Protalix BioTherapeutics Announces New Strategy for Accelerated Growth

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Prioritizing Pipeline Candidates to Focus on Bio-Better Products With a Clear Competitive Advantage

CARMIEL, Israel, Jan. 5, 2015 (GLOBE NEWSWIRE) -- 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.

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