

Protalix BioTherapeutics, Inc.
Form 8-K
December 10, 2009

**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): December 9, 2009 (December 9, 2009)

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

**Florida
(State or other jurisdiction
of incorporation)**

**000-33357
(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 December 9, 2009, Protalix BioTherapeutics, Inc. (the Company) issued a press release announcing the completion of its New Drug Application (NDA) submission with the U.S. Food and Drug Administration (FDA) for taliglucerase alfa, a plant-cell expressed form of glucocerebrosidase (GCD) for the potential treatment of Gaucher's disease.

The Company also announced the filing of its proposed pediatric investigation plan to the pediatric committee of the European Medicines Agency (EMA) for a clinical study in patients between the ages of two and 18. This event triggers a milestone payment to the Company of \$5 million from Pfizer Inc. (Pfizer), in accordance with the terms and conditions of the Exclusive License and Supply Agreement, dated November 30, 2009, between the Pfizer and the Company.

In addition, the Company announced that it would be presenting the full Phase III trial results that were submitted to the FDA in the Company's NDA filing at the Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2010, February 10-12, 2010, in Miami, Florida.

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 December 9, 2009.

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: December 9, 2009

By: /s/ David Aviezer

Name: David Aviezer, Ph.D.

Title: President and Chief Executive
Officer