Higher Single PRX-115 Doses Kept Plasma Uric Acid Levels Below Therapeutic Target for Longer Durations

November 9, 2026

Protalix BioTherapeutics Presents Data Supporting Potential for Less Frequent Dosing in Phase 2 RELEASE Study for Uncontrolled Gout

- The Company previously reported that higher single doses of PRX–115 lowered mean plasma uric acid for longer durations in participants with elevated plasma uric acid levels (ACR 2024)
- New individual patient data presented at ACR 2026 reinforce this finding and show the effect associated with PRX-115 plasma levels remaining measurable for up to 85 days
- The Company believes PRX-115 has best-in-class potential in uncontrolled gout, a high unmet need with top-line results from the Phase 2 RELEASE study expected in the second half of 2027

CARMIEL, Israel, Nov. 9, 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 individual participant results from a pharmacokinetic (PK) and pharmacodynamic (PD) analysis of the higher-dose cohorts of its Phase 1 single ascending dose study of PRX-115, a plant cell–expressed recombinant PEGylated uricase in development for uncontrolled gout. The Company is presenting the analysis in a poster at the American College of Rheumatology (ACR) Convergence 2026 taking place in Orlando, Florida from November 6-11, 2026.

Uncontrolled gout is a disease with low quality of life and high unmet need. Current uricase therapy has challenges including infusion burden, immunogenicity with loss of efficacy, and safety concerns. PRX-115 is designed for high specific activity, prolonged circulating half-life, and reduced immunogenicity.[1] In the Phase 1 study of adults with elevated plasma uric acid, single infusions of PRX–115 lowered plasma uric acid levels rapidly and were generally well–tolerated. At 36 mg, mean plasma uric acid levels stayed below the 6.0 mg/dL target for up to 12 weeks after a single infusion. These data support the Phase 2 RELEASE study (NCT07280156) of PRX-115 for the treatment of uncontrolled gout.

"Uncontrolled gout is a high unmet need, and PRX-115 has the potential to be a differentiated therapy," said Dror Bashan, President and Chief Executive Officer of Protalix BioTherapeutics. "The Phase 1 data support the potential for less frequent dosing, which could reduce infusion burden and improve patient adherence. The Phase 2 RELEASE study is designed to test two potential differentiators: dosing every four weeks without methotrexate and dosing every eight weeks with methotrexate. We anticipate top-line results in the second half of 2027."

Phase 1 Data Support Testing Longer Dosing Intervals in Phase 2 RELEASE Study

Plasma Uric Acid Lowering Increased With Dose and Lasted for Weeks

- The analysis is being presented at the ACR Convergence 2026 covers the 18 mg, 24 mg and 36 mg cohorts, with six participants per cohort who received a single infusion and were followed for 85 days.
- PRX-115 exposure increased with dose and persisted longer at higher doses.
- Participants with prolonged measurable PRX-115 concentrations kept plasma uric acid levels below the therapeutic target longer; declining concentrations matched gradual plasma uric acid recovery.

Safety data from the Phase 1 study showed PRX-115 was generally well tolerated, with mostly mild to moderate and transient related adverse events and one anaphylactic reaction that resolved; no other serious adverse events were reported (ACR 2024).[2]

Presentation Details

Meeting: American College of Rheumatology (ACR) Convergence 2026, Orlando, FL

Title: PRX-115, a Novel PEGylated Uricase: Focus on Plasma levels, Urate Responses and PK-PD Relations Following Single High-Dose Administrations

Abstract Number: 2652

Session: Poster Session C, Metabolic & Crystal Arthropathies - Basic & Clinical Science

Date and Time:	Tuesday, November 10, 2026, 10:30 AM to 12:30 PM ET
Location:	WB1&2
Presenter:	Orit Cohen-Barak, PhD, Protalix BioTherapeutics

The poster will be made available on the Company's website here: Publications | Protalix.

About Uncontrolled Gout

Gout is a metabolic disorder characterized by elevated blood uric acid that causes recurrent inflammatory arthritis and joint damage. An estimated 11.3 million people in the U.S. have gout.[3] Rheumatologists report that approximately 25% of their patients have blood uric acid levels above target, which can lead to uncontrolled gout.[2] An estimated 180,000 patients in the U.S. have uncontrolled gout.[4] Uncontrolled gout is a severe disease with high morbidity, severe pain, and low quality of life.

About PRX-115

PRX-115 is a recombinant PEGylated uricase in development for uncontrolled gout, produced using Protalix's ProCellEx® plant cell-based protein expression platform. Current uricase therapy has challenges including infusion burden, immunogenicity with loss of efficacy, and safety concerns. PRX-115 is designed for high specific activity, prolonged circulating half-life, and reduced immunogenicity.[5] In the Phase 1 study of adults with elevated plasma uric acid levels, single infusions of PRX-115 lowered plasma uric acid levels rapidly and were generally well tolerated. At 36 mg, mean plasma uric acid stayed below the 6.0 mg/dL target for up to 12 weeks after a single infusion. Protalix believes PRX-115 has best-in-class potential for uncontrolled gout.

About the Phase 2 RELEASE Study (PRX-115)

RELEASE (NCT07280156) is a Phase 2, double-blind, placebo-controlled study of PRX-115 in patients with uncontrolled gout. The study tests a fixed 36 mg dose in five treatment arms of 30 patients each: PRX-115 every 4 weeks without methotrexate, PRX-115 every 4, 6, or 8 weeks with methotrexate, and placebo. The primary endpoint is the proportion of patients who demonstrated a reduction in serum uric acid levels to below 6.0 mg/dL for at least 80% of the time during Month 6. Top–line results are expected in the second half of 2027.

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**.

[1] Schwabe C, Cohen-Barak O, Cole A, et al. Prolonged plasma urate-lowering after a single intravenous administration of PRX-115, a novel PEGylated uricase, in participants with elevated urate levels. Presented at: ACR Convergence 2024. Abstract L05.

[2] One participant in cohort 2 had an anaphylactic reaction 6 minutes into the infusion, after exposure to about 5% of the planned dose. The reaction resolved completely and the participant remained in the study. Antihistamine and steroid premedication was then given to all participants. No other participant had a similar reaction, and no other serious adverse events were reported. Source: ACR Convergence 2024 poster (abstract L05).

[3] GlobalData, August 2025

[4] Protalix internal research and proprietary market research (75 rheumatologists).

[5] Schwabe C, Cohen-Barak O, Cole A, et al. Prolonged plasma urate-lowering after a single intravenous administration of PRX-115, a novel PEGylated uricase, in participants with elevated urate levels. Presented at: ACR Convergence 2024. Abstract L05.

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. These statements generally relate to future events or the Company's future financial or operating performance. Actual outcomes and results may differ materially from what is expressed or forecast in such forward-looking statements. 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 of the clinical trial. Factors that might cause material differences include, among others: failure or delay in the commencement or completion of 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; inability to monitor patients adequately during or after treatment; and/or lack of sufficient funding to finance our clinical trials; the risk that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; our dependence on performance by third-party providers of services and supplies,

including without limitation, clinical trial services; delays in the approval or potential rejection of any applications we file with the FDA, European Medicines Agency or other health regulatory authorities for our other product candidates and other risks relating to the review process; risks relating to our evaluation and pursuit of strategic partnerships; risks related to our expectations with respect to the projected market of our products and 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; 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; ; the possible disruption of our operations due to the regional conflict in Iran and the military actions between Israel and Iran, the Hamas terrorist organization located in the Gaza Strip, Hezbollah, the Houthis terrorist group that controls parts of Yemen, 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 increased regional conflict; 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. You are cautioned not to place undue reliance on these forward-looking statements.

Investor Contact

Mike Moyer, Managing Director
LifeSci Advisors
+1-617-308-4306
mmoyer@lifesciadvisors.com

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