Protalix BioTherapeutics Provides Review of 2016 and Strategic Outlook for 2017

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Full Switch Plan Initiated and Published by Brazilian Ministry of Health for Gaucher Patients in Brazil Yielding Significant Revenue Stream

Fabry Phase III Clinical Trial Underway with Interim Results Expected in 2018

Phase II Clinical Trial for Cystic Fibrosis Positive Interim Data Reported with Full Results Expected During First Quarter of 2017

Phase II Clinical Trial of Oral anti TNF for Ulcerative Colitis Initiated with Results Expected in Second Half of 2017

New Pipeline Candidates for Indications for which there are Currently No Approved Drugs or that address Significant Unmet Medical Needs anticipated to be announced publicly and to progress into Clinical Development

CARMIEL, Israel, Jan. 09, 2017 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX) today announced a review of the Company's clinical and financial highlights for 2016, as well as an outlook for anticipated future strategic milestones.

"2016 was a building year for Protalix. We aggressively pushed our clinical pipeline programs forward, which included high level regulatory agency discussions and the initiation of clinical trials for all three of our disclosed leading assets," said Moshe Manor, Protalix's President and Chief Executive Officer. "Given our recent financing and the projected revenue stream from sales of alfataliglicerase in Brazil, we are well capitalized to deliver on our anticipated, value building milestones. Over the course of 2017 and into 2018, we expect to announce data from our phase III clinical trial on Fabry disease, final results from our phase II clinical trial of alidornase alfa for the treatment of Cystic Fibrosis and results from our phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis. We expect that 2017 will be an extremely important, inflection year for us, with a number of significant commercial and clinical milestones that should bring considerable value to our stockholders."

2016 and Recent Clinical Highlights

- Received purchase order from the Brazilian Ministry of Health for purchase of alfataliglicerase to treat Gaucher patients in Brazil. The order consists of a number of shipments during 2017, in increasing volumes, for a total of approximately $24.3 million. The size of the final shipment of the order represents annual revenues of approximately $42.0 million. The Brazilian Ministry of Health's order was published in the December publication of Brazil's Official Diary of the Union (Diário Oficial).
- Reported positive interim results from the Company's phase II clinical trial of alidornase alfa (PRX-110) for the treatment of Cystic Fibrosis, which results include a clinically meaningful increase in percent predicted forced expiratory volume in one second (ppFEV1).
- Initiated patient enrollment in the Company's phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis. The Company is developing OPRX-106 to be the first ever oral protein treatment, as currently there are no other oral protein treatments available.
- Received regulatory approval of alfataliglicerase in Brazil for children four years old and above with a confirmed diagnosis of Type I Gaucher disease.
- Worked closely with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) to determine the phase III clinical trial program for pegunigalsidase alfa (PRX-102) for the treatment of Fabry disease:
    - Initiated and enrolled patients in a global phase III trial of pegunigalsidase alfa versus Fabrazyme® to support a BLA filing in the United States, with a 12-month non-inferiority interim analysis to support an MAA filing with the EMA.
    - Determined a 12-month switch-over study from Replagal® will also be conducted to support FDA and EMA filings.
- Presented positive 6- and 12-month interim clinical data on pegunigalsidase alfa at the 12th Annual WORLD Symposium™ in March 2016.
- Exchanged $54.1 million principal amount of the Company's $69.0 million 4.50% Senior Convertible Notes due 2018 for $40.2 million principal amount of newly issued 7.50% Senior Secured Convertible Notes due 2021 and approximately 23.8 million shares of common stock. Concurrently, the Company sold, in a private placement, $22.5 million principal amount of 2021 Notes.
- The Company had a strong cash balance of approximately $63.0 million as of December 31, 2016, which is currently projected to fund operations into late 2019.

2017 Outlook and Projected Future Milestones

- Full results for the phase II efficacy and safety study of alidornase alfa expected to be announced during the first quarter of

2017.

- Full results for the phase II efficacy and safety study of OPRX-106 expected to be announced during the second half of 2017.
- Completion of enrollment in the phase III trial of pegunigalsidase alfa for the treatment of Fabry disease expected in 2017; interim data analysis anticipated in 2018 to support EMA and other regulatory filings outside of the United States.
    - If superiority to Fabrazyme is not yet achieved at that time, as shown in the interim data, the trial will continue for an additional year before reporting two-year data to support a U.S. regulatory filing.
- Present, via two key opinion leader (KOL) presentations and a poster, pegunigalsidase alfa clinical data at the 13th Annual WORLD Symposium™ to be held in February 2017.
- Present at the 5th Update on Fabry Nephropathy: Biomarkers, Progression and Treatment Opportunities in April 2017.
- Present, at the 40th European Cystic Fibrosis Conference, full data from the Company's phase II efficacy and safety study of alidornase alfa, in June 2017, and at the North American Cystic Fibrosis Conference in November 2017.
- Potential partnership for alidornase alfa.
- Potential collaboration for alidornase alfa with the Cystic Fibrosis Foundation.
- Potential partnership for oral anti-TNF.

A copy of the Company's January 2017 Corporate Update will be posted in the Presentations page of the Investors tab of its corporate website.

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 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights. Protalix's development pipeline includes the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa 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 "expect," "anticipate, "believe," "estimate," "project," "plan," "should" 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 the ultimate purchase by Fundação Oswaldo Cruz of alfataliglicerase pursuant to the stated purchase intentions of the Brazilian Ministry of Health of the stated amounts, if at all; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase generally; risks related to our commercialization efforts for alfataliglicerase in Brazil; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the amount of our future revenues, operations and expenditures; failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; 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; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; 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; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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 press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

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