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): January 13, 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** **(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 7.01 Regulation FD Disclosure

On January 13, 2014, Protalix BioTherapeutics, Inc. issued a press release announcing that Dr. David Aviezer, the Company's President and Chief Executive Officer, will discuss the Company's corporate objectives and key milestones in a presentation at the 32nd Annual J.P. Morgan Healthcare Conference on Thursday, January 16, 2014. Dr. Aviezer's presentation will include a discussion of the Company's 2014 strategic outlook and clinical highlights. A live webcast of the presentation will be available at www.protalix.com on the event calendar page, and will be archived for 90 days. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

All of the information furnished in Item 7.01 and Exhibit 99.1 hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and unless expressly set forth by specific reference in such filings, shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, whether made before or after the date hereof and regardless of any general incorporation language in such filings.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated January 13, 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: January 13, 2014

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

Protalix BioTherapeutics Provides Full-Year 2014 Strategic Outlook
Dr. Aviezer to Present at the 32nd Annual J.P. Morgan Healthcare Conference

CARMIEL, Israel, January 13, 2014 /GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE MKT:PLX, TASE:PLX), announced today that Dr. David Aviezer, the Company's President and Chief Executive Officer, will discuss the Company's corporate objectives and key milestones in a presentation at the 32nd Annual J.P. Morgan Healthcare Conference on Thursday, January 16, 2014 at 12:00 PM, Pacific Time. Dr. Aviezer's presentation will include a discussion of the Company's 2014 strategic outlook and clinical highlights. A live webcast of the presentation will be available at www.protalix.com on the event calendar page, and will be archived for 90 days.

"In 2014, Protalix anticipates achieving a number of milestones on both the commercial and clinical front that have the potential to add significant value," commented Dr. Aviezer. "We expect to see sales of ELELYSO® (taliglucerase alfa) increase across all approved and launched territories, primarily in the United States, Israel, Brazil, Chile and Mexico. Additionally, we expect ELELYSO to be approved in Canada, Australia and Argentina. On the clinical front, we plan to report data from two key clinical programs, Oral GCD for the treatment of Gaucher disease and PRX-102 for the treatment of Fabry disease, and to initiate clinical trials for our oral antiTNF and Dnase compounds."

2013 Highlights

ELELYSO/UPLYSO highlights

- Approved in Brazil, Mexico and Chile; the drug was already approved in the United States, Israel and Uruguay.
- In Israel, since the addition of ELELYSO to Israel's national healthcare reimbursement basket in early 2013, ELELYSO has become the drug of choice for naïve adult Gaucher patients. Substantially all newly treated adult Gaucher patients in Israel during 2013 received our drug.
- In Chile, during the fourth quarter of 2013, all adult Gaucher patients previously treated with other enzyme replacement therapies were successfully switched to UPLYSO/ELELYSO.
- An application for a pediatric indication of ELELYSO has been submitted to the U.S. Food and Drug Administration.
- The Company entered into a supply and technology transfer agreement in Brazil for UPLYSO, whereby Fiocruz committed to purchase at least approximately $40 million worth of the drug during the first two years of the agreement and at least approximately $40 million worth of the drug each subsequent year under the agreement. The first shipment of the drug to Brazil under the agreement with Fiocruz has just been made. In addition, in accordance with the technology transfer agreement, Fiocruz has initiated the regulatory process with ANVISA for the registration of the drug, which is another step in progressing the agreement contingent to the progression of the commercial aspects. Fiocruz has notified the Company that it has purchased a lot in the Brazilian state of Ciera where it plans to erect its UPLYSO manufacturing site in the future.

Clinical highlights

- The Company reported positive top-line phase I clinical trial results for Oral GCD in Gaucher patients.
- The Company disclosed three new compounds in development: Oral PRX-106, an oral formulation of antiTNF alpha for the treatment of immune and inflammatory mediated disorders; PRX-110 for the treatment of Cystic Fibrosis; and PRX-107, an alpha1-antitrypsin for the treatment of emphysema.
- The U.S. Patent and Trademark Office granted the Company a new patent entitled "Human lysosomal proteins from plant cell culture" (U.S. patent 8449876). This patent relates to plant cells expressing our GCD composition for oral treatment of Gaucher disease.

2014 Commercial and Clinical Milestones

ELELYSO/UPLYSO Milestones

- In Israel, the Company anticipates continued growth, and that approximately 25% of adult Gaucher patients will be treated with ELELYSO.
- In Brazil, in accordance with the technology transfer and supply agreement, the Company expects that a total of approximately $39 million will be invoiced through July 31, 2015.
- The Company anticipates that its collaboration with Pfizer Inc. will continue to be profitable in 2014, with the Company's share in the collaboration to continually increase. ELELYSO has recently been selected as the drug of choice for Gaucher patients by certain regional insurance providers in the United States, and similar agreements with certain other national and regional providers are currently being discussed. The Company is hopeful that some of these agreements will materialize during 2014; such agreements should contribute to further growth in the Company's share in the collaboration.
- Marketing approvals for ELELYSO/UPLYSO are currently pending in several countries, including Canada, Australia and Argentina. We are hoping to obtain approvals in 2014.

Clinical Milestones

- Report interim results from the Company's phase I/II clinical trial of PRX-102 in Fabry patients during the second half of 2014; full results during the first half of 2015.
- Report phase I clinical trial results for Oral GCD, including results from patients with low platelet counts, at the Lysosomal Storage Disease Network WORLD Symposium (LDN WORLD) in February 2014.
- Initiate next phase clinical trial of Oral GCD in the second half of 2014.
- Initiate phase I clinical trial of the Oral PRX-106 anti TNF for the oral treatment of autoimmune diseases in 2014.
- File investigational new drug application (IND) enabling the initiation of a phase I clinical trial of PRX-110 for the treatment of Cystic Fibrosis in 2014.

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®. 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 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, also 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; PRX-107 for the treatment of emphysema due to hereditary alpha1-antitrypsin deficiency; 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," "project," "plan" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the progress of our various clinical trials, potential future sales of our product and additional marketing approvals of our product. These 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 related to the commercialization efforts for taliglucerase alfa in the United States, Israel, Brazil and other countries; the risk of significant delays in the commercial introduction of taliglucerase alfa in other markets as planned; risks related to the acceptance and use of taliglucerase alfa or any of our product candidates, if approved, by physicians, patients and third-party payors; the risk that we will not be able to develop a successful sales and marketing organization for any of our product candidates in a timely manner, if at all; failure or delay in the commencement or completion of our preclinical studies and clinical trials which may be caused by several factors, including: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; inability to monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; lack of sufficient funding to finance our clinical trials; the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy, that our product candidates will not have the desired effects or includes undesirable side effects or other unexpected characteristics; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in the approval or the potential rejection of any application filed with or submitted to the regulatory authorities reviewing taliglucerase alfa outside of the United States, Israel, Brazil and other countries in which taliglucerase alfa is already approved; our ability to establish and maintain strategic license, collaboration and distribution arrangements, and to manage our relationships with Pfizer Inc., Fiocruz or any other collaborator, distributor or partner; delays in our preparation and filing of applications for regulatory approval of our other product candidates in the United States, the European Union and elsewhere; our expectations with respect to the potential commercial value of our product and product candidates; the risk that products that are competitive to our product candidates may be granted orphan drug status in certain territories and, therefore, our product candidates may be subject to potential marketing and commercialization restrictions; the impact of the development of competing therapies and/or technologies; any lack of progress of our research and development activities and our clinical activities with respect to any product candidate; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our 2018 convertible notes, or any other indebtedness; potential product liability risks; risks related to the potential infringement of a third party’s patents or other intellectual property rights; the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third parties; risks of securing adequate levels of product liability and clinical trial insurance coverage; and other factors described in our filings with the U.S. 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

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

Media Contact

Kari Watson
MacDougall Biomedical Communications
781-235-3060
kwatson@macbiocom.com

Source: Protalix BioTherapeutics, Inc.