Protalix BioTherapeutics Letter to Stockholders

January 5, 2026

CARMIEL, Israel, Jan. 5, 2026 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: PLX), a biopharmaceutical company focused on the discovery, development, production and commercialization of innovative therapeutics for rare diseases with significant unmet needs, today announced the following update from President and Chief Executive Officer, Dror Bashan, to its stockholders.

Dear Protalix Stockholders,

As we look forward to 2026, we remain focused on building with our partners a growing, profitable business and an innovative pipeline for patients with high-need rare diseases.

A core element of this plan is our advancement of PRX-115 for patients with uncontrolled gout. Clinical data from our Phase 1 trial demonstrate that PRX-115 provides a rapid and durable urate-lowering effect with a favorable tolerability profile, supporting its potential as a meaningful differentiated treatment option. Epidemiologic analyses confirm gout prevalence continues to rise worldwide, with U.S. rates increasing significantly over the last two decades.[1,2] Despite available therapies, a large proportion of patients remain uncontrolled due to treatment limitations and poor adherence.[3,4] Uncontrolled gout is a high–need, high–value indication and PRX-115 has the potential to deliver a differentiated clinical profile with rapid onset and durable urate control. PRX-115 emerges from our internal pipeline as a possible third molecule for commercialization.

In parallel, we are sharpening our strategic focus on rare kidney diseases to build a renal pipeline through innovation and partnerships — starting with PRX-119 as a long–acting DNase I for the treatment of inflammation and fibrosis.

This initiative reflects our conviction to continue delivering meaningful therapies for patients facing complex diseases with high unmet need while building durable, long–term value. Commercial execution through our partners remains a core driver of our near–term value and long-term growth.

Commercial Execution and Market Positioning

Throughout last year, we had consistent performance with our partner, Chiesi Global Rare Diseases, across the United States and key ex-U.S. markets, achieving solid Elfabrio® launch execution for the treatment of Fabry disease. Core indicators, including treated patient counts and market share across the United States, EU, and additional geographies, continue to track to plan.

Our future sales will continue to be anchored by Elfabrio through our partner, Chiesi, across the United States and key ex-U.S. markets. Our confidence in the Fabry market has been further validated by the recent acquisition,[5] and the global Fabry market is projected to reach approximately $3.4°billion by 2030. We believe Elfabrio is positioned to capture 15% to 20% of this market over the same period.

A re-examination of the negative opinion issued in November 2025 by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) regarding the proposed 2 mg/kg every-four-weeks (E4W) dosing regimen for Elfabrio is underway, with an appeal outcome expected in the first quarter of 2026. This effort reflects Chiesi's and Protalix's mutual commitment to expanding patient access by offering a more flexible dosing option. Importantly, this process does not affect the existing bi-weekly label, which remains intact.

We also expect steady and durable contributions from Elelyso®, supported by our longstanding collaboration with Pfizer Inc. and continued support through our partnership with Fundação Oswaldo Cruz (Fiocruz), an arm of the Brazilian Ministry of Health. These established revenue streams help underpin our operating resilience.

Pipeline Strategy and Progress

With a commercial foundation complemented by well-established partners, we are advancing a purpose-built R&D pipeline to address significant market opportunities with high unmet medical need. Our uncontrolled gout and rare renal disease programs align with areas of growing investments, increasing disease prevalence, and meaningful therapeutic gaps, allowing us to deploy capital toward initiatives that we believe have the potential to deliver substantial long-term returns.

PRX-115 for Uncontrolled Gout

- In October 2025, we submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in connection with our planned Phase 2 clinical trial of PRX-115, which became effective following the FDA's standard 30–day review period (NCT05745727), and the first clinical sites have been fully activated.
- Phase 1 data demonstrate that PRX-115 was generally well–tolerated, with mainly mild and transient events. Data also showed that a single dose reduced urate below the target levels (<6 mg/dL) across all cohorts and that the effect lasted for 12 weeks at higher doses.
- PRX–115 is engineered for high specific activity, enhanced stability, and reduced immunogenicity. We believe it has the potential to be a best–in–class therapy for uncontrolled gout, with once–every–four–weeks dosing without an immunomodulator or longer dosing intervals when used with methotrexate.

Focus on Rare Renal Indications (Preclinical Programs)

As we expand our portfolio, we are executing a focused strategy centered on rare kidney diseases, leveraging our platform strengths and a diversified modality mix to address high unmet needs.

- **PRX–119**: Our PEGylated, long–acting DNase I is designed to degrade neutrophil extracellular traps (NETs) and reduce downstream inflammation and fibrosis. PRX–119 has the potential to be a key pipeline asset.

- **Secarna Collaboration**: We recently announced an RNA–based collaboration with Secarna Pharmaceuticals utilizing Secarna's AI–powered OligoCreator® platform. This partnership combines our rare disease and biologics expertise with Secarna's AI–driven platform to jointly develop novel therapeutic candidates for rare renal indications.

Outlook: Building Durable Growth and Long–Term Value

Protalix enters 2026 with a profitable commercial business through our partners and a focused pipeline aligned to areas of high unmet need. We believe this foundation limits downside risk while preserving significant upside potential as we execute our clinical programs, expand our commercial footprint, and pursue strategic partnerships that can accelerate impact and scale.

Our priorities remain consistent:

1. Facilitate Chiesi's commercial performance with Elfabrio
2. Advance PRX–115 as a potential best–in–class therapy for uncontrolled gout
3. Advance rare renal programs leveraging our R&D strengths

We move forward with confidence, commitment, and an unwavering focus on creating long–term value for patients, partners, and shareholders alike.

On behalf of the entire Protalix team, thank you for your continued trust and support.

Truly yours,

Dror Bashan
President & Chief Executive Officer

About Protalix BioTherapeutics, Inc.
Protalix is a biopharmaceutical company focused on the discovery, development, production and commercialization of innovative therapeutics for rare diseases. Protalix has researched, developed and currently manufactures two enzyme replacement therapies that are currently available in multiple markets. These therapies are recombinant therapeutic proteins expressed through Protalix's proprietary plant cell-based expression system, ProCellEx®. ProCellEx is a unique plant cell-based system that enables Protalix to produce recombinant proteins in an industrial-scale manner with no exposure to mammalian cells. Protalix 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. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights to taliglucerase alfa, Elelyso®, for the treatment of Gaucher disease, excluding in Brazil where Protalix retains full rights.

Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of Elfabrio® which was approved by both the FDA and the European Medicines Agency (EMA) in May 2023. Protalix's development pipeline includes, among others, two proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets: PRX–115, a plant cell-expressed recombinant PEGylated uricase for the treatment of uncontrolled gout; and PRX–119, a plant cell-expressed long-acting DNase I for the treatment of NETs-related diseases. To learn more, please visit **www.protalix.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 "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" 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: risks related to the commercialization of Elfabrio® (pegunigalsidase alfa-iwxj), our approved product for the treatment of adult patients with Fabry disease; risks relating to Elfabrio's market acceptance, competition, reimbursement and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product; the possible disruption of our operations due to military actions conducted by Israel with the Hamas terrorist organization located in the Gaza Strip, the Hezbollah in Lebanon, the Houthis which control parts of Yemen, Iran and others, including as a result of the disruption of the operations of certain regulatory authorities and of certain of our suppliers, collaborative partners, licensees, clinical trial sites, distributors and customers, and the risk that the current hostilities will result in a greater regional conflict; risks related to the regulatory approval and commercial success of our other product and product candidates, if approved; risks related to our expectations with respect to the projected market of our products and product candidates; failure or delay in the commencement or completion of our preclinical studies 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 satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and/or 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, including the requested a re-examination of the negative opinion issued by the CHMP regarding the proposed dosing regimen of 2 mg/kg body weight infused E4W for Elfabrio, and other risks relating to the review process; risks related to the amount and sufficiency of our cash and cash equivalents and short-term bank deposits; risks related to any transactions we may effect in the public or private equity or debt markets to raise capital to finance future research and development activities, general and administrative expenses and working capital; risks associated with global conditions and developments such as new or increased tariffs, new trade restrictions, supply chain challenges, the inflationary environment and tight labor market, and instability in the banking industry, which may adversely impact our business, operations and ability to raise additional financing if and as required and on terms acceptable to us; risks relating to our evaluation and pursuit of strategic partnerships; the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy and 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 manage our relationship with our collaborators, distributors or partners, including, but not limited to, Pfizer and Chiesi; risks relating to changes to interim, top-line or preliminary data from clinical trials that we announce or publish; risks relating to the compliance by Fiocruz with its purchase obligations under our supply and technology transfer agreement, which may have a material adverse effect on us and may also result in the termination of such agreement; risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector; 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; risks related to our supply of drug products to Pfizer; potential product liability risks, and risks of securing adequate levels of related insurance coverage; the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties; risks relating to changes in healthcare laws, rules and regulations in the United States or

elsewhere; 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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[1] Punzi L, Scagnellato L, Galozzi P, et al. *Gout: one year in review 2025.* Clin Exp Rheumatol. 2025;43(5):799–808.

[2] Jacobsen J, Shattler K. *Gout Statistics & Facts 2025.* HealthCanal. Published November 28, 2023.

[3] American Arthritis Foundation. *Millions of Americans Struggle with Gout: The Ongoing Challenge of Treatment Adherence.* Published February 21, 2025.

[4] Kragh N, Worsfold A, Oladapo A, et al. *Burden of disease in patients with uncontrolled gout in the USA.* ISPOR 2024; Poster HSD103.

[5] As announced on December 19, 2025, BioMarin Pharmaceutical agreed to acquire Amicus Therapeutics for $4.8 billion, gaining Galafold® (migalastat) — a leading oral therapy for Fabry disease — along with Amicus' Pompe therapy franchise (Link to press release HERE)

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