Protalix BioTherapeutics Enters into an Exclusive Ex-US Partnership with Chiesi Farmaceutici for the Development and Commercialization of PRX-102 (pegunigalsidase alfa) for the Treatment of Fabry Disease

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Protalix grants Chiesi Ex-US rights to PRX-102, a chemically modified version of the recombinant protein alpha-Galactosidase-A protein

Protalix to receive $25 million upfront, an additional up to $25 million in development costs and an additional up to $320 million in potential regulatory and commercial milestone payments

Protalix to receive tiered royalties ranging from 15% to 35% on net sales

CARMIEL, Israel, Oct. 18, 2017 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®, today announced an Ex-US license and collaboration agreement with Chiesi Farmaceutici S.p.A., or Chiesi, for pegunigalsidase alfa, or PRX-102, the Company's chemically modified version of the recombinant protein alpha-Galactosidase-A protein that is currently being evaluated in phase III clinical trials for the treatment of Fabry disease. PRX-102 has demonstrated a significantly enhanced circulatory half-life and higher enzyme activity in the target organs affected by Fabry disease when compared to currently available versions of the molecule, and strong positive safety and efficacy data from its completed phase I/II clinical trial.

"We are pleased to partner with Chiesi, an international privately-held company with more than 80 years of experience and a strong focus on the development and commercialization of innovative medicines with commercial presence in virtually all markets outside the United States," commented Moshe Manor, Protalix's President and Chief Executive Officer. "The $50 million commitment made by Chiesi before any of our ongoing phase III clinical trial results read-out is not only a significant non-dilutive cash infusion for us, it also represents Chiesi's commitment to the Fabry market in general and our PRX-102 program in particular. With this transaction, we have secured significant and important funding while maintaining full rights to PRX-102 in the U.S. market."

Under the terms of the agreement, Protalix has licensed PRX-102 to Chiesi for all markets outside of the United States, and Protalix will receive an upfront payment of $25 million from Chiesi and additional payments of up to $25 million in development costs, capped at $10 million per year. Protalix is also eligible to receive an additional up to $320 million, in the aggregate, in regulatory and commercial milestone payments, and tiered royalties ranging from 15% to 35% on net sales. Protalix will continue to be the manufacturer of PRX-102 for clinical development purposes and commercial purposes after marketing approvals.

"With revenues of approximately $1.8 billion, the Chiesi Group is among the top 50 pharmaceutical companies in the world. By combining the respective strengths of Chiesi and Protalix to advance PRX-102, we look forward to bringing a novel, differentiated therapeutic option to patients suffering from Fabry disease who have a true need for an alternative treatment with an improved safety and efficacy profile," said Ugo Di Francesco, Chiesi's CEO. "PRX-102 complements our existing product portfolio in rare diseases and underscores our commitment to bringing novel therapeutics to patients across the globe."

Additional details regarding the collaboration can be found in Protalix's Form 8-K to be filed with the Securities and Exchange Commission.

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.

About Chiesi Farmaceutici S.p.A.

Based in Parma, Italy, Chiesi Farmaceutici is an international research-focused Healthcare Group, with over 80 years of experience in the pharmaceutical industry. Chiesi researches, develops and markets innovative drugs in the respiratory therapeutics, specialist medicine and rare disease areas. Its R&D organization is headquartered in Parma (Italy), and integrated with 6 other key R&D groups in France, the USA, the UK, Sweden and Denmark to advance Chiesi's pre-clinical, clinical and registration programmes. Chiesi employs nearly 5,000 people. For more information, visit www.chiesi.com.

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 our ability to maintain and manage our relationship with Chiesi Farmaceutici and any other collaborator, distributor or partner; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to our ability to obtain stockholder approval to increase the number of shares of common stock we are authorized to issue under our certificate of incorporation, as amended; 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 superiority, 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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