Protalix BioTherapeutics Issues Letter to Stockholders

May 30, 2023

CARMIEL, Israel, May 30, 2023 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: 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 stockholders and the investment community.

May 30, 2023

Dear Protalix Stockholders,

As we arrive at the halfway point of this remarkable year, I would like to take a moment to celebrate our success, as well as share our excitement for the future of Protalix.

The spring commenced with a bang. Elfabrio®, our primary development candidate, has been approved for the treatment of adult patients with Fabry disease, both in the United States and the European Union. These approvals mark a significant milestone in our history. Although we faced challenges during our path toward regulatory approval, our team persevered, and you with us. These approvals are a true testament to our commitment to delivering innovative solutions to patients in need.

Elfabrio is the second approved therapy based on our proprietary ProCellEx® plant cell-based protein expression system, a unique platform conceived of and developed by Protalix and brought to fruition by the talented scientists making up our team. ProCellEx represents a relatively new method for developing recombinant proteins in an industrial-scale manner. Elelyso®, our first approved drug product, was the first protein produced through plant cell-based expression in suspension to be approved by the FDA.

Chiesi Global Rare Diseases, our commercial partner for Elfabrio, is well prepared for a successful commercial launch, and I have every confidence that they will realize the full potential of this much needed therapeutic option. I would like to extend my heartfelt gratitude to Chiesi.

Now that we stand on the other side of this accomplishment, we are turning our attention to our pipeline programs which have shown potential for growth. We are excited to focus on these development programs, armed with the knowledge gained from our hard-earned experiences. We plan to share our insights and future strategic initiatives with you and extend an invitation for you to join us at our upcoming in-person investors event on June 27, 2023 at 8:00 am ET at the Lotte Palace Hotel in New York City. Additional details and registration information will soon be available on our website.

We are profoundly grateful for your confidence in our company and for standing by us throughout the years. We are excited about the path ahead and the opportunity to connect with you during the upcoming event where we will discuss our future plans that we are designing to drive Protalix's growth. With your continued support, we will work towards a fruitful future, creating value for you, our investors and, most importantly, for patients and their families.

Sincerely,

Dror Bashan, President & Chief Executive Officer

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. It is the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. This unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights to taliglucerase alfa for the treatment of Gaucher disease, Protalix's first product manufactured through ProCellEx, excluding in Brazil, where Protalix retains full rights. Protalix's second product, Elfabrio®, has been approved by both the FDA and the European Medicines Agency (EMA). Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of Elfabrio.

Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: PRX–115, a plant cell-expressed recombinant PEGylated uricase for the treatment of severe gout; PRX–119, a plant cell-expressed long action DNase I for the treatment of NETs–related diseases; 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," "may," "plan," "will," "would," "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 Protalix's current beliefs and expectations as to such future outcomes. Factors that might cause material differences include, among others: risks related to the commercialization of Elfabrio; the likelihood that the FDA, EMA or other applicable health regulatory authorities will approve an alternative dosing regimen for Elfabrio; risks related to the commercial success of Protalix's other product and product candidates, if approved; failure or delay in the commencement or completion of preclinical studies and clinical trials of our other product candidates 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 satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and inability to monitor patients adequately during or after treatment; delays in the approval or potential rejection of any applications we file with the FDA, EMA or other health regulatory authorities for our other product candidates, and other risks relating to the review process; risks associated with the novel coronavirus disease, or 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 the applicable claims of safety or efficacy, or 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 our collaborators, distributors or partners; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; 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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