

# PROTALIX BIOTHERAPEUTICS

*Pioneering solutions to transform the treatment of rare diseases*

CORPORATE PRESENTATION

November 2025

# 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 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 subsidiaries 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®; 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; 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 other product 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 other 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.

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# 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



**YARON NAOS**  
**SVP of Operations**

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.



# 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



# 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)<sup>1,2</sup>



## 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, possibly no need for co-administered methotrexate
- Phase 2 start anticipated in Q425 (IND has become effective following the FDA's standard 30-day review period)

### Pipeline for the future

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

## ProCellEx<sup>®</sup> Proprietary Discovery Platform



**Protein therapeutics:** Plant cell protein expression

**Chemical modifications:** PEGylation, others

**Drug delivery:** Exploring new modalities



## ProCellEx<sup>®</sup> Manufacturing



**Commercial Manufacturing**

# Two commercial products and a growing pipeline for the future

Developing recombinant proteins for rare diseases with unmet medical needs

|   | Indication      | Discovery and Preclinical | Phase 1 | Phase 2 | Phase 3 | Marketing Application | Status                                      |
|---|-----------------|---------------------------|---------|---------|---------|-----------------------|---|
| <b>Commercial portfolio</b>   |                 |                           |         |         |         |                       |   |
|  | Fabry Disease   |                           |         |         |         |                       | Approved (US and EU and additional markets) |
|  | Gaucher Disease |                           |         |         |         |                       | Approved in 23 markets, including US        |

## Development portfolio for the next phase of the company

|   |                        |  |  |  |  |  |                                |
|---|------------------------|--|--|--|--|--|--------------------------------|
| <b>PEGylated Uricase (PRX-115)</b>        | Uncontrolled Gout      |  |  |  |  |  | Phase 2 start expected in 4Q25 |
| <b>Long Acting (LA) DNase I (PRX-119)</b> | NETs-Related Diseases* |  |  |  |  |  |                                |
| <b>Research Programs</b>                  | Rare Renal Diseases    |  |  |  |  |  |                                |

# Well capitalized to advance Protalix to the next phase

## CASH STREAMS FROM STRONG PARTNERSHIPS

\$25.4M in 1H 2025 revenue from selling goods



## REVENUE

\$53M in revenue (FY 2024)



## CASH & CASH RUNWAY

\$33.4M (June 30, 2025); no debt and no warrants  
Anticipate cashflow positive in 1H/2027



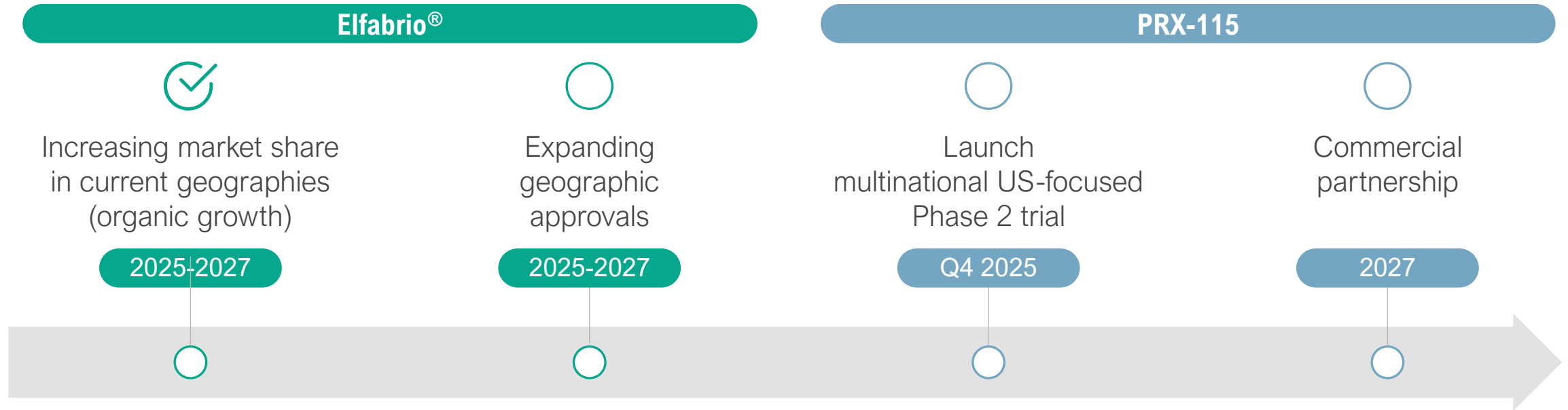
## DEVELOPMENT PORTFOLIO DRIVES FUTURE GROWTH

PRX-115 recombinant PEGylated uricase product candidate. Best-in-class potential. Phase 2 expected to start 4Q 2025. Anticipate looking for development and commercial partner ahead of Phase 3.



Financial strength to support ongoing operations and pipeline into 2027

# Key upcoming milestones and catalysts



*Continued internal R&D pipeline growth*

*Business development activities in rare renal diseases*

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

*Significant milestone payments expected in mid- and long-term*



## Phase 2 ready

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 gout
- Uncontrolled gout is a severe disease with high morbidity, high pain, and with low quality of life



### Current uricase therapy for uncontrolled gout

Krystexxa<sup>®</sup> (pegloticase) with/without methotrexate (MTX)

- Net sales of Krystexxa<sup>®</sup> reached \$1.2B (2024)\*

NASP (nano encapsulated sirolimusplus pegadricase, FDA accepted BLA Sept 2025)

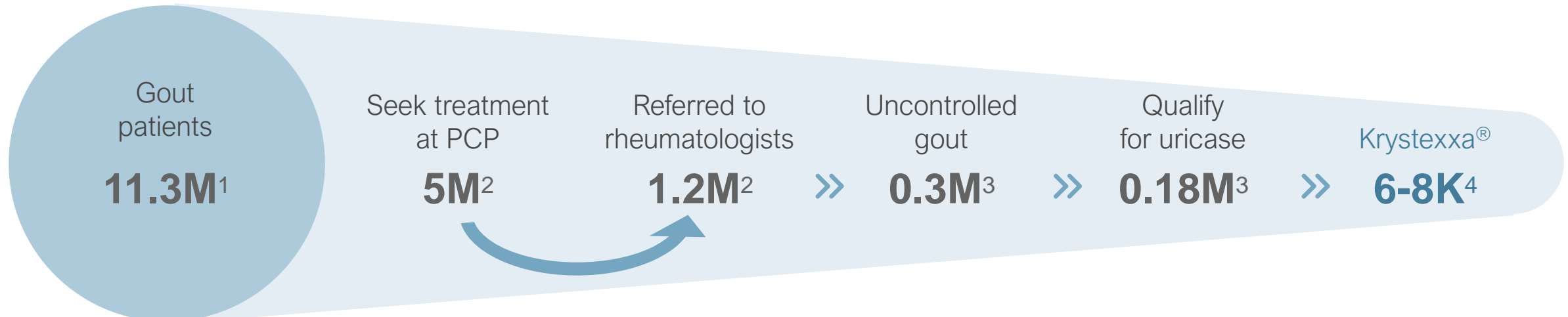
- Expected approval in 2026



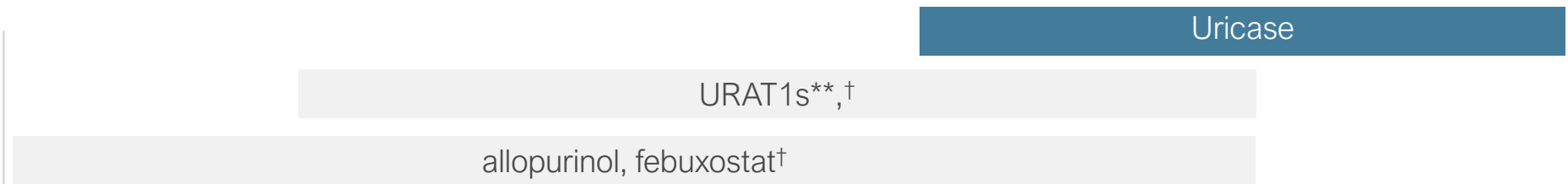
### Significant unmet needs and challenges

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

# The US Gout Market



## Treatments



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 \$1.2B (2024), yet less than 3% who qualify for uricase are currently treated**

# 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

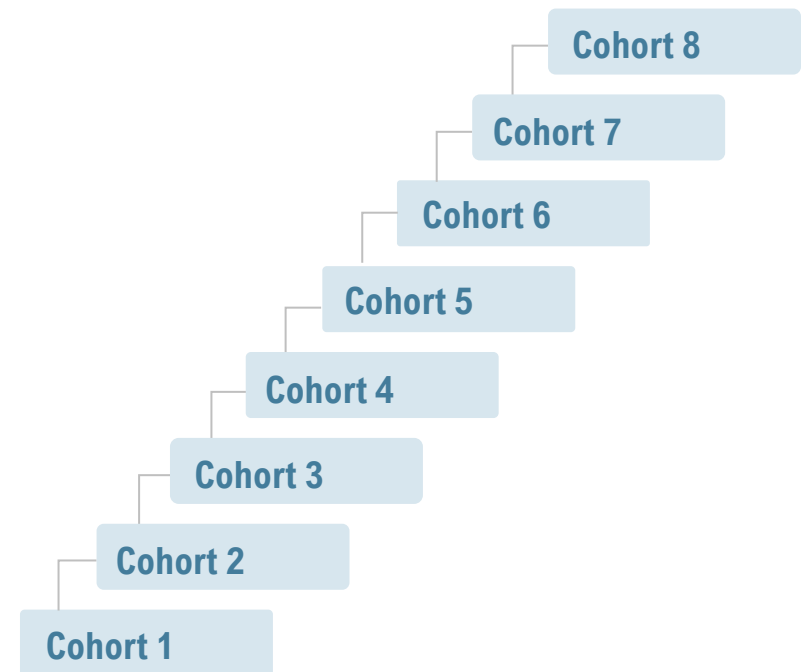
Secondary Endpoints: PK, PD (uric acid levels)

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



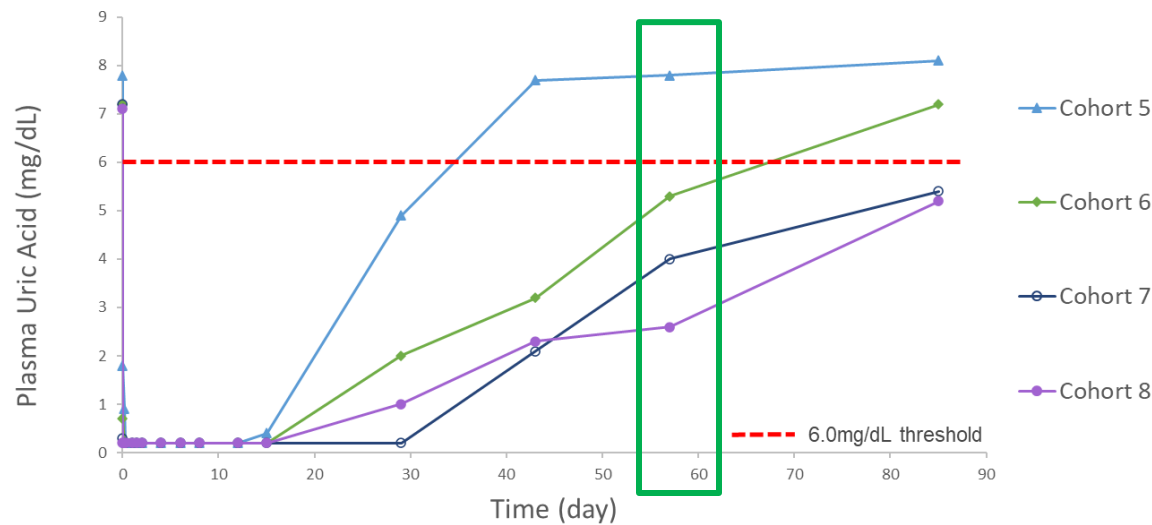
# PRX-115 best in class potential for uncontrolled gout

## 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



### Next Steps

- Phase 2 study in uncontrolled gout patients
- Initiation anticipated in 4Q25, IND has become effective following the FDA's standard 30-day review period.

### Expected Phase 2 differentiation(s)

- Improved dosing interval
  - IV infusion every 8 weeks
- No co-administration of immunomodulator, methotrexate (MTX) which is contraindicated in certain co-morbidities
- Favorable safety and immunogenicity profile

# PRX-115 Phase 2 double blind placebo-controlled study design

## 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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# Commercial products

*Reliably partnered and delivering revenue*



# Two commercial products sustaining future growth

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

## Fabry disease



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

Commercialization Partner



Approved in US, EU plus additional markets

### Commercial Potential

- Fabry Market: ~\$2.1B<sup>1</sup> (2024) expected to reach ~\$3.4B (2030)
- Elfabrio<sup>®</sup> poised to capture significant global market share (15% to 20%)
- Protalix royalties per year from Chiesi (15% to 35% tiered ex-US, 15% to 40% tiered US)
- Significant milestone payments expected in mid- and long-term

## Gaucher disease



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

Commercialization Partners



Approved in 23 markets





Worldwide (ex-Brazil) license with Pfizer in 2009

Brazil collaboration with Fundação Oswaldo Cruz in 2013

- Market share in Brazil: ~25%
- Sales ~\$11M in Brazil (FY2024)

# Fabry disease competitive landscape

~\$2.1B market (2024) expected to reach over \$3.4B (2030), CAGR of 8.2%<sup>1</sup>

| Product Name        | Fabrazyme®   | Replagal®   | Galafold®   | Elfabrio®   |
|---------------------|--|---|---|---|
| Parent Company      |               |  |  |  |
| Mechanism           | ERT  | ERT   | Pharmacological chaperone   | ERT<br>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   |
| 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%)*

# Commitment and execution from global partnership with Chiesi

## Committed Global Partner

- International research-focused biopharmaceutical group with sales in excess of €3.4B in 2024 (reflecting 13% growth year-on-year)
- Operating in close to 30 countries with over 7,500 employees; invested over 24% of 2024 revenue in research and development
- Strong sales and marketing partner poised to maximize the market potential of pegunigalsidase alfa as the centerpiece of their new strategic US-based Rare Disease division
- Elfabrio® launched in US, throughout EU and additional markets
- 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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# **Growth strategy**

*Next phase of the company*

# Research strategy - leveraging internal strengths to fuel the next phase of company

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<sup>®</sup> 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

# Protalix delivers innovation from concept to the market



Two commercial products



Three revenue streams



Growing pipeline for the next phase of the company

- PRX-115 best-in-class potential for uncontrolled gout
- Research focus – Renal Rare Diseases

Revenues  
USD 53M 2024

Cash  
USD 29.4M Q3/2025

Debt  
No Debt / Warrants

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