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 5, 2015

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**	**20100**
(Address of principal executive offices)	**(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 2.02. Results of Operations and Financial Condition

On January 5, 2015, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing the Company's newly implemented strategy for accelerated growth. The release includes an estimate of the Company's current cash position. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 8.01. Other Events

As set forth in Item 2.02, on January 5, 2015, the Company issued a press release announcing its newly implemented strategy for accelerated growth.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated January 5, 2015 (disclosure referenced in Item. 2.02 is furnished with this report, not filed).

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 5, 2015

By: /s/ Moshe Manor
Name: Moshe Manor
Title: President and
Chief Executive Officer

Protalix BioTherapeutics Announces New Strategy for Accelerated Growth

Prioritizing Pipeline Candidates to Focus on Bio-better Products with a Clear Competitive Advantage

CARMIEL, Israel, January 5, 2015 /GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE MKT:PLX, TASE:PLX), announced today the Company's newly implemented strategy for accelerated growth. The strategy centers around prioritizing existing and new pipeline candidates to focus on bio-better products with potentially clinically superior profiles that offer a clear competitive advantage. The following highlights the details of the strategic plan.

PRX-102 for Fabry disease

PRX-102 is designed to be an improved enzyme replacement therapy product for Fabry disease given its potential for clinically superior outcomes and enhanced safety when compared to currently marketed enzyme replacement therapies. The product remains a key focus for the Company and will aggressively be pushed through clinical development. Interim efficacy and safety data from the Company's ongoing Phase I/II trial will be presented during Protalix's corporate presentation at the JP Morgan Healthcare Conference on January 15, 2015.

Oral Anti-TNF (PRX-106) for Inflammatory Bowel Disease

Oral Anti-TNF represents a novel mode of administering a recombinant anti-TNF protein. The Company plans to initiate clinical efficacy trials of Oral Anti-TNF for the treatment of Inflammatory Bowel Disease (IBD) in a non-IND setting during 2015. Upon reviewing the proof of concept (POC) data, expected in early 2016, the Company intends to collaborate with a well-suited partner for further development.

AIR DNase (PRX-110) for Cystic Fibrosis

AIR DNase has an actin inhibition resistance that is designed to improve lung function and lower the incidence of recurrent infections by enhancing the enzyme's efficacy in patients sputa. The product has demonstrated improved disease parameters in animal models and human sputum testing when compared to the currently marketed product. The Company plans to initiate clinical efficacy trials of AIR DNase for the treatment of Cystic Fibrosis (CF) in a non-IND setting during 2015. Upon reviewing the results of the trial, expected in early 2016, the Company intends to collaborate with a well-suited partner for further development.

Oral GCD (PRX-112) for Gaucher Disease

Oral GCD represents a novel mode of administrating taliglucerase alfa, the Company's approved enzyme replacement therapy for Gaucher disease. The initial clinical data generated for this compound in pre-clinical and Phase I trials is promising. In 2015, Protalix will focus on improving the drug's formulation and delivery in order to transform it into a commercially viable product.

Potential Pipeline Candidates

Protalix aims to expand the Company's pipeline by leveraging the advantages of the ProCellEx® proprietary protein expression technology. The focus will be on biologics with improved clinical profiles than the currently marketed proteins for these indications. Biosimilars will not be a focus for the Company, and will only be considered in the case of proteins that are highly difficult to express or that represent opportunities for early market entry arising from Protalix' plant cell based intellectual property advantages.

Elelyso™ for Gaucher Disease

The Company anticipates continuing to increase market share in Israel. Additionally, management intends to continue to work closely with its collaboration partner, Pfizer Inc., and with the Brazilian government to increase sales globally.

"We are very excited with our new path forward as there are a number of key value creating milestones that have the potential to significantly increase shareholder value," commented Mr. Moshe Manor, President and CEO of Protalix. "We will have three molecules in clinical trials in 2015 which will all report efficacy data over the next 15 months, and collectively target markets over $5 billion. We have a strong cash position of approximately $54 million which will provide the financial resources necessary to implement our strategic objectives."

Upcoming Milestones

- Report interim efficacy and safety results from Phase I/II trial of PRX-102 in early January 2015; additional details to be presented at the WORLD symposium, February 9-13, 2015 in Orlando, FL
- Initiate POC efficacy study for oral Anti-TNF in 2015
- Initiate POC efficacy study for AIR DNase in 2015
- Report interim efficacy and safety results from Phase I/II trial of PRX-102 for the 1 mg/kg dose in Q3 2015
- Report final safety and efficacy results from Phase I/II trial of PRX-102 in Q4 2015
- Report results from POC efficacy study for oral Anti-TNF in early 2016
- Report results from POC efficacy study for AIR DNase in early 2016
- Initiate Phase III trial for PRX 102 in early 2016

About Protalix BioTherapeutics, Inc.

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, by the Australian Therapeutic Goods Administration (TGA) in May 2014 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; PRX-106, an orally-delivered treatment for the treatment of Inflammatory Bowel Disease; PRX-110 for the treatment of Cystic Fibrosis; 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,” “plan” 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 related to management transitions; risks related to the commercialization of our drug product; failure or delay in the commencement or completion of our preclinical 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; and lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of our product candidates will not support our claims of safety or efficacy, that our product candidates will not have the desired effects or will be associated with 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 our preparation and filing of applications for regulatory approval; delays in the approval or potential rejection of any applications we file with the FDA or other health regulatory authorities, and other risks relating to the review process; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary 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

Source: Protalix BioTherapeutics, Inc.