Protalix BioTherapeutics Issues 2020 Letter to Shareholders

December 30, 2020

CARMIEL, Israel, Dec. 30, 2020 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: PLX) (TASE: PLX), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx® plant cell-based protein expression system, today announced the following letter from its President and Chief Executive Officer, Dror Bashan, to its shareholders and the investment community.

Dear Protalix shareholders,

As we look forward to 2021 with great anticipation, I want to take a moment to reflect on our transformational accomplishments this past year, which has been unlike any we could have imagined. Together with our development and commercialization partner, Chiesi Global Rare Diseases, we submitted to the U.S. Food and Drug Administration (FDA) a Biologics License Application (BLA) for PRX–102 for the treatment of adult patients with Fabry disease, bringing us one step closer to the anticipated commercialization of this important treatment option. We also solidified our financial foundation and advanced our pipeline of candidates utilizing ProCellEx®, our proprietary protein expression system platform technology. At the same time, we continued to seek multiple collaborative partnerships to complement our core platform. Despite the many external challenges we faced this year, our team has been committed to accomplishing our goals and remained focused, and we persevered to position us for another year of value-adding milestones and transformational catalysts.

Advancing PRX-102 (pegunigalsidase alfa) for the treatment of Fabry Disease

Following the successful outcome of our Phase I/II clinical study of PRX–102, in May 2020, we, together with Chiesi, submitted the PRX–102 BLA to the FDA. The FDA accepted the filing under its Accelerated Approval pathway and granted Priority Review designation to PRX–102. The action date under the Prescription Drug User Fee Act (PDUFA) for the BLA has been updated to April 27, 2021.

Fabry disease represents a tremendous opportunity in a multi-billion dollar market ready for a potential better treatment option. We believe PRX–102, if approved, will meaningfully improve the quality of life for many Fabry patients and, together with Chiesi, we are preparing for the anticipated commercial launch.

Our PRX–102 phase III development program consists of three studies: the BRIDGE study; the BRIGHT study; and the BALANCE study. The BRIDGE and BRIGHT studies have been completed. Topline results of the data generated in the BRIDGE Study, which we released in May this year, showed substantial improvement in renal function, as measured by mean annualized estimated Glomerular Filtration Rate (eGFR slope), and an amelioration of the course of disease in both male and female Fabry patients who were switched from agalsidase alfa to PRX–102. Agalsidase alfa is marketed by Takeda Pharmaceutical Company Limited (Shire Plc) as Replagal®. Earlier today, we announced final results from our BRIDGE study, and we anticipate an announcement of the topline data from our BRIGHT study in the first quarter of 2021. We expect interim results from our BALANCE study in the first half of 2021.

We look forward to commercializing PRX-102 assuming the anticipated approval of the BLA in the second half of 2021.

Partnerships and Collaborations

This year, we continued expanding our relationships with other companies to leverage our pipeline through strong partnerships and collaborations.

In July 2020 we entered into a non-binding term sheet with SarcoMed USA Inc. The arrangement, if consummated, will relate to the development and commercialization of PRX–110 (alidornase alfa) for the treatment of pulmonary sarcoidosis and related diseases. We expect to be able to provide an update regarding SarcoMed USA in the next few weeks.

Earlier in the year, in March 2020, we announced an agreement with Kirin Holdings Company, Limited (Kirin) to conduct a feasibility study to evaluate production of a novel complex protein utilizing ProCellEx. We received a non-refundable payment of $1.0 million and Kirin will provide research funding to conduct cell-line engineering and protein expression studies on the target protein.

Solid Financial Balance Sheet Supporting Corporate Strategy

We raised approximately $44 million in March 2020 from the sale of common stock and warrants in a private placement to certain existing and new institutional and other accredited investors.

Subsequent to the completion of the private placement, we established an at-the-market (ATM) offering through Bank of America Securities Inc. through which we have the ability to raise up to $30 million. This transaction signifies the quality of the banking counterparties that were eager to work with us in this process and indicative of the growing interest in Protalix from institutional investors.

Enhanced Management Team

We continued adding to the senior executive management team with the appointment of Yael Hayon, Ph.D. as Vice President, Research and Development. Dr. Hayon is an important addition to the team as we advance our pipeline, bringing to the company over a decade of pharmaceutical research and development experience in both the scientific operations and administrative functions.

Looking Forward

We believe we are well positioned for success with an anticipated commercial product launch planned in a multi-billion dollar target market, a solid financial base to support growth and a pipeline of potential opportunities. We are excited to welcome 2021 and look forward to a bright future as a company. I thank our employees for their tireless efforts to get us to this point, as well as the physicians and patients who have participated and are participating in our trials.

Finally, we would like to thank you, our shareholders, for your support and we look forward to sharing our future successes with you.

Sincerely,
Dror Bashan, President & Chief Executive Officer, Director
Protalix Biotherapeutics, Inc.

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 was the first company to gain FDA approval of a protein produced through plant cell-based in suspension expression system. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the 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 consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human α–Galactosidase–A protein for the proposed treatment of Fabry disease; OPRX–106, an orally-delivered anti-inflammatory treatment; alidornase alfa for the treatment of Cystic Fibrosis; and others. Protalix has partnered with Chiesi Global Rare Diseases, both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

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 and the final results of a clinical trial may be different than the preliminary findings for the clinical trial. Factors that might cause material differences include, among others: failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: risks that the FDA will not accept an application for accelerated approval of PRX-102 with the data generated to date or will request additional data or other conditions of our submission of any application for accelerated approval of PRX-102; 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 slower than expected rates of patient recruitment; risks associated with the novel coronavirus disease (COVID-19) outbreak, which may adversely impact our business, preclinical studies and 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 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 of our future revenues and expenditures; the risk that despite the FDA's grant of fast track designation for PRX-102, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA's ability to withdraw the fast track designation at any time; 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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