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): March 9, 2026

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-33357**	**65-0643773**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2 University Plaza Suite 100 Hackensack, NJ		**07601**
(Address of principal executive offices)		**(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 March 9, 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 European Commission (EC) has approved the 2 mg/kg every-4-weeks (E4W) dosing regimen for Elfabrio® (pegunigalsidase alfa) in adults living with Fabry disease who are stable with an ERT (Enzyme Replacement Therapy). The EC decision follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending the additional dosing regimen. 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
99.1	Press Release dated March 9, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: March 9, 2026

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan
Name: Dror Bashan
Title: President and
Chief Executive Officer

Chiesi Global Rare Diseases and Protalix BioTherapeutics Announce European Commission Approval of Additional Dosing Regimen of Every Four Weeks for Elfabrio® (pegunigalsidase alfa)

This press release is intended for US audiences for transparency relative to global news for the Fabry community. This dosing regimen for Elfabrio is not approved in the US. In the US, the FDA-approved dosing regimen remains 1mg/kg every 2 weeks. Please see Important Safety Information below and the Full Prescribing Information, including Boxed Warning.

European Commission approved dosing regimen reduces the burden for eligible patients, their families, and the broader healthcare system by extending infusion interval frequency from every-two-weeks to every-four-weeks for those stable with an enzyme replacement therapy (ERT)

With this decision, announced ahead of Fabry Disease Awareness Month in April, Chiesi Global Rare Diseases will work with countries across the EU to support broader access to this additional dosing schedule for the adult Fabry community

PARMA, Italy and CARMIEL, Israel – March 9, 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 that the European Commission (EC) has approved the 2mg/kg every-4-weeks (E4W) dosing regimen for Elfabrio® (pegunigalsidase alfa) in adults living with Fabry disease who are stable with an ERT. The EC decision follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending the additional dosing regimen.

“The European Commission approval for 2mg/kg body weight E4W dosing regimen for pegunigalsidase alfa represents a meaningful advancement for adults living with Fabry disease and their families,” said **Giacomo Chiesi, Executive Vice President, Chiesi Global Rare Diseases**. “Because Fabry disease requires lifelong treatment, the cadence of therapy inevitably becomes part of everyday life for patients and caregivers. By introducing an option that extends the infusion interval from every two weeks to every four weeks for eligible patients on stable ERT, we are offering families greater flexibility and the possibility to ease the overall burden of treatment. Ultimately, our goal is simple but profound: to help people spend less time managing their disease and more time living their lives. This milestone reflects our commitment to innovation that goes beyond delivering therapies—by listening to and understanding the real experiences of the Fabry community.”

“In Fabry disease, long-term treatment decisions must balance disease management with the realities of lifelong therapy,” said **Prof. Aleš Linhart, DrSc, FESC**. “The approval of pegunigalsidase alfa 2mg/kg every-4-weeks provides an additional option that may help reduce cumulative treatment burden for appropriate patients while maintaining continuity of care.”

“This approval strengthens the treatment landscape for Fabry disease across the European Union by introducing an additional dosing approach that has the potential to enhance long-term care,” said **Dror Bashan, President and Chief Executive Officer, Protalix BioTherapeutics**. “The authorization reflects not only scientific progress, but also a commitment to optimizing care delivery in a way that supports both patients and healthcare systems.”

“For many people living with Fabry disease, treatment is a lifelong commitment that impacts nearly every aspect of daily life,” said **Mary Pavlou, President, Fabry International Network (FIN)**. “This approval allows for fewer infusion visits, helping reduce the ongoing burden on patients and families, allowing them to spend more time living their lives beyond treatment.”

The EC approval is informed by results from an open-label, switch-over study, BRIGHT (formally PB-102-F50), designed to assess the adverse-event profile, efficacy, and pharmacokinetics (PK) of the alternative dosing regimen of pegunigalsidase alfa 2-mg/kg E4W for 52 weeks,[1] and its ongoing open-label extension study CLI-06657AA1-03 (formerly PB-102-F51).[2]

Protalix is entitled to a regulatory milestone payment of $25 million from Chiesi in connection with the EC’s approval of the E4W dosing regimen.

This EU approval does not change the FDA-approved dosing regimen, which 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 α--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 ± 10.3 hours.

Indication and Important Safety Information

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

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 (≥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®

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.[3] 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.[4]

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 therapy — are critical in managing symptoms and slowing disease progression.[3]

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.

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.
And Follow @ChiesiGlobalRareDiseases on LinkedIn, Facebook, Instagram and X

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 US 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 pegunigalsidase alfa, 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**.

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 pegunigalsidase alfa in adults with Fabry disease; risks related to the commercialization of pegunigalsidase alfa; risks relating to pegunigalsidase alfa 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 US 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) Holida, M, et al., (2024). A phase III, open-label clinical trial evaluating pegunigalsidase alfa administered every 4 weeks in adults with Fabry disease previously treated with other enzyme. Journal of Inherited Metabolic Disease. doi:10.1002/jimd.12795.

2) Bernat et al., (2025). Extending the interval between pegunigalsidase alfa infusions in patients with Fabry disease: five-year interim results from the ongoing BRIGHT51 study Abstract presented at ICIEM Congress 2025.

3) Mehta, A., & Hughes, D. A. (2024). Fabry disease. In M. P. Adam, S. Bick, G. M. Mirzaa, et al. (Eds.), GeneReviews®. University of Washington, Seattle.

4) Cleveland Clinic. (2025, October 9). Fabry disease: Symptoms & causes.