™

CARMIEL, Israel, June 11, 2012 /GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX, TASE:PLX), announced today that it has received a \$25 million milestone payment from Pfizer Inc. as part of the companies' global commercial agreement for ELELYSO™ (taliglucerase alfa). This payment was triggered by the U.S. Food and Drug Administration's (FDA) approval of ELELYSO for the treatment of type 1 Gaucher disease on May 1, 2012.

On November 30, 2009, Pfizer and Protalix entered into an exclusive license and supply agreement relating to the development and commercialization of ELELYSO. Under the terms of the agreement, Protalix granted Pfizer an exclusive, worldwide license to ELELYSO except in Israel. Except with respect to Protalix's commercialization efforts in Israel, Pfizer and Protalix share the revenues and expenses related to the worldwide commercialization of ELEYSO on a 60 percent/40 percent basis, respectively, with certain agreed upon limits on the amounts of shared expenses. Protalix retained exclusive commercialization rights to the Israeli market for ELELYSO, including all revenues and expenses.

Upon signing the license and supply agreement in November 2009, Pfizer made an upfront payment of \$60 million to Protalix and subsequently made a \$5 million payment to Protalix upon Protalix's achievement of a performance milestone.

On March 31, 2012, Protalix had cash and cash equivalents \$45.6 million. On a proforma basis, including the receipt of the \$25 million milestone payment for the approval of ELELYSO in the United States, cash and cash equivalents on March 31, 2012 would have been \$70.6 million.

#### **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<sup>TM</sup> (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**

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#### **Media Contact**

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