
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 11, 2010 (February 11, 2010)

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 Sunit 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 February 11, 2010, Protalix BioTherapeutics, Inc. (the “Company”) issued a press release announcing that additional data from the Company’s pivotal Phase III clinical trial of taliglucerase alfa in patients with Gaucher disease was presented at the Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2010 in Miami, Florida, during an oral session titled “Novel Enzyme Replacement Therapy for Gaucher Disease: Phase III Pivotal Clinical Trial with Plant Cell Expressed Recombinant Glucocerebrosidase (prGCD) — taliglucerase alfa.” The oral presentation was made by Hanna Rosenbaum M.D., Director of Hematology Day Care Unit, RAMBAM Medical Center, Haifa, Israel, and study investigator. 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 February 11, 2010.

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 11, 2010

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

Protalix Presents Additional Phase III Data for taliglucerase alfa at the WORLD Symposium

CARMIEL, Israel, February 11, 2010 (Business Wire) — Protalix BioTherapeutics, Inc. (NYSE-Amex:PLX), announced today that additional data from the Company's pivotal Phase III clinical trial of taliglucerase alfa in patients with Gaucher disease was presented at the Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2010 in Miami, Florida, during an oral session titled, "Novel Enzyme Replacement Therapy for Gaucher Disease: Phase III Pivotal Clinical Trial with Plant Cell Expressed Recombinant Glucocerebrosidase (prGCD) — taliglucerase alfa." The oral presentation was made by Hanna Rosenbaum M.D., Director of Hematology Day Care Unit, RAMBAM Medical Center, Haifa, Israel, and study investigator.

"I believe the data from the Phase III trial demonstrates that taliglucerase alfa is well tolerated and clinically effective in treating Gaucher disease," said Dr. Hanna Rosenbaum.

The pivotal Phase III clinical trial was a multi-center, world-wide, randomized, double-blind, parallel group, dose-ranging study to assess the safety and efficacy of taliglucerase alfa in 31 treatment-naive patients suffering from Gaucher disease. In the trial, patients were selected randomly for one of two dosing arms (60 U/kg or 30 U/kg) and received intravenous infusions of taliglucerase alfa once every two weeks for a nine month period. The primary endpoint of the study was a 20% mean reduction from baseline in spleen volume after nine months, as measured by MRI. Major secondary endpoints were an increase in hemoglobin, decrease in liver volume and increase in platelet count. The trial enrolled patients at 11 centers throughout Europe, Israel, North America, South America and South Africa.

taliglucerase alfa significantly reduced mean spleen volume after nine months compared with baseline in both treatment groups. The 60 U/kg group demonstrated a statistically significant mean reduction in spleen volume of 38.0% ($p < 0.0001$) and the 30 U/kg group demonstrated a significant mean reduction in spleen volume of 26.9% ($p < 0.0001$). In addition, the primary endpoint was achieved in both treatment groups after only 6 months of therapy.

Statistically significant improvements were also observed for the secondary endpoints after nine months when compared to baseline for the 60 U/kg dose. Patients demonstrated a mean increase in hemoglobin of 2.2 g/dL or 22.2% ($p < 0.0001$), a mean decrease in liver volume of 11.1% ($p < 0.0001$) and a mean elevation in platelet count of 41,494 ml or 72.1% ($p = 0.0031$). For patients in the 30 U/kg dose, statistically significant improvements after nine months compared with baselines were observed for hemoglobin level (increased 1.6 g/dL or 14.8%; $p = 0.0010$) and liver size (decreased 10.48%; $p = 0.0041$); a nominal elevation in platelet count was also seen (11,427 ml or 13.7%; $p = 0.0460$).

Thirty patients in the trial had Chitotriosidase measurements, a biomarker for clinical symptoms of Gaucher disease. In these patients, Chitotriosidase decreased from baseline in both the 30U/kg and 60U/kg groups by 47.3% and 58.4% respectively.

The safety analysis for both treatment groups showed that taliglucerase alfa was well tolerated and no serious or severe adverse events were reported. Two patients in the trial developed antibodies to taliglucerase alfa and no patients developed neutralizing antibodies. In addition, two patients experienced hypersensitivity reactions to taliglucerase alfa. No anti-taliglucerase antibodies were detected in these patients and both reactions were treated in the physicians' clinic and reversed.

Most adverse events were considered unrelated to taliglucerase alfa. The most frequent mild to moderate adverse event was headache. Other mild to moderate adverse events included dizziness, muscle spasm, chest discomfort, nausea, skin irritation and arthralgia.

“The Phase III results reported today not only support the use taliglucerase alfa for the treatment of Gaucher disease, but also support the Company’s plant cell based platform technology,” said Dr. David Aviezer, President and CEO of Protalix. “Patients who successfully completed this pivotal study have continued to receive taliglucerase alfa as part of our ongoing extension trial, some for over two and a half years.”

The Company is currently conducting a world-wide switch over study investigating the efficacy and safety of switching to taliglucerase alfa from the currently approved enzyme replacement therapy. In addition, taliglucerase alfa is being provided to patients in the United States under an Expanded Access protocol and to patients in the European Union, Israel and other countries under Named Patient provisions.

About Gaucher disease

Gaucher disease, an inherited condition, is the most prevalent lysosomal storage disorder, with an incidence of about one in 20,000 live births. People with Gaucher disease do not have enough of an enzyme, b-glucosidase (glucocerebrosidase) that breaks down a certain type of fat molecule. As a result, lipid engorged cells (called Gaucher cells) amass in different parts of the body, primarily the spleen, liver and bone marrow. Accumulation of Gaucher cells may cause spleen and liver enlargement, anemia, excessive bleeding and bruising, bone disease and a number of other signs and symptoms.

About Protalix

Protalix is a biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins expressed through its proprietary plant cell

based expression system. Protalix's ProCellEx(TM) presents a proprietary method for the expression of recombinant proteins that Protalix believes will allow for the industrial-scale production of recombinant therapeutic proteins in an environment free of mammalian components and viruses. Protalix is also advancing additional recombinant biopharmaceutical drug development programs. Taliglucerase alfa is an enzyme replacement therapy in development under a Special Protocol Assessment with the FDA for Gaucher disease. In August 2009, the FDA granted orphan drug status and fast track designation to taliglucerase alfa for the treatment of Gaucher disease and Protalix filed a rolling NDA submission with the FDA in December 2009. In November 2009, Protalix granted Pfizer Inc. exclusive, worldwide rights to develop and commercialize taliglucerase alfa for the treatment of Gaucher disease, except in Israel. Protalix retained the right to commercialize taliglucerase alfa in Israel.

Safe Harbor Statement:

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 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: the successful preclinical development of our product candidates; the completion of clinical trials; the review process of the FDA, the EMEA, other foreign regulatory bodies and other governmental regulatory bodies, including the FDA's and the EMEA's review of any filings we make in connection with the treatment protocol; delays in the FDA's, the EMEA's or other health regulatory authorities' approval of any applications we file or refusals to approve such filings; refusals by such regulatory authorities to approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product; the identification of lead compounds; the risk that we may fail to satisfy certain conditions relating to grants we have received from the Office of the Chief Scientist of Israel's Ministry of Industry and Trade which may lead to our being required to refund grants previously received together with interest and penalties; the risk that the Office of the Chief Scientist may not deliver to us all of the funds awarded to us; uncertainties related to the ability to attract and retain partners for our technologies and products under development; 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. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA, EMEA 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, EMEA or any other foreign regulatory authority of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information.

Investor Contact:

Marcy Nanus
The Trout Group, LLC
Telephone: 646-378-2927
Email: mnanus@troutgroup.com

Media Contact:

Brad Miles
BMC Communications Group, LLC
Telephone: 212-477-9007 x17
Email: brad@bmccommunications.com