

Protalix BioTherapeutics, Inc.
Form 8-K
August 16, 2010

**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 16, 2010 (August 10, 2010)

**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))
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Item 8.01. Other Events

On August 10, 2010, Pfizer Inc. (Pfizer) entered into a \$30 million short-term supply agreement with the ministry of health of a Latin American country pursuant to which Protalix BioTherapeutics, Inc. and Pfizer will provide taliglucerase alfa to Gaucher disease patients in such country. Pfizer holds the exclusive, worldwide rights to commercialize taliglucerase alfa for the treatment of Gaucher disease, except in Israel.

CAUTIONARY STATEMENT REGARDING 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. 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 the Company's 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: the successful preclinical development of the Company's product candidates; the completion of the Company's clinical trials; the review process of the FDA, other foreign regulatory bodies and other governmental regulatory bodies, including the FDA's review of any filings the Company makes in connection with the treatment protocol for taliglucerase alfa and including the risk that regulatory authorities may find that the data from the Company's clinical trials and other studies is insufficient for regulatory approval; delays in the FDA's or other health regulatory authorities' approval of any applications the Company files, or refusals to approve such filings, including the NDA the Company filed with the FDA for taliglucerase alfa for the treatment of Gaucher disease; refusals by such regulatory authorities to approve the marketing and sale of a drug product even after acceptance of an application the Company files for any such drug product; and other factors described in the Company's 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. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA or any other foreign regulatory authority may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain approval from the FDA or any other foreign regulatory authority of any of the Company's drug candidates in a timely manner, if at all, will severely undermine the Company's business and results of operations by reducing the Company's potential marketable products and its ability to generate corresponding product revenues. The statements in this release are valid only as of the date hereof and the Company disclaims any obligation to update this information.

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 16, 2010

By: /s/ David Aviezer

Name: David Aviezer, Ph.D.

Title: President and Chief Executive
Officer