Protalix BioTherapeutics Receives Letter Detailing Intended Purchases of Approximately $24 Million of alfataliglicerase to Treat Gaucher Patients in Brazil

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CARMIEL, Israel, Dec. 14, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX) (the "Company") announced today that the Company received a letter from Fundação Oswaldo Cruz (Fiocruz), an arm of the Brazilian Ministry of Health (the "Brazilian Ministry"), detailing intended purchases by the Brazilian Ministry of alfataliglicerase to treat Gaucher patients in Brazil. The letter requests three shipments of alfataliglicerase; the first shipment to be made in the middle of 2017, and the last at the end of 2017. The Company estimates total revenues from these shipments to be approximately $24 million in aggregate.

"To date, we have sold relatively small quantities of alfataliglicerase to the Brazilian Ministry of Health, which has allowed physicians and patients in Brazil to experience firsthand the drug's beneficial efficacy and safety profile," said Mr. Moshe Manor, Protalix's President and Chief Executive Officer. "The Brazilian Ministry's request to purchase considerably larger quantities comes on the heels of advanced negotiations with the ministry regarding the potential of alfataliglicerase becoming the preferred enzyme replacement therapy for the approximately 700 Gaucher patients treated in Brazil. The anticipated revenues could reduce our cash consumption rate by as much as a third in 2017; if we were to continue to experience increased demand from the Brazilian Ministry to the extent indicated in the letter, the anticipated revenues would have the potential to reach a breakeven point."

Gaucher disease is a rare lysosomal storage disorder. Alfataliglicerase is a plant cell-expressed form of the glucocerebrosidase enzyme that was approved by the Brazilian National Health Surveillance Agency in March 2013 for the long-term treatment of adults with Type I Gaucher disease and in November 2016 for the long-term treatment of children four years of age and above with Type I Gaucher disease.

The Company owns all rights to alfataliglicerase in Brazil.

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(R). 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: PRX-102, 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; 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 "expect," "anticipate, "believe," "estimate," "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 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 operating expenses; 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; 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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