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): May 21, 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 7.01 Regulation FD Disclosure

On May 21, 2026, Protalix BioTherapeutics, Inc., a Delaware corporation, posted a corporate presentation to its website. A copy of the corporate presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 to this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	May 2026 Corporate Presentation
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: May 21, 2026

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1


PROTALIX
Biotherapeutic
PROTALIX BIOTHERAPEUTICS
Pioneering solutions to transform the treatment of rare diseases
CORPORATE PRESENTATION
May 2026

Forward-Looking Statements

This presentation contains forward-looking statements that involve risks and uncertainties within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on management's current expectations or plans, and projections for future operating and financial performance, based on assumptions currently believed to be valid. Forward-looking statements can be identified by the use of words such as "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and other words or phrases of similar import, as they relate to Protalix, its subsidiary, or its management, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this presentation include, among other things, statements regarding our cash runway and the commercialization of our products. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, risks related to the commercialization of Elfabrio®; that Elfabrio's revenue, expenses, and costs may not be as expected; Elfabrio's market acceptance, competition, reimbursement, and regulatory actions, including as a result of the boxed warning contained in the U.S. Food and Drug Administration, or FDA, approval received for the product; 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 potential commercial value 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; inability to monitor patients adequately during or after treatment; and/or lack of sufficient funding to finance our clinical trials; 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 product candidates, and other risks relating to the review process; our ability to manage our relationship with our collaborators, distributors, or partners, including, but not limited to, Pfizer Inc., and Chiesi Global Rare Diseases; and other factors described in our filings with the U.S. Securities and Exchange Commission. In addition, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Given these uncertainties, investors should not place undue reliance on these forward-looking statements. Except as required by law, Protalix undertakes no obligation to update or revise the information contained in this presentation whether as a result of new information, future events, or circumstances or otherwise.

Third-Party Information

This presentation also contains estimates other data made by independent pa and Protalix relating to market size and growth other data related to the industry which Protalix operates. This data involve number of assumptions and limitations, and are cautioned not to give undue weight to estimates. Neither Protalix nor any other pe makes any representation as to the accurac completeness of such data. In light of foregoing, you are urged not to rely on any forv looking statement or third-party data in reac any conclusion or making any investment dec about any securities of the Company. appropriateness of a particular investmen strategy will depend on an investor's indiv circumstances and objectives. We recomn that investors independently evaluate spe investments and strategies.

PROTALIX
Biotherapeutics

Experienced leadership team

Dror Bashan
President and CEO

Mr. Bashan has over 20 years of experience in the pharmaceutical industry with roles ranging from business development, marketing, sales and finance, providing him with both cross regional and cross discipline experience and a deep knowledge of the global pharmaceutical and health industries.

GILAD MAMLOK
SVP & CFO

Mr. Mamlok brings 30 yrs experience in healthcare/ technology companies. His has extensive experience in capital markets transactions, mergers and acquisitions and BD. Previously, he served as the CFO of TytoCare and CFO of Sol-Gel Technologies. Earlier, he served in other medical device and technology companies, including Given Imaging for 10 years (acquired by Covidien) and Nice.

Fernando Sallés, PH.D., CLP
Chief Business Officer

Dr. Salles has spent >25 years in senior strategic/BD roles. Most recently as CBO at Kallyope. Previously at IMAB, Teva, Merck, Schering-Plough and Organon. Notable transactions: Acquired phase 2b ready asset, novel obesity target to Novo Nordisk, BioCentury/Bay Helix deal of the year award for IMab - AbbVie >$2B

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YARON NAOS
Chief Operating Officer

Mr. Naos has been with Protalix for >20 years. He has a wealth of hands-on experience and knowledge in the field of pharmaceutical development. Previously, he was R&D Product Manager at Dexxon Pharmaceutical Co., one of Israel's largest pharmaceutical companies, where he was responsible for technology transfer from R&D to production

SHOSHI TESSLER, PH.D.
VP, Clinical Dev & Regulatory Affairs

Dr. Tessler has >20yrs experience in the pharma, leading innovative drug development projects, from discovery to market. Previously, she served as VP, R&D of Biosight and of Enzymotec. (currently part of International Flavors & Fragrances Inc.) and as a Project Champion at Innovative R&D, Teva.

ORI KALID, PH.D.
VP of R&D

Dr. Kalid brings >20 years of leadership experience in pharmaceutical R&D. Previously he was co-founder and CEO of Silverskate Bio, as well as co-founder and CEO of Pi Therapeutics. He also served at Hotaru Innovation Partners, PREDIX/EPIX Pharmaceuticals and Karyopharm Therapeutics.

teva
SOL-GEL
GIVEN IMAGING
Karyopharm Therapeutics
MERCK
I-MAB BIOPHARMA
Organon
IFF
Pi Therapeutics
KALLYOPE
Dexcel pharma
Schering-Plough

Accomplished Board of Directors

ELIOT FORSTER, PH.D.
Chairman

DROR BASHAN
President & CEO, Director

POL F. BOUDES, M.D.
Director

GWEN A. MELINCOFF
Director

AHARON SCHWARTZ, PH.D.
Director

AMOS BAR SHALEV
Director

SHMUEL "MULI" BEN ZVI, PH.D.
Director

Christian Else
Director

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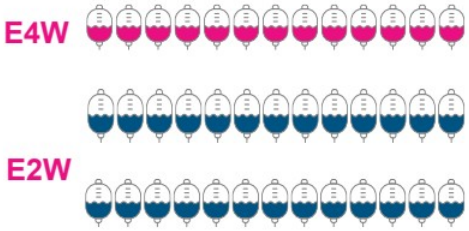
EC and MHRA approve E4W dosing for Elfabrio® for adults with Fabry disease[1]

Now the only ERT in the EU and UK offering an every-4-weeks (E4W) option, reducing treatment burden from standard bi-weekly regimens



Quality-of-life improvement for Fabry patients in the EU

50% reduction
in infusion days

E4W dosing clinically validated

ELFABRIO (peguniglsidase alfa-iwxj)

BRIGHT study
- E4W maintained clinical and renal outcomes in stable patients

Long-term extension data
- Confirmed durable response and
- Comparable safety profile

PopPK + exposure-response analysis
- Support for E4W regimen

Regulatory milestone payment of $25 million received from Chiesi

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1: European Commission (EC) approved a novel 2mg/kg every-4-weeks (E4W) dosing regimen for Elfabrio in adults with Fabry disease who are stable on an enzyme replacement therapy (ERT) (March 2026); MHRA (UK) approved the same E4W dosing regimen (May 2026); FDA-approved dosing regimen for Elfabrio in the United States remains 1mg/kg every 2 weeks; EU=European Union; UK=United Kingdom.

Protalix delivers innovations from concept to market

Proven execution of delivering protein products for rare diseases with a pipeline for the future

Revenue generating

Partnered commercial products

Enzyme replacement therapies (ERTs)[1,2]

ELFABRIO® (pegunigalsidase alfa-iwxj)

elelyso™ (taliglucerase alfa) for injection

Chiesi

Pfizer

FIOCRUZ Fundação Oswaldo Cruz

Next phase of the company

PRX-115 best-in-class potential for uncontrolled gout

- Uncontrolled gout has high unmet need
- Potentially differentiated based on Phase 1 data: less frequent dosing, less immunogenicity
- Phase 2 PRX-115 trial actively enrolling (NCT05745727)

Pipeline for the future

- 3-year goal: 5-7 programs spanning discovery to clinic
- Rare disease discovery and developme with a focus on renal indications

ProCellEx® Proprietary Discovery Platform

Protein therapeutics: Plant cell-based protein expression
Chemical modifications: PEGylation, others
Drug delivery: Exploring new modalities

ProCellEx® Manufacturing

Commercial Manufacturing

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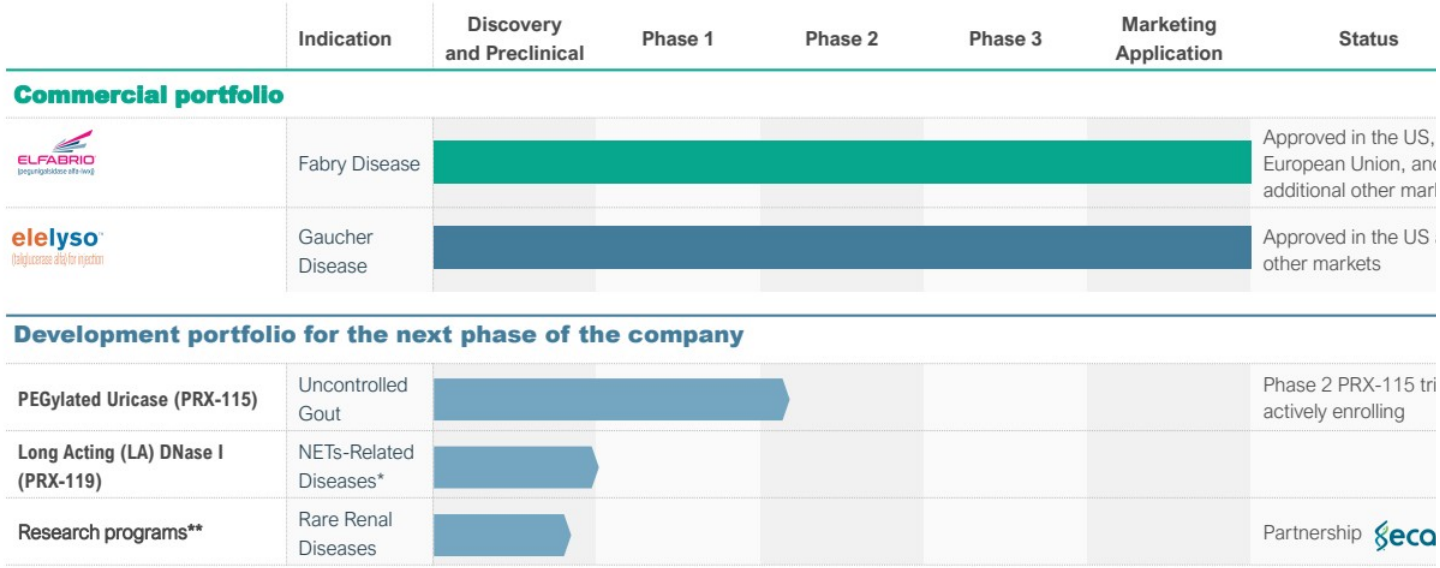
1: Elfabrio has been approved for marketing in the United States, the European Union, and additional markets. Chiesi Global Rare Diseases, a business unit of the Chiesi Group, is our global partner
2: Elelyso is approved in 23 markets. Pfizer Inc. is our global partner, with the exception of Brazil where we partner with Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health

Two commercial products and a growing pipeline for the future

Developing recombinant proteins for rare diseases with unmet medical needs



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* Neutrophil extracellular traps (NETs)
**Includes internal programs and a collaboration and option agreement with Secarna Pharmaceuticals

Well-capitalized to advance Protalix to the next phase

REVENUES	$33.8M in revenue, which includes the $25M milestone (Q1 2026)
CASH & CASH RUNWAY and OUTSTANDING SHARES	$51.1M (as of: March 31, 2026); no debt no warrants ~80.5M shares of common stock outstanding (May 1, 2026)
DEVELOPMENT PORTFOLIO DRIVES FUTURE GROWTH	PRX-115 recombinant PEGylated uricase product candidate. Best-in-class potential. Phase 2 PRX-115 trial actively enrolling.

Financial strength to support ongoing operations and pipeline

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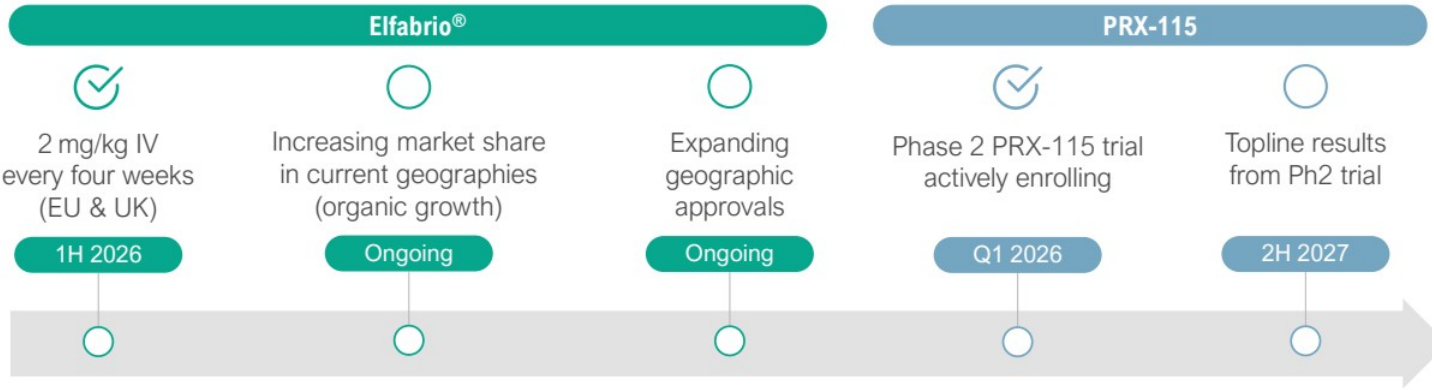
Key upcoming milestones and catalysts



Continued internal R&D pipeline growth

Business development activities in rare renal diseases

3 revenue streams and projected consistent growth in the medium-term

Significant milestone payments expected in mid- and long-term

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Phase 2
Actively enrolling
PRX-115 in development for
uncontrolled gout

Uncontrolled gout: limited options and disadvantages with current therapy

An unsatisfied market

Gout and uncontrolled gout

- Metabolic disorder characterized by elevated blood urate that causes recurrent inflammatory arthritis and joint damage
- Rheumatologists report that ~25% of their patients have above target urate blood levels which can lead to uncontrolled
- Uncontrolled gout is a severe disease with high morbidity and high pain with low quality of life

Current uricase therapy for uncontrolled gout

Krystexxa® (pegloticase) with/without methotrexate (MTX)

- Net sales of Krystexxa reached $1.3B (2025)

NASP (nano encapsulated sirolimus plus pegadricase)
PDUFA Date – June 2026

Significant unmet needs and challenges

- Infusion logistics and burden
- Immunogenicity and loss of efficacy
- Safety concerns
- Clinical inertia and physician familiarity
- Costs and insurance coverage

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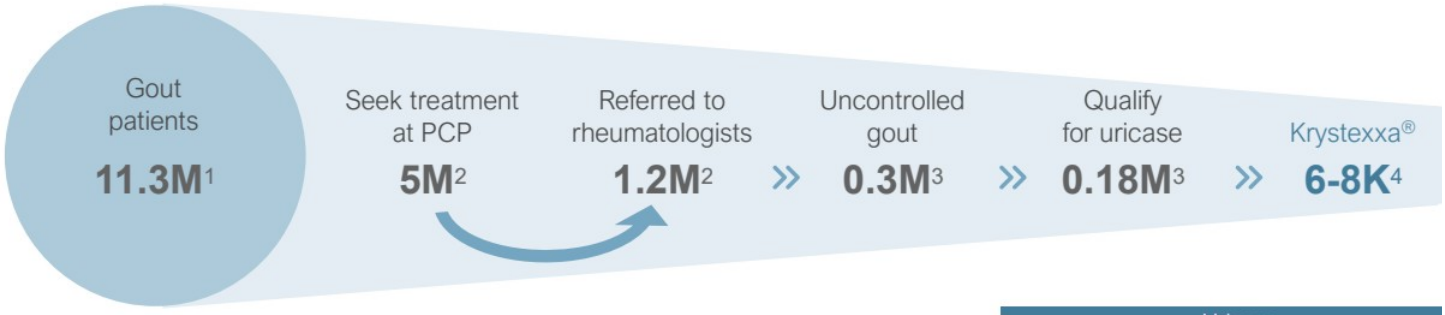
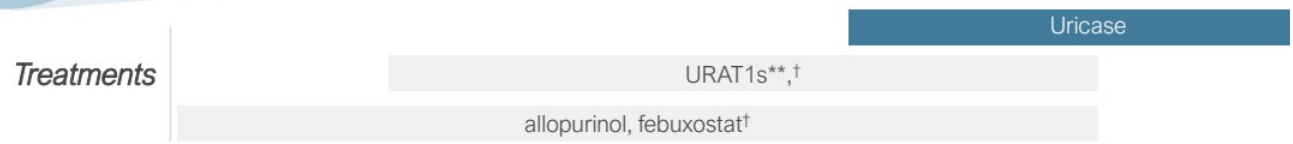
*Internal research

The US Gout Market





The market is poised to expand significantly as newer therapies and competitors enter and further expand disease awareness and reduce clinical inertia

A **differentiated best-in-class uricase like PRX-115** is poised to increase the market further and capture significant market share

Sales of Krystexxa are $1.3B (2025), yet less than 5% who qualify for uricase are currently treated

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1. Global Data – Aug 2025; 2. ACR Open Rheumatology Vol. 2 March 2020; 3. proprietary PRX Mkt Research 75 Rheums; 4. Internal estimates proprietary calculation ** Urate transporter 1 inhibitor; none currently available in the US
† Neither the xanthine oxidase inhibitors nor the URAT1s should be co-administered with uricases

PRX-115 Phase 1 single ascending dose study: encouraging data supports Phase 2

Recombinant PEGylated uricase enzyme produced via ProCellEx®

Study Scheme

Primary Endpoint: Safety and tolerability

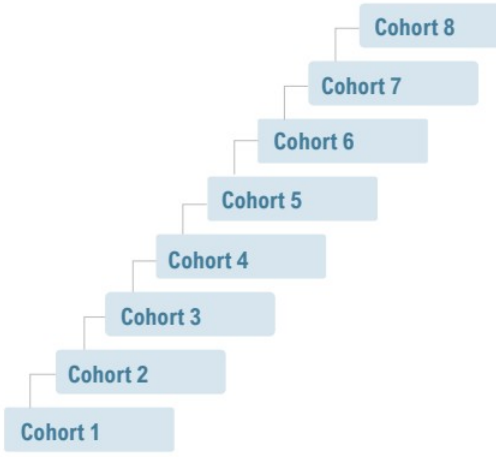
Secondary Endpoints: PK, PD (uric acid levels)

Subjects with elevated uric acid

N = 8 per cohort (6 PRX-115 + 2 placebo in each cohort)

Dose escalation meeting by blinded Safety Monitoring Committee (SMC) following completion of each cohort

For subject safety, each cohort/dose level started at least 7 days from the dosing of the previous cohort



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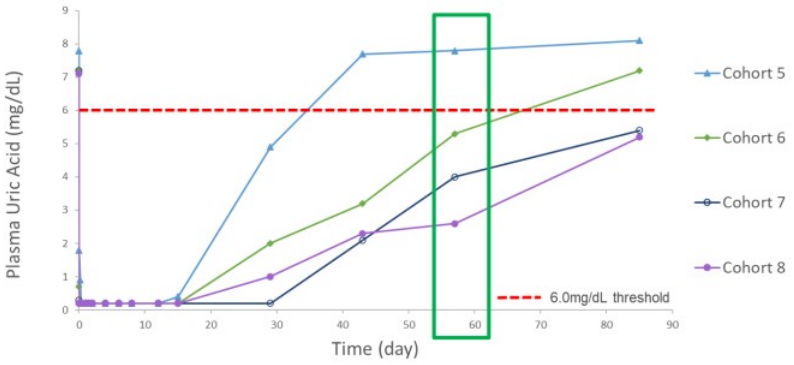
PRX-115 best in class potential for uncontrolled gout

Addresses an important unmet medical need

PRX-115 Phase 1 outcome

- Favorable tolerability profile
- Ability to reduce uric acid levels rapidly and maintain below 6.0 mg/dL for greater than 8 weeks

Plasma Uric Acid Concentrations Over Time



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Phase 2 RELEASE study

- Actively enrolling (NCT07280156)
- Trial in uncontrolled gout patients
- Fixed 36 mg dose across extended dosing intervals with and without methotrexate (MTX)
- Top-line results anticipated in 2H 2027

Targeted Phase 2 differentiation(s)

- IV infusion every 4 weeks without requirement for co-administration of the immunomodulator MTX
- Improved dosing interval
  - IV infusion every 6 or 8 weeks in the presence of MTX
- Favorable safety and immunogenicity profile

PRX-115 Phase 2 double blind placebo-controlled study design: actively enrolling

Fixed Dose at Various Dosing Intervals

Patient Population: uncontrolled gout

Primary Endpoint: proportion of patients who achieve a reduction in serum uric acid (sUA) to <6.0 mg/dL for at least 80% of the time during Month 6

Secondary Endpoints: additional uric acid parameters, safety, and immunogenicity

Exploratory Endpoints: tophi, flares, swollen & tender joints, quality of life (QoL), pharmacokinetics (PK)

PRX-115 IV Dosing Regimens and Treatment Arms

Arm A*	every 4 weeks w/o MTX	N=30
Arm B	every 4 weeks + MTX	N=30
Arm C	every 6 weeks + MTX	N=30
Arm D*	every 8 weeks + MTX	N=30
Arm E	Placebo	N=30

* Key differentiators no MTX (A); 8-wk dosing interval (D)

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MTX = Methotrexate


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Commercial product
Reliably partnered and delivering revenu

Two commercial products sustaining future growth

Enzyme replacement therapies (ERTs) continue to be the gold standard treatment for lysosomal storage diseases

Fabry disease

ELFABRIO® (pegunigalsidase alfa-iwxj)

Rare X-linked disorder (~1/40,000-60,000 males WW) with progressive renal, cardiac, and neurological burden

Commercialization Partner: Chiesi

Approved in US, EU plus additional markets

Commercial Potential

- Fabry Market: ~$2.2B[1] (2025) expected to reach ~$3.2B (2031)
- Elfabrio® poised to capture significant global market share (15% to 20%)
- Protalix royalties per year from Chiesi (15% to 35% ex-US, 15% to 40% US)
- Significant milestone payments potential in mid- and long-term

Gaucher disease

elelyso™ (taliglucerase alfa) for injection

Rare autosomal recessive disorder (~1/40,000 WW) with systemic visceral and skeletal disease-causing disability and organ dysfunction

Commercialization Partners: Pfizer; FIOCRUZ Fundação Oswaldo Cruz

Approved in 23 markets

Worldwide (ex-Brazil) license with Pfizer

Brazil collaboration with Fundação Oswaldo Cruz

- Market share in Brazil: ~25%
- Sales ~$11M in Brazil (FY2025)

1 GlobalData extracted (forecast) March 2026

Fabry disease competitive landscape

~$2.2B market (2025) expected to reach over ~$3.2B (2031), CAGR of 6.4%[1]

Product Name	Fabrazyme®	Replagal®	Galafold®	Elfabrio®
Parent Company	sanofi	Takeda	Amicus Therapeutics	PROTALIX Biotherapeutics Chie
Mechanism	ERT	ERT	Pharmacological chaperone	ERT longer half-life (pegylated)
Approved for	Adults & pediatric patients 2+ years (US). Adults, children and adolescents aged 8+ years (EU)	Adults, children and adolescents aged 7+ years (EU only)	Accelerated approval in adults (US). Adults and adolescents 12+ years (EU)	Adults (US, EU and others). Global pediatric study ongoing
Dosing	1 mg/kg every 2 weeks	0.2 mg/kg every 2 weeks	123 mg every other day	1 mg/kg every 2 weeks **2 mg/kg every 4 weeks (EU & U**
Administration mode	Intravenous infusions	Intravenous infusions	Oral	Intravenous infusions
Approval Date	Full approval in 2021; accelerated approval in 2003 (US); 2001 (EU)	Not approved in US; 2001 (EU)	2018 (US); 2016 (EU)	2023 (US and EU)

Elfabrio is poised to capture meaningful global market share (15% to 20%)

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1 Source global data extracted Aug 2025

Commitment and execution from global partnership with Chiesi

Committed Global Partner [1]

- International research-focused biopharmaceutical group with sales of €3.6B in 2025 (reflecting 8% growth year-on-year)
- Air (respiratory) - €1.9B, Rare - €906M (22.3% growth), Care (Specialty) - €904M
  - The Rare Diseases unit now accounts for approximately 25% of total Group sales, contributing 50% of overall growth in 2025.
- Annual R&D investment of €885M in 2025
- Experience with data generation/ongoing post-marketing studies to support further uptake

Chiesi Farmaceutici S.p.A.

- Experienced sales team
- Strategic focus on rare diseases
- Specific expertise in Fabry disease
- Ideally suited to bring Elfabrio to patients with Fabry disease

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1 – update based on 2025 Annual Report


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Growth strategy
Next phase of the company

Research strategy - leveraging internal strengths to fuel the company's next phase

Proven ability to drive discovery, development, and registration of new drugs

Rare renal disease focus

- ADPKD, Alport, FSGS, others
- Modality agnostic: nucleic acids, peptides, small molecules, etc.

3-year goal

5-7 programs spanning discovery to clinic

Internal development

ProCellEx® platform

Leveraging existing platforms

Expand Applications

Protein therapeutics

Plant cell-based expression

Chemical modification

PEGylation, other

Drug delivery

Exploring new modalities

Business development

- Innovative platform in-licensing
- China dedicated scouting activity
- Opportunistic in-licensing
- Commercial partnership establishment

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Protalix delivers innovation from concept to the market

Two commercial products

ELFABRIO (pegunigalsidase alfa-iwxj)

elelyso™ (taliglucerase alfa) for injection

Three revenue streams

Chiesi

Pfizer

FIOCRUZ Fundação Oswaldo Cruz

Growing pipeline for the company's next phase

- PRX-115 best-in-class potential for uncontrolled gout
- Collaboration and Option Agreement with Secarna
- Internal research focus – Rare Renal Diseases (includes collaboration with Secarna)

Secarna

Revenues	Cash and Shares Outstanding	Debt
USD 33.8M for Q1 2026	USD 51.1M (March 31, 2026) 80.5M shares of common stock*	No Debt / Warrants

PROTALIX Biotherapeutics

* (as of May 1, 2026)


PROTALIX BIOTHERAPEUTICS
Pioneering solutions to transform the treatment of rare diseases
CORPORATE PRESENTATION
May 2026