PROTALIX Biotherapeutics

PROTALIX BIOTHERAPEUTICS

CORPORATE PRESENTATION

December 2024

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Third-Party Information

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Investment Highlights

A strong foundation to further expand into the Rare Disease space

Two Approved Drugs

Elelyso® (alfataliglicerase in Brazil): FDA approved, commercially marketed drug for Gaucher disease

Elfabrio® (pegunigalsidase alfa) has been approved for marketing by the FDA and the European Commission[1] for Fabry disease[2]

Clinical and Regulatory Expertise in Rare Genetic Space

Strong clinical and regulatory expertise for biologics and world-class network of Lysosomal Storage Disorder disease experts

Clinically-Validated Platforms

Proprietary ProCellEx® platform for recombinant protein expression cGMP[3] manufacturing facility successfully inspected and audited by multiple regulatory agencies, including the FDA & EMA

Growing Development Pipeline

PRX-115: Uricase for uncontrolled gout

PRX-119: Long Acting DNase I for NETs-related diseases

Multiple other product candidates, in discovery and preclinical phases

Strong Partnerships

Chiesi Farmaceutici S.p.A.
Pfizer Inc.
Fundação Oswaldo Cruz (Fiocruz)

Revenue-Generating

Multiple revenue streams, including sales to Pfizer, Fiocruz (Brazil) and Chiesi

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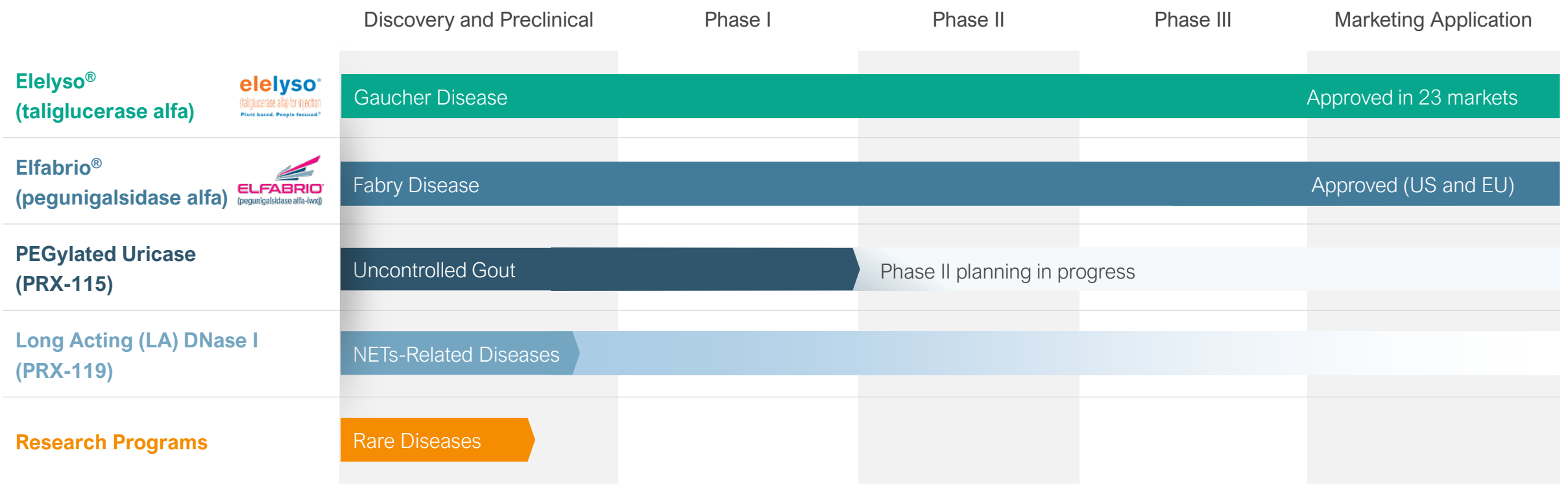
(1) Also approved in the United Kingdom, Israel and other jurisdictions.
(2) For the treatment of adult patients with Fabry disease.
(3) cGMP = Current Good Manufacturing Practice.

Product Pipeline

Recombinant proteins designed to have potentially improved therapeutic profiles that target unmet medical needs and established pharmaceutical markets



Note: Current pipeline candidates are generally recombinant proteins expressed via our proprietary ProCellEx® system

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Approved Products

Elelyso® for Gaucher Disease

First plant cell derived recombinant protein approved by the FDA

Gaucher Disease

- Rare autosomal recessive disorder: affects 1 in 40,000 people
- Glucocerebrosidase (GCD) enzyme deficiency resulting in accumulation of glucosylceramide, a lipid, in bone marrow, lungs, spleen, liver and sometimes brain

Symptoms and Treatment

- Possible symptoms include enlarged liver and spleen, various bone disorders, easy bruising and bleeding and anemia
- Left untreated, it can cause permanent body damage and decreased life expectancy
- Standard of Care: Enzyme Replacement Therapy

Product

elelyso® (taliglucerase alfa) for injection
Plant based. People focused.®

- Elelyso (alfataliglicerase in Brazil) is a proprietary, recombinant form of GCD for long-term treatment of patients with a confirmed diagnosis of type 1 Gaucher disease
- Expressed through our ProCellEx® platform

Commercial Potential

FDA APPROVED

- Approved in 23 markets
- Worldwide exclusive license agreement with Pfizer in 2009, amended in 2015 (excluding Brazil)
- Sales ~$10.4M in Brazil (FY2023) via Fundação Oswaldo Cruz
- Market share in Brazil: ~25%

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1. Approved in 23 markets including the US, Australia, Canada, Israel, Brazil, Russia and Turkey. In 2010, the European Committee for Medicinal Products for Human Use (CHMP) gave a positive opinion but also concluded that the medicine cannot be granted marketing authorization in the EU because of the market exclusivity that had been granted to Vpriv® (Shire) which was authorized in August 2010 for the same condition. The orphan market exclusivity expired in August 2022.

Elfabrio® for Fabry Disease

Second plant cell derived recombinant protein approved by the FDA

Fabry Disease

- Rare X-linked disease: affecting about one in every 40,000 to 60,000 men worldwide
- α-galactosidase-A enzyme deficiency leads to accumulation of the fatty substance globotriaosylceramide (Gb_3) in blood and blood vessel walls throughout the body

Symptoms and Treatment

- Progressive disease that can lead to renal failure, cardiomyopathy with potentially malignant cardiac arrhythmias and strokes
- Symptoms such as abdominal and neuropathic pain can appear in patients as young as two years old
- Standard of Care: Enzyme Replacement Therapy (Replagal® or Fabrazyme®[1,2])

Product

ELFABRIO (pegunigalsidase alfa-iwxj)

- Elfabrio (pegunigalsidase alfa): Chemically Modified, Plant Cell Derived, PEGylated, Covalently Linked Homodimer
- Approved for marketing by the EC, FDA and others
- Expressed through our ProCellEx® platform

Commercial Potential

FDA APPROVED

EUROPEAN MEDICINES AGENCY

Chiesi

- Fabry: ~$2B (2023) expected to reach ~$3.1B (2030); Poised to capture significant global market share (15-20%)
- Will potentially be entitled to $120M-$150M royalties per year from Chiesi[3]

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1. Does not include Galafold®, a small molecule drug indicated for adult Fabry patients with an amenable GLA variant.
2. Replagal® is not approved in the US.
3. Based on projected 15-20% share of projected market size increase to ~$3.1 billion by 2030.

Fabry Disease Competitive Landscape

~$2B market (2023) expected to reach over $3.1B (2030), CAGR of 6.8%

Product Name	Fabrazyme®	Replagal®	Galafold®	Elfabrio®
Parent Company	sanofi	Takeda	Amicus Therapeutics	PROTALIX Biotherapeutics
Mechanism	ERT	ERT	Pharmacological chaperone	ERT
Approved for	Adults and pediatric patients 2+ years (US); Adults, children and adolescents aged 8+ years. (EU)	Adults (EU only)	Accelerated approval in adults (US) Adults and adolescents 16+ years (EU)	Adults (US, EU and others)
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 (15-20%)

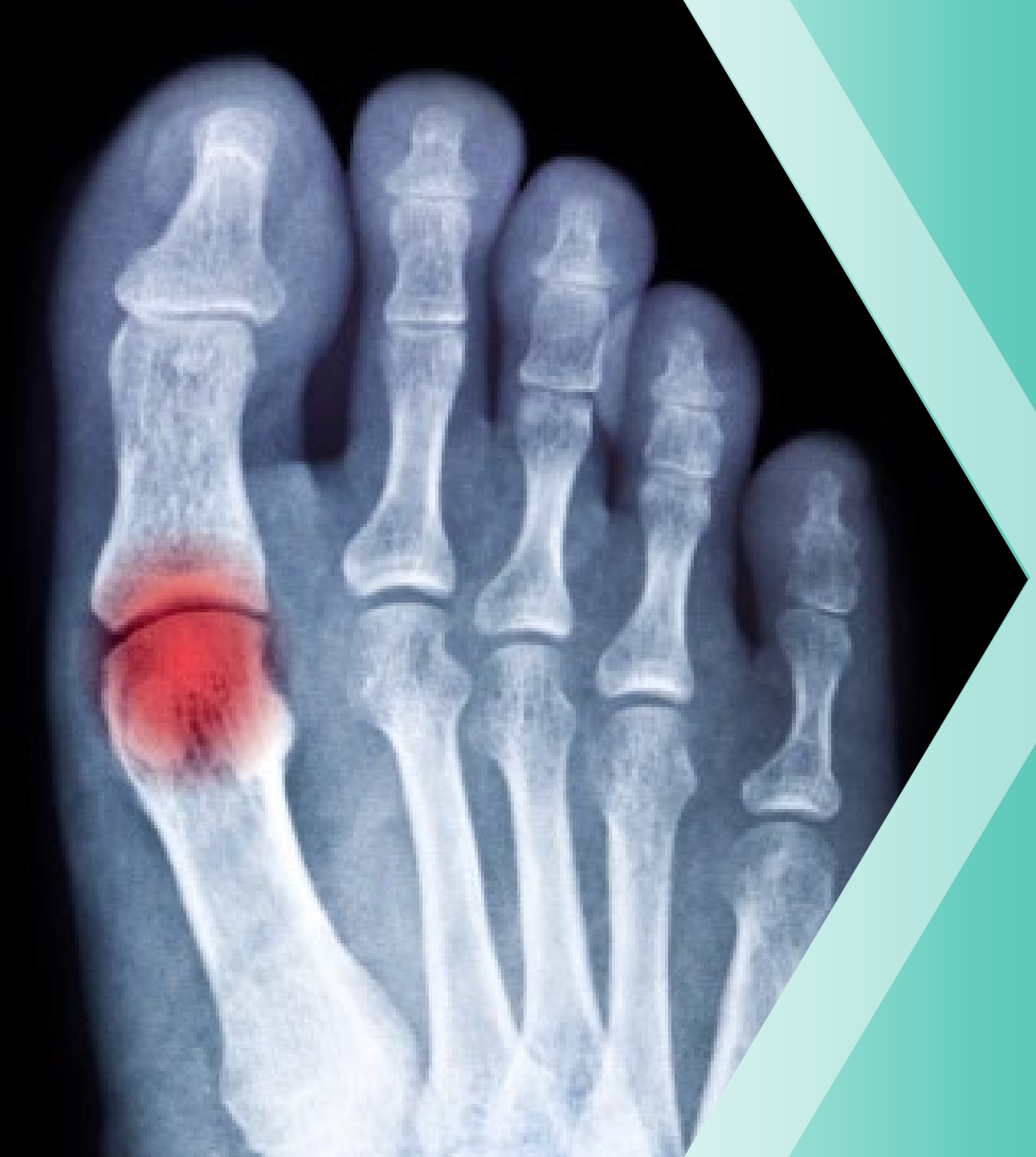
Committed Commercial Partner

Global Partnership with Chiesi Farmaceutici S.p.A.

- International research-focused biopharmaceutical group with sales in excess of $3B in 2023 (reflecting 10% growth year-on-year
- Operating in close to 30 countries with over 7,000 employees
- 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® launches underway in US, throughout EU and additional markets

- Committed global partner with experienced sales team
- Strategic focus on rare diseases
- Specific expertise in Fabry disease
- Ideally suited to bring Elfabrio to patients with Fabry disease[1]

(1) Tiered royalties of 15-35% (ex-US); 15-40% (US).



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PRX-115 in Development for Uncontrolled Gout

Gout

Most Common Inflammatory Arthritis

Gout affects approximately 14 million people in the US

~5% (estimated) of the gout population is considered to have chronic refractory gout

Accumulation of Excess Uric Acid

Hyperuricemia leads to accumulation of urate crystals (tophi) almost anywhere in the body, including bones and joints, as well as organs such as the heart and kidney

Triggers recurrent episodes of sudden, pronounced acute inflammation, known as gout flares

Systemic Disease

Symptoms: severe acute pain, inflammation, stiffness, limited range of motion

Co-morbidities: hypertension, cardiovascular disease, renal impairment, diabetes, obesity, hyperlipidemia, and frequently in a combination known as the metabolic syndrome

Currently Available Therapies

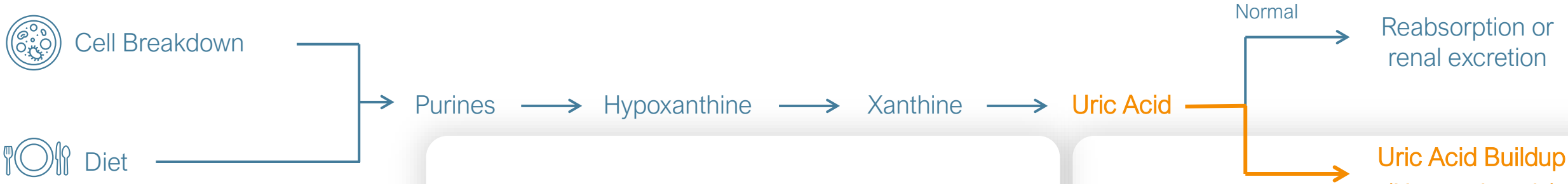
First-line xanthine oxidase inhibitors (XOIs): Allopurinol and Febuxostat

One recombinant uricase approved for chronic gout in adult patients refractory to conventional therapy as every two-week injection: Krystexxa® [1]

[1] Krystexxa has a “Black Box” safety warning for anaphylaxis and infusion reactions. It is not approved for use in the EU.

Currently Available Urate-Lowering Therapies

Unmet need still remains in uncontrolled gout patients



Xanthine Oxidase Inhibitors (XOIs):

Xanthine oxidase

Allopurinol
Febuxostat

First-line oral treatment

Reduces uric acid levels by blocking its synthesis

However, uncontrolled gout patients typically do not reach target uric acid levels with XOI treatment alone and experience recurrent flares

Recombinant Uricase:

KRYSTEXXA pegloticase

Approved for refractory gout

IV infusion every two weeks

Eliminates excess uric acid

However, it has an extensive side effect profile due to anti-drug antibodies, requiring combination with methotrexate[1]

[1] Krystexxa has a "Black Box" safety warning for anaphylaxis and infusion reactions. It is not marketed in the EU.

PRX-115: Significant Potential in Uncontrolled Gout

Uncontrolled Gout
Unmet Need

An estimated **5%** of the gout population is considered to have chronic refractory disease

Uncontrolled gout patients typically do not reach target uric acid levels with (XOI) treatment alone and experience recurrent, painful flares

There remains an unmet need for treatment options for patients with uncontrolled gout who are not able to lower uric acid levels, or who experience unwanted side effects with currently available treatments

PRX-115 may represent a much-needed alternative treatment option for uncontrolled gout

~$1.4B Global Gout Market[1]

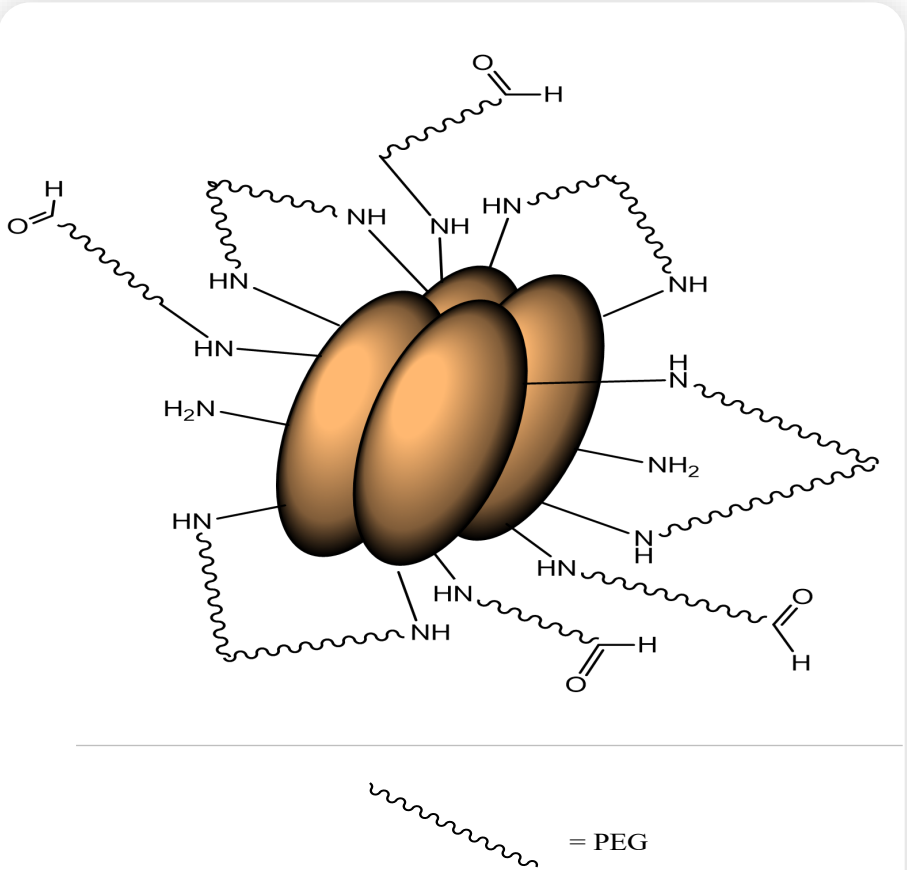
Expected CAGR of 6.4% from 2022–2029

Krystexxa net sales were ~$1B in 2023

1. Projected for 2024.

PRX-115: Chemically Modified, Plant Cell Derived, PEGylated, Covalently Linked Homotetramer

- PRX-115 is a PEGylated enzyme designed to potentially have lower immunogenicity by masking immunogenic epitopes and an improved safety profile
- PRX-115 is a plant cell-based recombinant *Candida Utilis* Uricase with substitution of Cystein to Lysin at position 250 that prevents enzyme aggregation and di-sulfide bond formation between the Uricase tetramers
- Chemically modified using proprietary modification with 40x 3.4 kDa Bis-Ald PEG molecules, resulting in cross-linking between subunits and >99.5% of backbone masking for reducing immunogenicity, increasing half-life and retaining efficacy



3.4kD PEG

PRX-115 Phase I Single Ascending Dose Study Design

Study Scheme

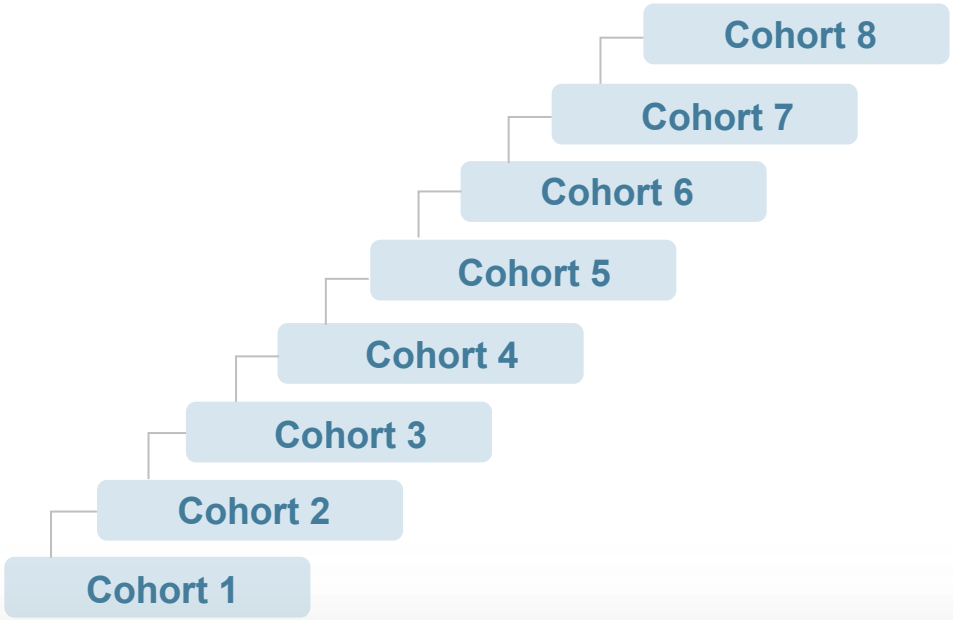
Primary Endpoint: Safety and tolerability

Secondary Endpoints: PK, PD (uric acid levels)

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

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

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



Study schedule per patient

Participant Demographics and Baseline Characteristics

Parameter	Statistic	Pooled PRX-115	Pooled Placebo	Overall
	n	48	16	64
Age (years)	Mean	35.9	33.4	35.3
	SD	12.3	10.8	11.9
Sex n(%)	Female	16(33.3)	5(31.3)	21(32.8)
	Male	32(66.7)	11(68.8)	43(67.2)
Race n(%)	American Indian or Alaska Native	0	0	0
	Asian	7(14.6)	5(31.3)	12(18.8)
	Black or African American	1(2.1)	0	1(1.6)
	Native Hawaiian or other Pacific Islander	8(16.7)	2(12.5)	10(15.6)
	White	31(64.6)	8(50.0)	39(60.9)
	Other	3(6.3)	2(12.5)	5(7.8)
Weight (kg)	Mean	87.52	85.87	87.11
	SD	18.06	18.37	18.01
Body Mass Index (kg/m^2)	Mean	29.16	28.01	28.87
	SD	5.03	5.35	5.10
Plasma Urate (mg/dL)	Mean per cohort	7.0-8.5	7.0	7.0-8.5

Overall Summary of Adverse Events*

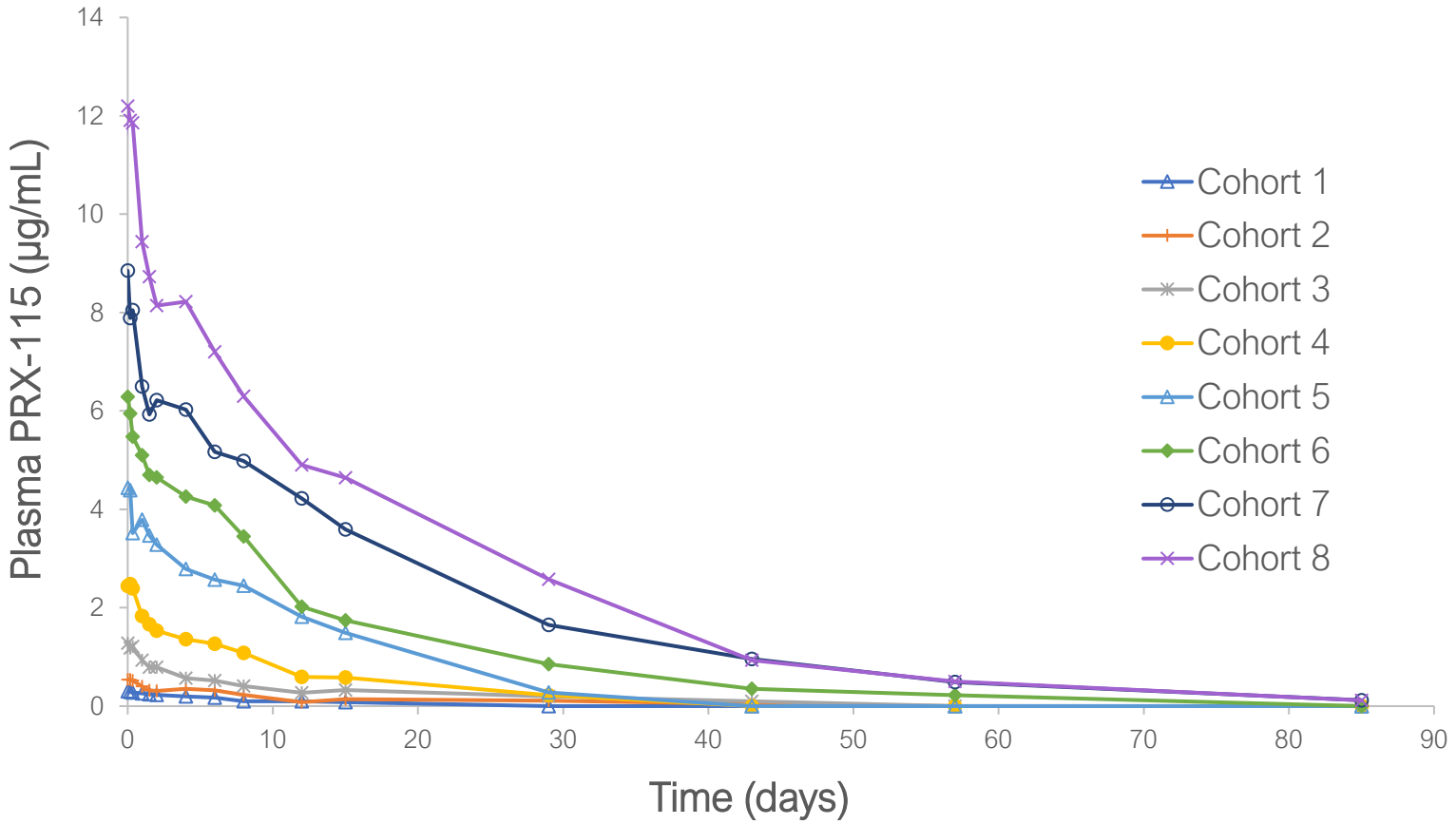
	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5	Cohort 6	Cohort 7	Cohort 8	Pooled PRX-115	Pooled Placebo
N	6	6	6	6	6	6	6	6	48	16
TEAE n(%)	5(83.3)	6(100.0)	5(83.3)	3(50.0)	6(100.0)	5(83.3)	3(50.0)	4(66.7)	37(77.1)	13(81.3)
Related TEAE n(%)	1(16.7)	5(83.3)	3 (50.0)	1(16.7)	1(16.7)	0	0	1(16.7)	12(25.0)	3(18.8)
Serious Related TEAE n(%)	0	1(16.7)	0	0	0	0	0	0	1(2.4)	0
TEAE Leading to Study Drug Discontinuation n(%)	0	1(16.7)	0	0	0	0	0	0	1(2.1)	0
TEAE Leading to Study Discontinuation n(%)	0	0	0	0	0	0	0	0	0	0

*Number of subjects reporting at least one adverse event.
TEAE: Treatment-emergent adverse event.

PRX-115 Pharmacokinetic Profile

Dose-dependent increase in PRX-115 exposure with single administration

PRX-115 Mean Plasma Concentrations Throughout 85-day Follow-up Period (n=48)

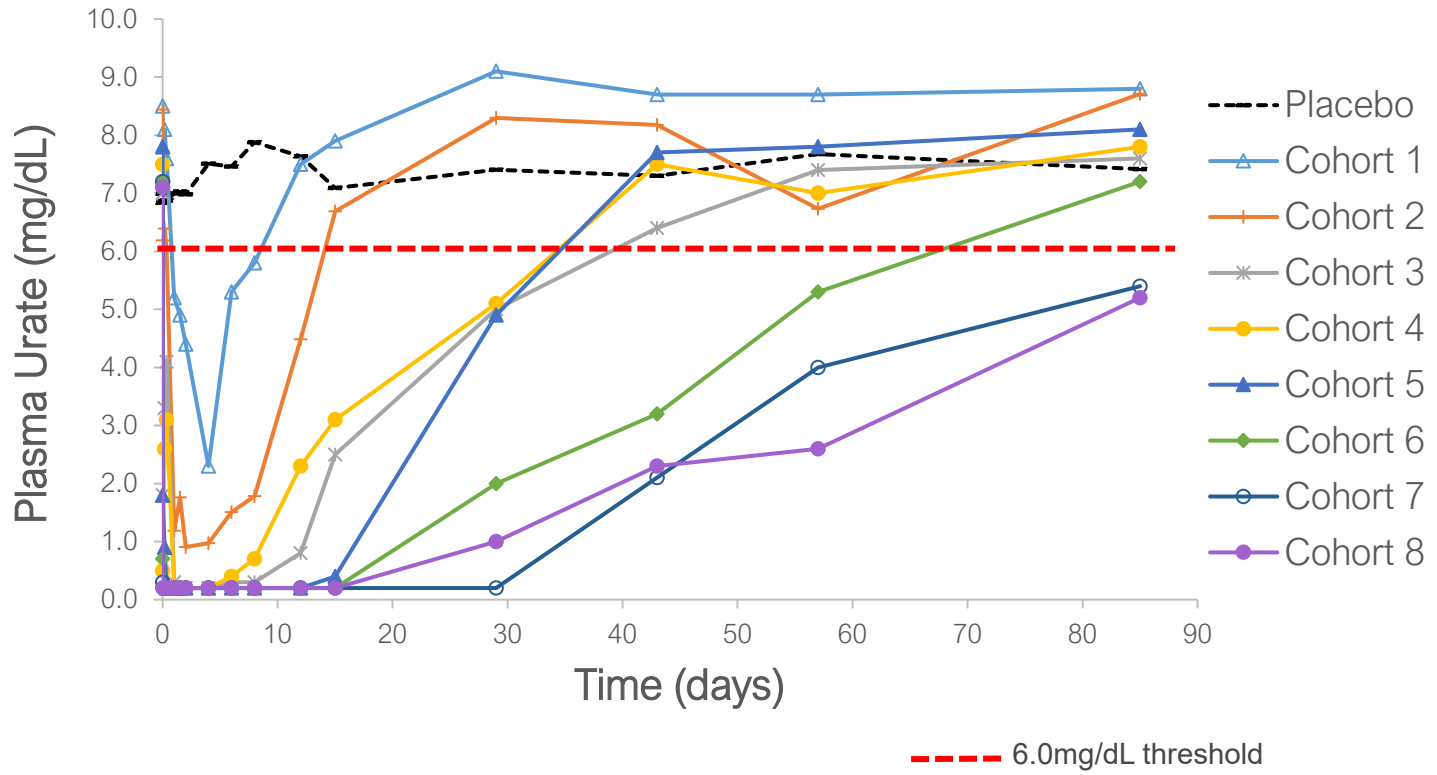


Detectable exposures were observed in plasma for up to 12 weeks in participants in highest dose cohorts 6, 7 and 8

PRX-115 Pharmacodynamic Results

Rapid reduction of plasma uric acid below 6 mg/dL following single administration of PRX-115

Uric Acid Mean Plasma Concentrations Throughout 85-day Follow-up Period (n=64)



Effect of PRX-115 on plasma uric acid levels and duration of response is dose dependent

Plasma urate levels remained below 6.0 mg/dL for up to 12 weeks at the highest dose levels

Cohort 2 excludes one patient who received 5% of the full dose.

PRX-115 Phase I Single Ascending Dose Study Summary

First-in-Human trial enrolled 64 subjects with elevated uric acid levels across 8 dose cohorts

Safety and Immunogenicity

Favorable tolerability profile

12 of 48 PRX-115-treated subjects experienced a study drug-related adverse event (AE)

Majority of study drug-related AEs were mild to moderate and transient in nature

One subject in cohort 2 experienced an immediate anaphylactic reaction; fully resolved

No other serious AEs were reported

No related AEs were reported in dose cohorts 6 and 7

PRX-115 immunogenicity is still under evaluation, including correlation to PK, PD and safety

PK / PD

PRX-115 exposures increased in dose-dependent manner

Detectable PRX-115 levels were observed in plasma for up to 12 weeks from subjects in cohorts 6, 7 and 8

Rapid reduction of plasma uric acid levels to below 6.0 mg/dL

Reduction of plasma uric acid occurred in dose-dependent manner and lasted beyond 4 weeks

Phase 2 Planning In Progress

PRX-115 Summary

Recombinant PEGylated Uricase Enzyme for Potential Treatment of Uncontrolled Gout

Addressable Market

Approximately 14 million US gout patients, of which ~5% considered to have chronic refractory disease

Status

Phase I First-in-Human study completed (8 cohorts); data is locked and currently being analyzed

Phase II planning in progress

Next Steps

Phase II study in uncontrolled gout patients--initiation anticipated in 2H 2025

Asset Overview

- Recombinant PEGylated uricase enzyme produced via ProCellEx® plant cell-based expression system
- Favorable tolerability profile demonstrated by preliminary phase I data for subjects with elevated uric acid levels
- Demonstrated stable PK profile, long half-life in preliminary phase I data
- Demonstrated ability to reduce uric acid levels to recommended guideline of below 6.0 mg/dL

Market Overview

~$1.4B market for gout overall and growing

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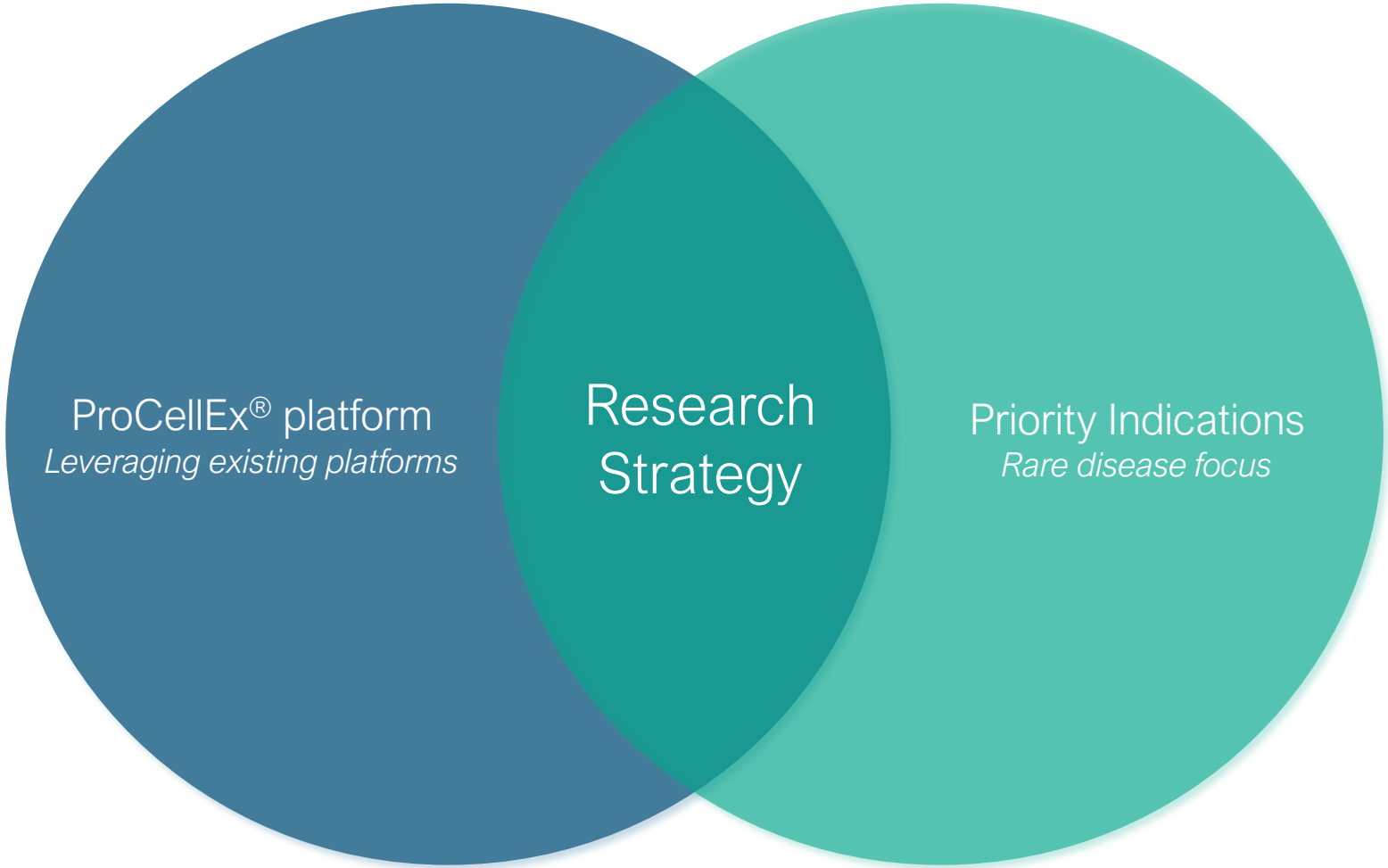
Corporate Strategy

Research Strategy to Fuel Next Stage of Growth

Goal: Within 3 years, 4-5 discovery to Phase II programs in the pipeline



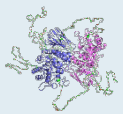
Potential Expansion of ProCellEx® Platform for Drug Delivery

Exploring platform expansion to include drug delivery modalities for optimized delivery of therapeutic proteins

- Unmet need: efficient and targeted delivery of therapeutic proteins
- Potential applications:
  - Package recombinant proteins in delivery modalities produced in the ProCellEx Platform
  - Package other cargos (e.g., ASO / siRNAi) in delivery modalities derived from ProCellEx platform (potential academic/industry collaborations) and/or Biotech companies
  - Unlocking additional indications:
    - Specific targeting for delivery to certain organs to address tissue-specific unmet need
- Initial validation and feasibility studies in progress

ProCellEx Platform

Protein therapeutics: Plant cell-based expression

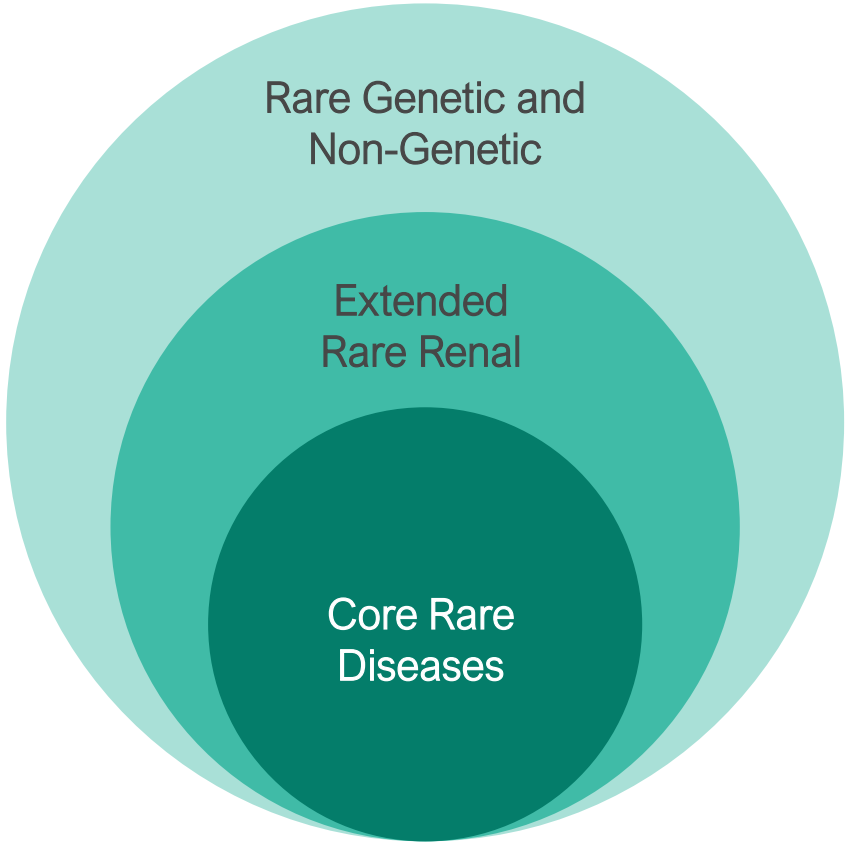


Chemical modification: PEGylation

Drug delivery: Exploring new modalities

Focus on High Unmet Needs in Rare Disease Space

Focus on Rare Disease Space



Therapeutic Area Strategy: Focus on Rare Disease Space

- Protalix conducted systematic analysis to identify potential key areas of focus in rare disease space
- Both genetic and non-genetic opportunities
- Potential to prioritize rare renal diseases as the core of Protalix's development pipeline
- High unmet renal diseases include: ADPKD, Alport syndrome, FSGS and others

Systematic Approach to BD&L

- Proactive BD&L strategy to complement internal portfolio, exploring:
  - Regular deal making, academic/ industry collaborations, development of internal expertise
- Protalix is also reviewing emerging innovative platforms

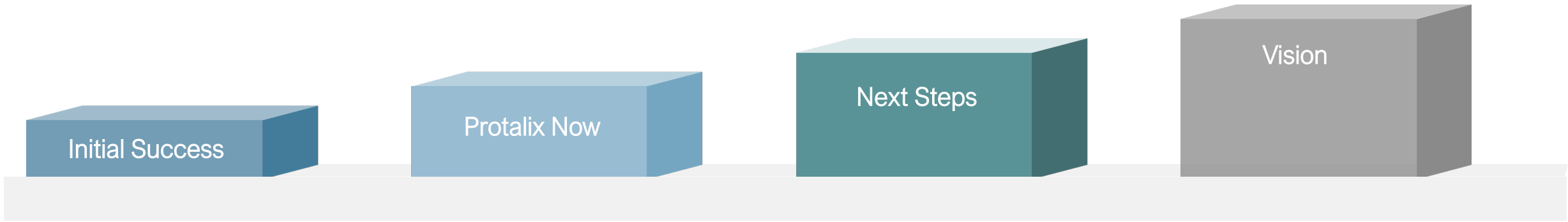
Evolving Protalix: Addressing High Unmet Needs in the Rare Disease Space

Leveraging track record of success into other rare diseases

Strategy

Track Record of Success in Rare Genetic Space

Striving for Continued Success in Rare Diseases



Initial Success

May 2012:

Protalix's 1st approved product

elelyso® (taliglucerase alfa) for injection
Plant based. People focused.®

Protalix Now

May 2023:

Protalix's 2nd approved product

ELFABRIO® (pegunigalsidase alfa-iwxj)

Next Steps

Within 3 years, 4-5 discovery to PhII programs

ProCellEx® Platform expansion to include drug delivery modalities

BD&L: Preclinical/Clinical Pipeline

Develop highly innovative rare disease treatments addressing significant unmet needs

Vision

Building a significant pipeline with innovative rare disease clinical programs

Fully Integrated with End-to-End capabilities

Commercial infrastructure to support novel products

Leveraging novel technology platforms with broad potential in rare diseases

Well Capitalized to Advance Protalix to Next Phase

CASH & CASH RUNWAY
$27.4 M (Q3 2024)
Sufficient to support ongoing operations[1]

CASH STREAMS
Three revenue and cash streams from Pfizer, Fundação Oswaldo Cruz (Fiocruz) and Chiesi

EQUITY OPPORTUNITIES
$20M At-the-Market Equity Facility w/HCW

REVENUE
$34.8M in revenue (nine months of 2024)

NO DEBT[2]

STRONG PARTNERSHIPS
Chiesi Farmaceutici S.p.A.
Pfizer Inc.
Fiocruz

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1.Based on current cash and cash equivalents and expected receipt of milestones; based on a number of assumptions and may vary significantly from our expectations. See Forward Looking Statements.
2. Cash repayment of outstanding 7.50% Senior Secured Convertible Promissory Notes in September 2024.

Experienced Leadership Team

DROR BASHAN
President & CEO

Mr. Bashan has served as our President and Chief Executive Officer since June 2019. He 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.

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

Dr. Tessler joined Protalix in October 2023. She has over 20 years of experience in the pharmaceutical industry, leading a broad range of innovative drug development projects and activities, from lead-stage to phase III clinical trials and marketing applications. Prior to Protalix, she served as VP, R&D of Biosight Ltd. and of Enzymotec Ltd. (currently part of International Flavors & Fragrances Inc.) and as a Sr. Director Project Champion at Innovative R&D of Teva.

EYAL RUBIN
SVP & CFO

Mr. Rubin has served as our SVP and Chief Financial Officer since September 2019. He brings to Protalix over 20 years of finance and capital markets experience, an extensive background in financial planning and operations, management and strategy and a deep knowledge of the biotechnology and pharmaceutical industries. Prior to Protalix, he served as EVP and CFO of BrainStorm Cell Therapeutics Inc., where he was responsible for corporate finance, accounting and investor relations activities.

YARON NAOS
SVP of Operations

Mr. Naos joined Protalix Ltd. in 2004 as a Senior Director for Operations and became our SVP, Operations. He has a wealth of hands-on experience and knowledge in the field of pharmaceutical development. Prior to Protalix, he served for a decade as 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, and R&D activities that led to the commercialization of products.

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

Dr. Ori Kalid joined Protalix as Vice President of Research and Development in June 2024, bringing over 20 years of leadership experience in multidisciplinary pharmaceutical R&D. Before joining Protalix, Ori co-founded and served as the CEO of SILVERSKATE BIO, an immunology startup. He was co-founder and CEO of Pi Therapeutics, 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