

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): January 30, 2026

**Protalix BioTherapeutics, Inc.**  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-33357  
(Commission File Number)

65-0643773  
(IRS Employer  
Identification No.)

2 University Plaza  
Suite 100  
Hackensack, NJ  
(Address of principal executive offices)

07601  
(Zip Code)

Registrant's telephone number, including area code 201-696-9345

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value	PLX	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01 Other Events**

On January 30, 2026, Protalix BioTherapeutics, Inc., a Delaware corporation (the “Company”), issued a press release, together with its development and commercialization partner, Chiesi Global Rare Diseases, a unit of Chiesi Farmaceutici S.p.A., announcing that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of the 2 mg/kg every-4-weeks (E4W) dosing regimen for Elfabrio<sup>®</sup> in Fabry disease adult patients stable with an ERT (Enzyme Replacement Therapy) treatment. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

Exhibit No.	Description
<a href="#">99.1</a>	<a href="#">Press Release dated January 30, 2026</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 30, 2026

**PROTALIX BIOTHERAPEUTICS, INC.**

By: /s/ Dror Bashan

Name: Dror Bashan

Title: President and Chief Executive Officer

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**Chiesi Global Rare Diseases and Protalix BioTherapeutics Receive Positive CHMP Opinion for an Additional Dosing Regimen of Every Four Weeks for Elfabrio® (pegunigalsidase alfa) in the EU**

*Committee for Medicinal Products for Human Use (CHMP) issues a positive opinion following re-examination, which will be reviewed by the European Commission (EC), with a decision anticipated by March 2026*

*If approved by the EC, this dosing regimen would reduce the burden to eligible patients, their families, and the broader healthcare system due to the current requirement to visit infusion centres every two weeks for treatment*

*This dosing regimen for Elfabrio is not approved in the U.S. In the U.S., the approved dosing regimen remains 1 mg/kg every 2 weeks. Please consult with your healthcare provider*

**PARMA, Italy and CARMIEL, Israel – Jan. 30, 2026** – Chiesi Global Rare Diseases, a business unit of the Chiesi Group established to deliver innovative therapies and solutions for people living with rare diseases, and 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 an update on Elfabrio® (pegunigalsidase alfa). The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of the 2mg/kg every-4-weeks (E4W) dosing regimen for Elfabrio in Fabry disease adult patients stable with an ERT (Enzyme Replacement Therapy) treatment. This positive opinion follows the CHMP’s re-examination of the company’s application for the additional dosing regimen.

“It is our privilege to provide the Fabry community with a safe and effective option, and we are thrilled that the CHMP positive opinion supporting an every-four-week dosing regimen brings us one step forward to further reducing treatment burden in this condition,” said **Giacomo Chiesi, Executive Vice President, Chiesi Global Rare Diseases**. “We’re focused on evolving treatments based on real-world needs, so that people have not just the right care, but care that fits naturally into their lives. By extending the time between infusions, our aim is that people living with this condition can focus on what truly matters, living their lives.”

“Expanding the range of treatment options is critical to better meet the needs of people with Fabry disease,” said **Prof. Aleš Linhart, DrSc, FESC**. “Beyond managing the condition effectively, this extended administration protocol acknowledges the importance of meeting patient preferences in order to reduce disruptions to their daily lives.”

“The CHMP’s positive opinion is another testament to Protalix’s commitment to advancing treatments for people living with Fabry disease and, together with Chiesi, we are grateful to all of the patients and investigators and their staff members who participated in our clinical trial programs,” said **Dror Bashan, President and Chief Executive Officer of Protalix**. “The CHMP’s positive opinion is a powerful validation of Protalix’s innovative pipeline and our proprietary ProCellEx® manufacturing platform, built on years of rigorous research and clinical progress.”

“The CHMP positive opinion on the every-four-week regimen recognizes the importance of reducing treatment burden for people living with Fabry and their families,” said **Mary Pavlou, President, Fabry International Network (FIN)**. “Extending infusion intervals allows therapy to better fit into everyday life, supporting work, study, and family commitments. This step reflects care that adapts to real life and respects the priorities of those who live with the disease.”

The CHMP opinion is based on results from an open-label, switch-over study, BRIGHT (formally PB-102-F50), designed to assess the safety, efficacy, and pharmacokinetics (PK) of the new dosing regimen of pegunigalsidase alfa 2 mg/kg E4W for 52 weeks, and its ongoing open-label extension study CLI-06657AA1-03 (formerly PB-102-F51, with a median exposure of almost 6 years). Further support is provided by an updated Population Pharmacokinetics (PopPK) model and exposure–response analysis, which leverage data from multiple clinical studies.

Protalix will be eligible to receive a regulatory milestone payment of \$25 million from Chiesi if the E4W dosing regimen is approved by the EC.

***This dosing regimen for Elfabrio is not approved in the U.S. In the U.S., the approved dosing regimen remains 1 mg/kg every 2 weeks. Please consult with your healthcare provider.***

### **About ELFABRIO**

ELFABRIO (pegunigalsidase alfa-iwxj), a PEGylated enzyme replacement therapy (ERT) to treat Fabry disease, is a plant cell culture-expressed, and chemically modified stabilized recombinant version of the  $\alpha$ -Galactosidase--A enzyme. Protein sub-units are covalently bound via chemical cross-linking using short PEG moieties, resulting in a molecule with stable pharmacokinetic parameters. In clinical studies, ELFABRIO has been observed to have an initial half-life of  $78.9 \pm 10.3$  hours.

### **Important Safety Information**

#### **Indication**

Elfabrio<sup>®</sup> (pegunigalsidase alfa-iwxj) is indicated for the treatment of adults with confirmed Fabry disease.

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## Important Safety Information

### WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with Elfabrio have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Elfabrio administration. If a severe hypersensitivity reaction (eg, anaphylaxis) occurs, discontinue Elfabrio immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to Elfabrio may be considered.

Prior to Elfabrio administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and infusion-associated reactions (IARs), and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Elfabrio administration and initiate appropriate medical treatment.
- If a mild to moderate hypersensitivity reaction or IAR occurs, consider slowing the infusion rate or temporarily withholding the dose.

In clinical trials, 20 (14%) Elfabrio-treated patients experienced hypersensitivity reactions. Four Elfabrio-treated patients (3%) experienced anaphylaxis reactions that occurred within 5 to 40 minutes of the start of the initial infusion. The signs and symptoms of hypersensitivity reactions and anaphylaxis included headache, nausea, vomiting, throat tightness, facial and oral edema, truncal rash, tachycardia, hypotension, rigors, urticaria, intense pruritus, moderate upper airway obstructions, macroglossia, and mild lip edema.

In clinical trials, 41 (29%) Elfabrio-treated patients experienced one or more infusion-associated reactions, including hypersensitivity, nausea, chills, pruritus, rash, chest pain, dizziness, vomiting, asthenia, pain, sneezing, dyspnea, nasal congestion, throat irritation, abdominal pain, erythema, diarrhea, burning sensation, neuralgia, headache, paresthesia, tremor, agitation, increased body temperature, flushing, bradycardia, myalgia, hypertension, and hypotension.

A case of membranoproliferative glomerulonephritis with immune depositions in the kidney was reported during clinical trials. Monitor serum creatinine and urinary protein-to-creatinine ratio. If glomerulonephritis is suspected, discontinue treatment until a diagnostic evaluation can be conducted.

When switching to Elfabrio from a prior enzyme replacement therapy, the risk of hypersensitivity reactions and infusion-associated reactions may be increased in certain patients with pre-existing anti-drug antibodies (ADAs). Consider monitoring IgG and IgE ADAs and clinical or pharmacodynamic response (eg, plasma lyso-Gb3 levels). The most common adverse reactions ( $\geq 15\%$ ) were infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

Please see [Full Prescribing Information](#) for Elfabrio including Boxed Warning, for Elfabrio<sup>®</sup> (pegunigalsidase alfa)."

## About Fabry Disease

Fabry disease is a rare, inherited lysosomal storage disorder caused by mutations in the GLA gene, which leads to a deficiency of the enzyme alpha-galactosidase A. This deficiency results in an accumulation of a fatty substance called globotriaosylceramide (GL-3) in the body's cells, affecting the heart, kidneys, skin, nervous system, and other organs.<sup>1</sup> Fabry disease can cause a range of serious signs and symptoms, including fatigue, chronic pain, gastrointestinal issues, decreased ability to sweat, progressive kidney failure, heart complications, and increased risk of stroke.<sup>2</sup>

The condition affects both males and females and can present from childhood through adulthood, often with delayed diagnosis or misdiagnosis. While Fabry disease is rare, early detection and access to appropriate treatment — such as enzyme replacement therapy or pharmacological chaperones — are critical in managing symptoms and slowing disease progression.<sup>1</sup>

### **About Chiesi Group**

Chiesi is a research-oriented international biopharmaceutical group that develops and markets innovative therapeutic solutions in respiratory health, rare diseases, and specialty care. The company's mission is to improve people's quality of life and act responsibly towards both the community and the environment.

By changing its legal status to a Benefit Corporation in Italy, the US, France and Colombia, Chiesi's commitment to creating shared value for society as a whole is legally binding and central to company-wide decision-making. As a certified B Corp since 2019, Chiesi is part of a global community of businesses that meet high standards of social and environmental impact. The company aims to reach Net-Zero greenhouse gases (GHG) emissions by 2035.

With 90 years of experience, Chiesi is headquartered in Parma (Italy), with 31 affiliates worldwide, and counts more than 7,500 employees. The Group's research and development center in Parma works alongside 6 other important R&D hubs in France, the US, Canada, China, the UK, and Sweden.

For more information visit [www.chiesi.com](http://www.chiesi.com).

### **About Chiesi Global Rare Diseases**

Chiesi Global Rare Diseases is a business unit of the Chiesi Group established to deliver innovative therapies and solutions for people living with rare diseases. As a family business, Chiesi Group strives to create a world where it is common to have therapy for all diseases and acts as a force for good, for society and the planet. The goal of the Global Rare Diseases unit is to ensure equal access so as many people as possible can experience their most fulfilling life. The unit collaborates with the rare disease community around the globe to bring voice to underserved people in the health care system.

For more information visit [www.chiesirarediseases.com](http://www.chiesirarediseases.com).

Follow @ChiesiGlobalRareDiseases on [LinkedIn](#), [Facebook](#), [Instagram](#), [X](#) and [YouTube](#).

### **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<sup>®</sup>. 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<sup>®</sup>, 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 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](http://www.protalix.com).

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### **Protalix BioTherapeutics, Inc. 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: the risk that the EC will not approve the CHMP’s positive opinion recommending approval of the 2mg/kg every-4-weeks (E4W) dosing regimen for Elfabrio in adults with Fabry disease; risks related to the commercialization of Elfabrio; risks relating to Elfabrio market acceptance, competition, reimbursement and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product; delays in the approval or potential rejection of any applications filed with the FDA, EMA or other health regulatory authorities for Protalix’s product candidates, and other risks relating to the review process; the risk that the results of clinical trials will not support the applicable claims of safety or efficacy; ; risks relating to changes to published interim, topline or preliminary data from clinical trials; 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 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 Protalix disclaims any obligation to update this information, except as may be required by law.

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## References

- 1) Mehta, A., & Hughes, D. A. (2024). *Fabry disease*. In M. P. Adam, S. Bick, G. M. Mirzaa, et al. (Eds.), *GeneReviews*<sup>®</sup>. University of Washington, Seattle.
  - 2) Cleveland Clinic. (2025, October 9). *Fabry disease: Symptoms & causes*.
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