PROTALIX Biotherapeutics

Protalix BioTherapeutics, Inc.

CORPORATE UPDATE | JANUARY 2020

Note Regarding Forward-Looking Statements

This presentation (the "Presentation") contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements, including, among others, statements regarding expectations as to regulatory approvals, market opportunity for, and potential sales of, the Company's product and product candidates, goals as to product candidate development and timing of the Company's clinical trials, are based on the Company's current intent, belief and expectations. These statements are not guarantees of future performance and are subject to certain risks and uncertainties that are difficult to predict. Factors that might cause material differences include, among others: risks related to the Company's ability to identify and complete strategic alternatives on attractive terms or at all within the time period required to regain compliance with the continued listing standards of the NYSE American; risks related to the Company's ability to continue as a going concern absent a refinancing or restructuring; risks related to any transactions the Company may effect in the public or private equity markets to raise capital to finance future research and development activities, general and administrative expenses and working capital; failure or delay in the commencement or completion of the Company's preclinical and clinical trials which may be caused by several factors, including: risks that the FDA will not accept an application for accelerated approval of PRX-102 with the data generated to date or will request additional data or other conditions of the Company's submission of any application for accelerated approval of PRX-102; slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to monitor patients adequately during or after treatment; and inability or unwillingness of medical investigators and institutional review boards to follow the Company's clinical protocols; the risk that the results of the clinical trials of the Company's product candidates will not support the Company's claims of safety or efficacy, that the Company's product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks relating to the Company's ability to maintain and manage the Company's relationship with Chiesi Farmaceutici S.p.A. and any other collaborator, distributor or partner; risks related to the Company's commercialization efforts for alfataliglicerase in Brazil; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under the supply and technology transfer agreement; the risk that despite the FDA's grant of fast track designation for PRX-102, the Company may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA's ability to withdraw the fast track designation at any time; the Company's dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in the Company's preparation and filing of applications for regulatory approval; the inherent risks and uncertainties in developing drug platforms and products of the type the Company is developing; the impact of development of competing therapies and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; and other factors described in the Company's filings with the U.S. Securities and Exchange Commission. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. The Company 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.

Investment Highlights

Plant cell expressed recombinant proteins with improved therapeutic profiles

Revenue Generating	Marketed drug for Gaucher disease elelyso® (taliglucerase alfa) for injection Plant based. People focused.® alfataliglicerase
Pipeline	Pipeline products in active clinical phase development: pegunigalsidase alfa (PRX-102)/Fabry disease, tulinercept (OPRX-106)/ Inflammatory Bowel Disease, alidornase alfa (PRX-110)/DNase for multiple indications. Other products in seed and preclinical phases
Regulatory	BLA submission for Fabry disease anticipated by April 2020
Partnerships	Chiesi Pfizer FIOCRUZ FUNDAÇÃO OSWALDO CRUZ
Platform	Advantageous proprietary ProCellEx® platform for recombinant protein expression and cGMP manufacturing facility successfully inspected and audited by multiple regulatory agencies, including the US FDA and EU EMA
Management	Highly experienced management with proven track record

Note: cGMP = Current Good Manufacturing Practice.

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.

YOSEPH SHAALTIEL, PH.D.
EVP of R&D

Yoseph Shaaltiel, Ph.D. founded Protalix Ltd. and has served as our Executive Vice President, Research and Development since 2006. Prior to establishing Protalix Ltd., Dr. Shaaltiel was a Research Associate at the MIGAL Technological Center. He served as Deputy Head of the Biology Department of the Biological and Chemical Center of the Israeli Defense Forces and as a Biochemist at Makor Chemicals Ltd.

EINAT BRILL ALMON, PH.D.
SVP of Product Development

Dr. Almon joined Protalix in December 2004 as a Senior Director and became our Senior Vice President, Product Development. She has many years of experience in the management of life science companies and projects including biotechnology and agrobiotech, with direct experience in clinical, regulatory, device and scientific software development, as well as a strong background and work experience in intellectual property.

EYAL RUBIN, CPA
SVP & CFO

Mr. Rubin has served as our Senior Vice President 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

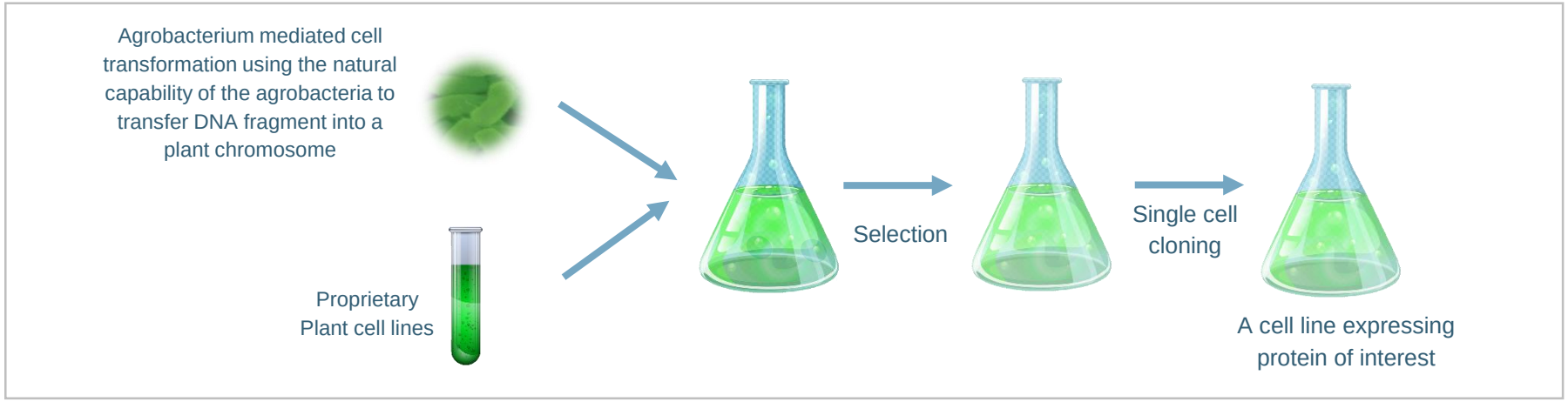
Mr. Naos joined Protalix Ltd. in 2004 as a Senior Director for Operations and became our Senior Vice President, Operations. He has a wealth of hands-on experience and knowledge in the field of pharmaceutical development. Prior to Protalix, he served for a decade as R&D Product Manager at Dexxon Pharmaceutical Co., one of Israel's largest pharmaceutical companies, where he was responsible for technology transfer from R&D to production, and in charge of R&D activities that led to the commercialization of many products.

ProCellEx® Platform

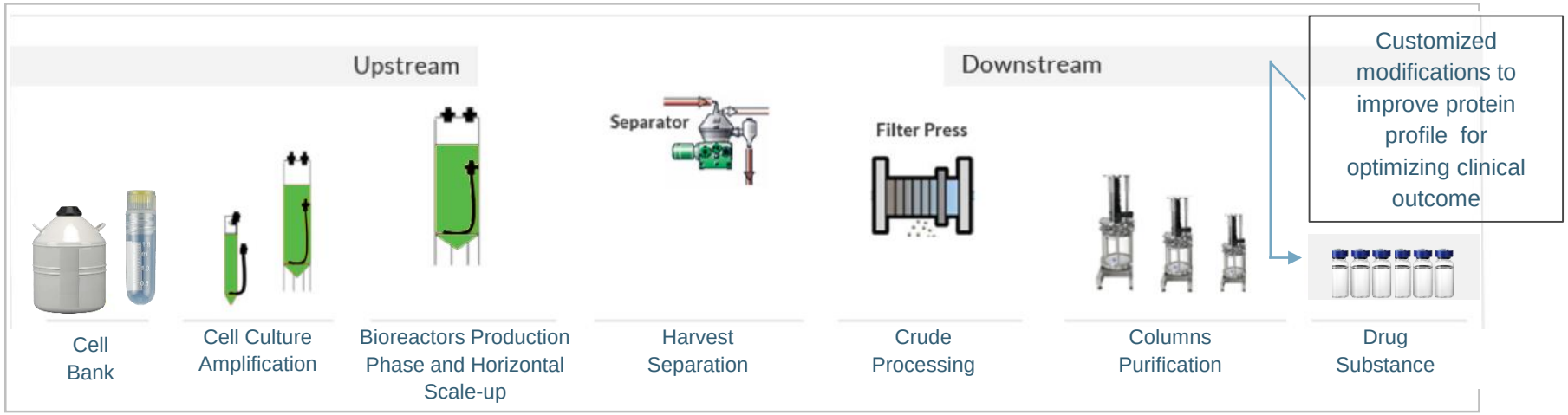
First and only company to gain FDA approval of a protein produced through plant cell based expression

Unique capabilities of tailoring genetic engineering and protein engineering tools for pre/post-production modifications, customized for each individual protein candidate

DEVELOPMENT OF TRANSGENIC CELL LINES FOR PRODUCTION OF TARGET PROTEIN



PROCESS OVERVIEW



Elelyso® for Gaucher Disease

First plant cell derived recombinant protein approved by the FDA

Validation of the ProCellEx® platform

Gaucher disease (go-SHAY) is a rare genetic disorder characterized by the deposition of glucocerebroside in cells of the macrophage-monocyte system. Possible symptoms include enlarged liver and spleen, various bone disorders, easy bruising, and anemia. Left untreated, Gaucher disease can cause permanent body damage and decrease life expectancy

Approved in 23 markets[1]. Monetized through a world-wide exclusive license agreement with Pfizer in 2009, amended in 2015 (excluding Brazil).

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

1. Approved in 22 markets including the US, Australia, Canada, Israel, Brazil, Russia and Turkey. 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 ten-year market exclusivity that had been granted to Vpriv® (Shire), which was authorized in August 2010 for the same condition.

Protalix maintains product rights in Brazil

Known as BioManguinhos alfataliglicerase, the product is commercialized in Brazil through a special supply and technology transfer agreement with Fundação Oswaldo Cruz, an arm of the Brazilian Ministry of Health, signed in 2013.

Protalix receives direct revenues from the Brazilian government:

- Gaucher patients are entitled to receive enzyme replacement therapy paid by the Brazilian Ministry of Health
- Clinical treatment guidelines place alfataliglicerase as the therapy of choice for newly diagnosed patients
- Estimated use by over 20% of treated patients in the country

Alfataliglicerase is the only enzyme replacement therapy (ERT) alternative to Sanofi/Genzyme's ERT product for Gaucher disease

Promising Proprietary Technology and Pipeline Opportunities

ProCellEx® Technology

Proprietary ProCellEx® platform is used to produce proteins through a plant cell culture, which allows for unique advantages in the areas of intellectual property, manufacturing enhancements, easy scale-up, no risk of viral contamination and proprietary product candidates with improved characteristics

Experience in Bringing Products to Market

Critical experience attained from bringing Elelyso® from concept to market. This experience has been leveraged to guide PRX-102 through clinical trials and planned BLA submission under accelerated approval. Steady revenue stream from sales of alfataliglicerase to the Brazilian Government

PRX-102 Royalties and Milestones

Pegunigalsidase alfa presents high promising sales potential and significant growth opportunity supported by a global pharma partner

Promising Pipeline

Positive preclinical and phase IIa clinical data results support feasibility of pipeline, with potential for significant safety and/or efficacy improvement

Advantages of Proprietary Plant Based Platform (ProCellEx®)

Experienced internal interdisciplinary capabilities to improve biologic dynamics (e.g., glycosylation, half-life, immunogenicity) of a protein

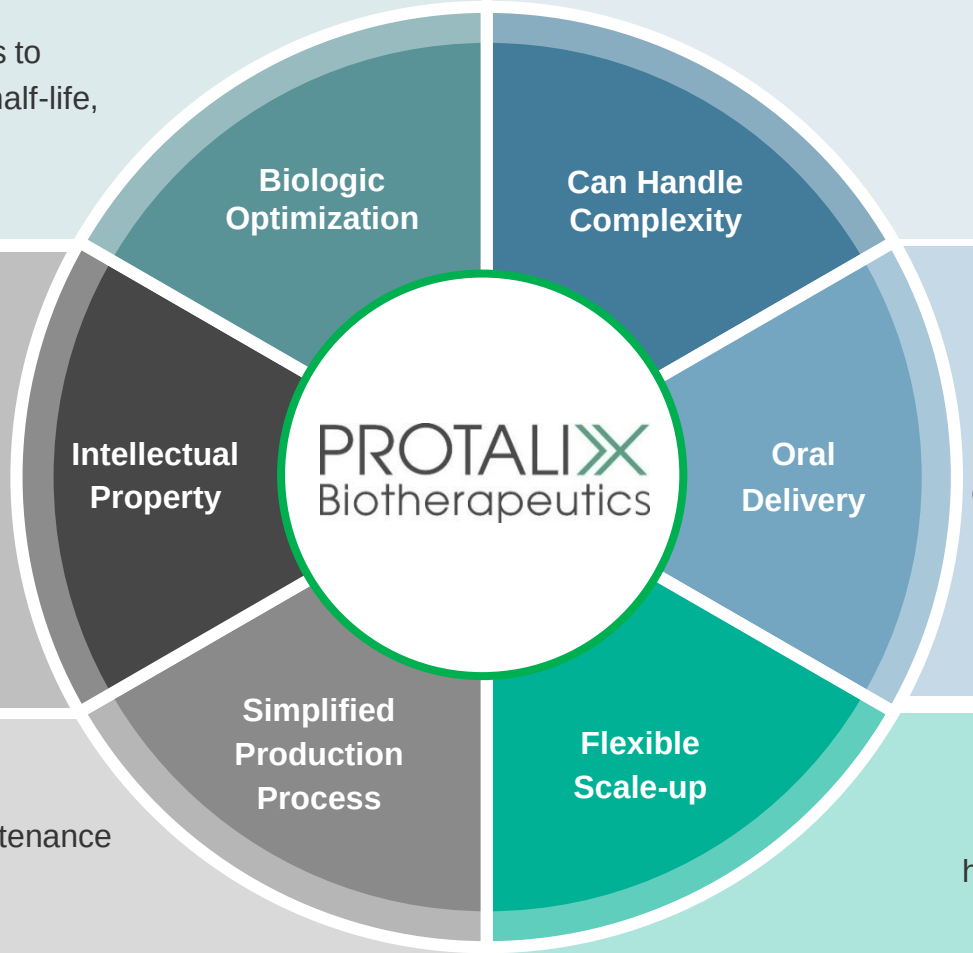
Ability to express certain proteins that are difficult to express in other systems

IP advantages due to proprietary manufacturing processes and development of 2nd generation, improved products

Protein protected inside plant cell enabling oral delivery of proteins to gastrointestinal tract

Production at room temperature, simplified maintenance with no viral contamination risk

Flexible infrastructure design allows for rapid horizontal scale-up (or scale-down), as required



Source: Company Information.

Commercial Success in Brazil

Sales in Brazil provide a consistent revenue stream for 5+ years, further validating the Company's ability to bring a treatment from concept to market and support long-term production

~700

existing treated Gaucher patients

~20%

Gaucher patients treated with alfataliglicerase (Elelyso ®)

~$9.1M

2019 sales to Brazilian Ministry of Health

~35

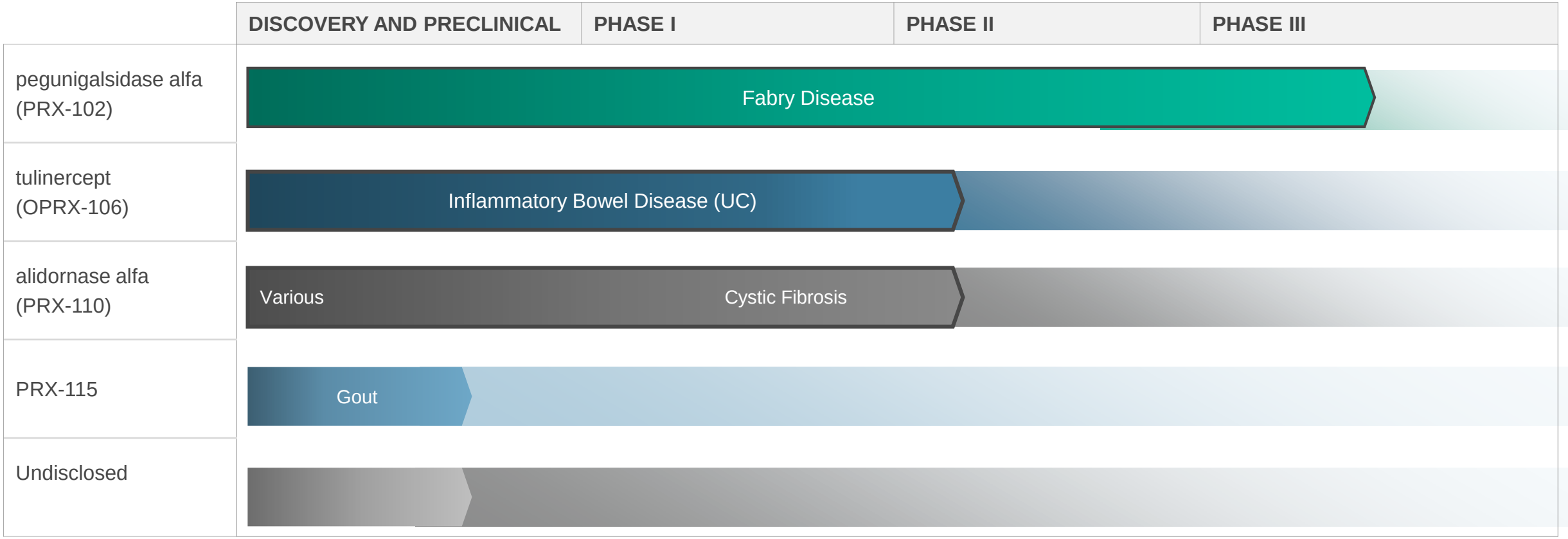
Expected newly diagnosed patients per year; entitled to government funded treatment

10-15%

Annual growth expected from direct sales for the next 3–5 years

Product Pipeline

Recombinant proteins with improved therapeutic profiles that target unmet medical needs and established pharmaceutical markets



All of our pipeline candidates are proteins expressed via our proprietary ProCellEx® system.

Pegunigalsidase alfa (PRX-102) for Fabry Disease

Rare genetic disease
occurs in one of every 40,000 people.

~$1.4bn+ growing market (expected CAGR ~10%)

Fabry disease is mostly treated with
enzyme replacement therapy (ERT), meaning the replacement of the missing alpha Galactosidase-A enzyme with a recombinant form of the protein via intravenous infusion 1x every 2 weeks.

Fabry Disease Competitive Landscape

	In Development			
Product	pegunigalsidase alfa 1mg/kg/2 weeks 2mg/kg/4 weeks PRX-102	Fabrazyme agalsidase beta	REPLAGAL agalsidase alfa	Galafold (migalastat) 123 mg capsule
Parent Company	PROTALIX Biotherapeutics	SANOFI	Shire	Amicus Therapeutics
Mechanism	Second Generation ERT	ERT		Pharmacological Chaperon
	• Longer active enzyme and potentially lower immunogenicity • Potential to demonstrate superiority based on 24 month head- to-head active control study • Two alternative dose and regimen for all Fabry disease subpopulations including option for once-monthly	• Renal function declines even for patients on long term ERT[1] • Limited effect due to:[2,3] (i) little functional enzyme and incomplete tissue penetration and (ii) presence of anti-drug antibodies, including neutralizing antibodies • Poor Quality of Life: – (i) Lack of symptom relief on the second week, (ii) infusion reactions and (iii) high burden of treatment		Applicable only for certain amenable mutations
Treatment Type	**Bi-weekly or Monthly Infusions**	**Bi-weekly Infusions**		**Oral**
Dosing	• 1mg / kg 2 weeks; • 2mg / kg 4 weeks	1mg / kg 2 weeks	0.2mg / kg 2 weeks	123mg every other day

Sources: FDA, ClinicalTrials.gov. (1) Rombach, et al 2013. (2) Fabry Expert Panel Consensus: Kidney Disease: Improving Global Outcomes (KDIGO) Conference, Oct 2016. (3) Lenders et al 2018.

*Pegunigalsidase alfa is an investigational product candidate not approved by the FDA

Pegunigalsidase alfa (PRX-102) for Fabry Disease

pegunigalsidase alfa **(PRX-102)**

Chemically modified plant recombinant alpha-Galactosidase-A designed to provide active and stable enzyme throughout infusion interval for a potentially improved clinical benefit

Current data have shown:

- Circulatory half-life of ~80 hours and active enzyme throughout the infusion interval
- Targeted enzyme activity in organs affected by Fabry disease.
- Safety and lower immunogenicity
- Reduction of globotriaosylceramide (Gb3) burden in kidney biopsies
- Potential for improved kidney function following switch to pegunigalsidase alfa from Replagal

Current trials ongoing in two dosing and regimens

Goal of meeting two important unmet needs:

- Demonstrating potential greater clinical benefit in renal function and other clinical and QOL measures
- Lowering the treatment burden of bi-weekly infusions – Improving patient's QOL

Pegunigalsidase alfa (PRX-102) Clinical Program

	Design	Number of Patients	Next Data Read-Out
balance (a Fabry clinical study)	1mg / kg 2 weeks Randomized Double Blind Head-to-Head vs. Fabrazyme® *24 mos.*	**78** 100% Enrolled	Interim Results – 12 mos. follow up Expected H1 2021 *(Basis for EMA Submission)*
bridge (a Fabry clinical study)	1mg / kg 2 weeks Open Label Switch Over from Replagal® *12 mos.*	**22** 100% Enrolled	Final Results Expected Q2 2020
bright	2mg / kg 4 weeks Open Label Switch Over from Fabrazyme® and Replagal® *12 mos.*	**30** 100% Enrolled	Final Results Expected Q4 2020

Commercialization Strategy

Global Partnership with Chiesi Farmaceutici S.p.A.

world-renowned global pharmaceutical company, signing two exclusive global licensing and supply agreements (ex-US and US)

Investment of $50m in upfront payments and development cost reimbursement of up to $45m (in aggregate)

Up to $1+ billion in potential milestone payments

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

Tulinercept (OPRX-106) for Inflammatory Bowel Disease (IBD)

Tulinercept is a cutting edge development candidate for IBD expressed via ProCellEx® for oral delivery of recombinant proteins whereby the plant cell wall increases resistance and delays to degradation as compared to proteins produced via mammalian cells, and allows for a natural oral administration vehicle.

OVERVIEW

- IBD is a collective reference to autoimmune inflammatory diseases of the gastrointestinal system, causing inflammation and sores on the lining of the digestive tract
  - Treatment usually begins with anti-inflammatory medications. As the severity of the disease increases, patients are generally treated with tumor necrosis factor (TNF)-alpha inhibitors (anti-TNF), which modulate the immune response
- The current anti-TNF therapies (infused and injected) are characterized by high immunogenicity and up to a 40% loss of response, most likely due to neutralizing antibodies
- Anti-TNF alfa biologics currently on the market have “Black Box” safety warnings for malignancies and infections. Similarly, other mechanisms for the treatment of IBD bear serious safety precautions

OVERVIEW OF CLINICAL TRIALS TO DATE

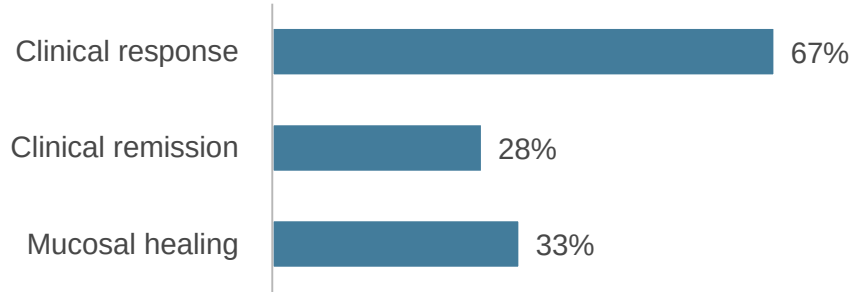
- Two clinical trials of tulinercept were completed for Ulcerative Colitis (UC):
  - **Phase I** – Healthy volunteers: safe and well tolerated
  - **Phase IIa** – Positive results from 18 UC patients who completed the study(1)
- Two doses explored for induction of remission by week 8

Sources: Colombel. *Clinical and Translational Gastroenterology*. 2016; Ben Horin. *Alimentary Pharmacology and Therapeutics.* 2011; Remicade, Humira, Simponi, Entyvio, Xeljanz prescribing information.
1. 24 patients were enrolled, 6 patients withdrew, none related to adverse events. Drop out rate consistent with other UC trials reported in similar populations.

Tulinercept (OPRX-106) for IBD

CLINICAL RESULTS FROM PHASE IIA

- 89% of patients experienced improvements in Mayo Score; 72% improved rectal bleeding; 72% improvement in fecal calprotectin and 61% improvement in Geboes score
- Well tolerated; adverse events (AEs) were mild to moderate and transient



- No systemic exposure of the drug was detected
- No anti-drug antibodies were detected

POSITIONING & UPSIDE

- Anti-TNF alfa mechanism – known and established first line treatment for steroid refractory and lack of response to 5-ASA
- Low likelihood for loss of response due to lack of immunogenicity
- Local activity in the gut and lack of systemic exposure translates to a better safety profile and removes safety concerns of infections and malignancy which appear in anti-TNF and JAK-inhibitors
- Oral therapy – convenience in-line with newer innovative therapies

Sources: Colombel. *Clinical and Translational Gastroenterology*. 2016; Ben Horin. *Alimentary Pharmacology and Therapeutics.* 2011; Remicade, Humira, Simponi, Entyvio, Xeljanz prescribing information.
1. 24 patients were enrolled, 6 patients withdrew, none related to adverse events. Drop out rate consistent with other UC trials reported in similar populations.

Alidornase alfa (PRX-110): Actin Inhibition Resistant DNase

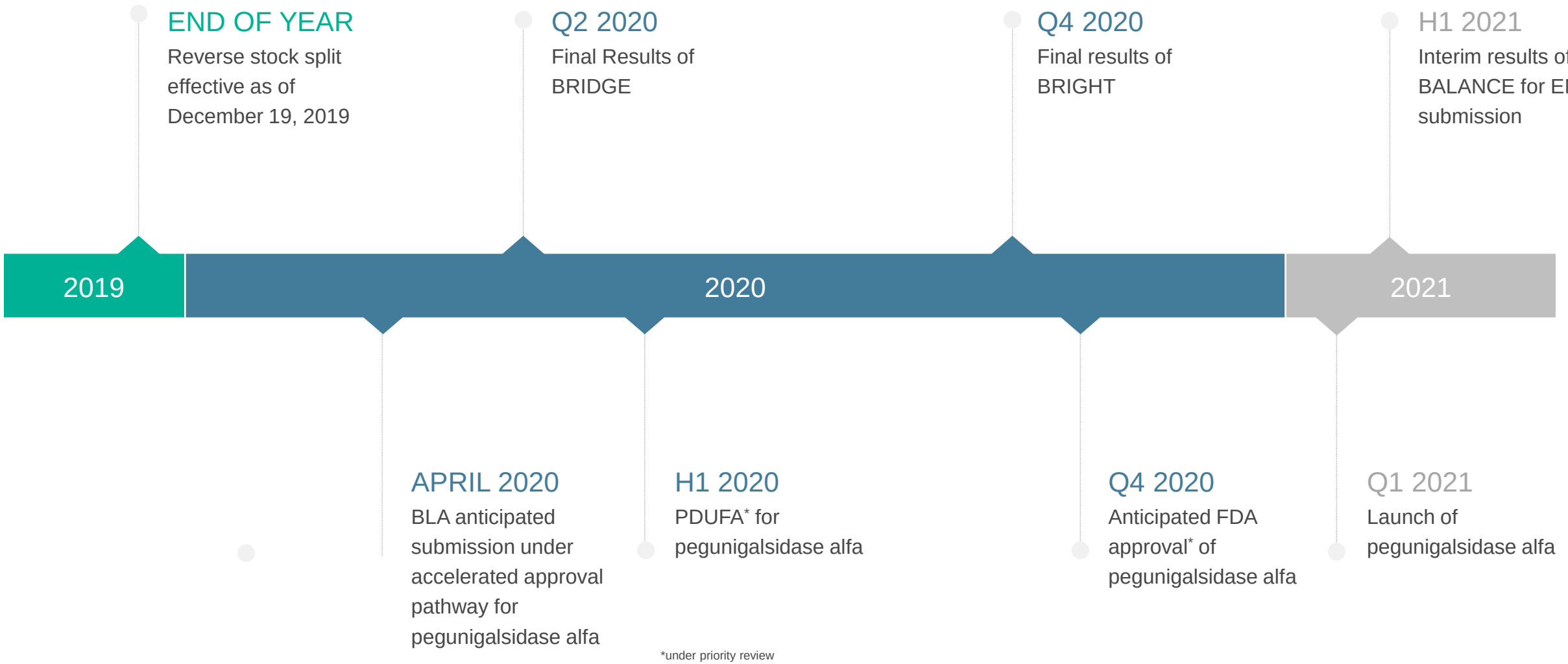
OVERVIEW

- Alidornase alfa is a plant cell expressed recombinant human DNase I chemically modified to resist inhibition by actin, thus enhancing enzymatic activity
- Recombinant human DNase I enzymatically cleaves DNA, yet its activity is inhibited by actin, which is present in the blood
- In vitro studies have shown that alidornase alfa has a highly improved catalytic efficiency and affinity to DNA, compared to DNase I, even more so in the presence of actin
- Alidornase alfa was previously tested in Cystic Fibrosis (CF) patients with phase IIa trial completed in 2018. Alidornase alfa was generally well tolerated in this clinical trial with no serious adverse events reported, and all adverse events that occurred during the study were mild and transient in nature
- In human sputa samples of CF patients, alidornase alfa exhibits greater activity compared to DNase I, without actin inhibition resistance, in breaking down extracellular DNA and lowering sputum viscosity

POSITIONING

- Biologically active and safe in humans, alidornase alfa is being developed for other indications where it might have a potential benefit
- Long acting DNase I is being developed for undisclosed indications

Protalix Upcoming Expected Milestones



*under priority review

Patent Summary

Patent Name / Int. App. No.	Global Pending Jurisdictions	Granted Jurisdictions	Nominal Expiry
Production of High Mannose Proteins in Plant Culture / PCT/ Il2004 / 000181	Brazil	Japan, Israel, Canada, Russian Federation, Mexico, India, Australia, South Africa, Republic of Korea, Singapore, Europe, Hong Kong, Ukraine, China, USA	2024(1)
Cell/Tissue Culturing Device, System and Method / PCT/ Il2005 / 000228	N.A.	Israel	2025
System and Method for Production of Antibodies in Plant Cell Culture / PCT/ Il2005 / 001075	N.A.	USA, Israel	2025
Mucosal or Enteral Administration of Biologically Active Macromolecules / PCT / Il2006 / 000832	N.A.	Europe, Israel	2026
Saccharide-containing Protein Conjugates and uses thereof / PCT / Il2008 / 001143	N.A.	USA	2028
Large Scale Disposable Bioreactor / PCT/ Il2008 / 000614	Brazil, [Europe], [Israel]	Australia, Canada, China, Europe, Hong Kong, India, Israel, Republic of Korea, Russian Federation, Singapore, South Africa, USA	2028(2)
Stabilized Alpha-galactosidase and uses thereof / PCT/ Il2011 / 000209	Brazil, India, Canada, [Israel]	South Africa, Russian Federation, Singapore, Israel, New Zealand, Republic of Korea, Australia, China, Japan, USA, Europe, Hong Kong	2031
Nucleic Acid Construct for Expression of Alpha-galactosidase in Plants and Plant Cells / PCT/ Il2011 / 000719	Brazil	India, China, Republic of Korea, Japan, Israel, Europe, Hong Kong, USA	2031

1. Patent granted in Australia expires in 2029
2. Patent granted in USA expires in 2032

Patent Summary

Patent Name / Int. App. No.	Global Pending Jurisdictions	Granted Jurisdictions	Nominal Expiry
Therapeutic Regimen for the Treatment of Fabry using Stabilized Alpha-galactosidase / PCT/ Il2018 / 050018	USA, Europe, Brazil, Japan, Canada, Australia, Chile, Israel, South Africa, Republic of Korea, China, New Zealand, Russian Federation, Mexico	N.A.	N.A.
Dry Powder Formulations of DNase 1 / PCT / Il2013 / 050094	N.A.	Israel, USA	2033
DNase I Polypeptides, Polynucleotides Encoding Same, Methods of Producing DNase I and uses thereof in Therapy / PCT / Il2013 / 050097	Israel, Brazil	Europe	2033
Inhalable Liquid Formulations of DNase I / PCT / Il2013 / 050096	N.A.	Israel, USA	2033
Modified DNase and uses thereof / PCT / Il2016 / 050003	USA, Europe, Canada, China, Australia, New Zealand, South Africa, Israel, Hong Kong	N.A.	N.A.
Chimeric Polypeptides, Polynucleotides Encoding Same, Cells Expressing Same and Methods of Producing Same / PCT / Il2014 / 050227	USA	N.A.	N.A.
TNF Alpha Inhibitor Polypeptides, Polynucleotides Encoding Same, Cells Expressing Same and Methods of Producing Same / PCT / IL2014 / 050228	China, Brazil, Canada, Israel, Europe, USA	Australia, Japan	2034
Use of Plant Cells Expressing a TNF Alpha Polypeptide Inhibitor in Therapy / PCT / IL2014 / 050231	Israel, China, Japan, Brazil, Canada	USA, Europe, Australia	2034
Chimeric Polypeptides, Polynucleotides Encoding Same, Cells Expressing Same And Methods of Producing Same / [PCT]	N.A.	USA	2035

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Regulatory	BLA Submission for Fabry disease anticipated by April 2020
Partnerships	Chiesi Pfizer FIOCRUZ FUNDAÇÃO OSWALDO CRUZ
Platform	Advantageous proprietary ProCellEx® platform for recombinant protein expression and cGMP manufacturing facility successfully inspected and audited by multiple regulatory agencies, including the US FDA and EMA
Management	Highly experienced management with proven track record

Note: cGMP = Current Good Manufacturing Practice.

Appendix

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PROTALIX Biotherapeutics

Inflammatory Bowel Disease Competitive Landscape

	In Development						
Treatment Type	**Anti-TNF Biologics (Oral)**	**Anti-TNF Biologics (Infused and Injected)**			**Anti-Integrin (Infused)**	**JAK inhibitors (Oral)**	**IL-12 (Infused)[1]**
Product	Oral anti-TNF-α **tulinercept (OPRX-106)***	Remicade® INFLIXIMAB	HUMIRA® adalimumab	Simponi® golimumab	Entyvio® vedolizumab	XELJANZ® [tofacitinib citrate] 5 mg tablets	Stelara® (ustekinumab)
Parent Company	PROTALIX Biotherapeutics	Johnson & Johnson	abbvie	Johnson & Johnson	Takeda	Pfizer	janssen
	PROPOSITION • Biologically active in the gut, leading to no systemic exposure which may potentially result in a better safety profile • Does not produce antibodies, potentially reducing risk of loss of response • Likelihood of being prescribed earlier in the disease cycle due to lower safety concerns and better convenience	• Loss of response – up to 40% of patients – most likely due to neutralizing antibodies • "Black Box" safety warnings			**Safety precautions** include: • Infections • Risk of PML (Progressive Multifocal Leukoencep-halopathy)	**"Black Box" Safety warnings**: • Infections • Malignancies	**Safety precautions** include: • Infections • Malignancies • Risk of RPLS

* OPRX-106 is an investigational product candidate not approved by the FDA.
Sources: FDA; ClinicalTrials.gov; Remicade, Humira, Simponi, Entyvio, Xeljanz prescribing information.
1. Stelara® can also be injected subcutaneously.

Overview of Product Portfolio

Protalix's pipeline of recombinant protein therapeutics provides the Company with significant potential near and long term cash flow generation, with potential upside from sales of alfataliglicerase in Brazil.

Revenue Generating	Indication	Stage in Process	Competitors	Market	Economics
elelyso® (taliglucerase alfa) for injection Plant based. People focused.®	**Gaucher Disease**	In market (since 2012)	• Cerezyme®, Sanofi • VPRIV®, Shire/Takeda • Cerdelga®, Sanofi • Zavesca , Actelion	**c. $1.5bn global market size**	• **Global (excl. Brazil)**: Pfizer retains 100% of revenue and reimburses 100% of direct costs • **Brazil**: Protalix maintains distribution rights through supply and technology transfer agreement with the Brazilian Ministry of Health
Pipeline	**Indication**	**Stage in Process**	**Competitors**	**Market**	**Economics**
pegunigalsidase alfa (PRX-102)	Fabry Disease	• Completed Phase I/II naïve patient study[1] • Phase III clinical trials – switch from competing treatments[1] – BALANCE (enrollment completed), Head-to-head superiority (1mg / kg 2 week) – BRIGHT (enrollment completed), safety and efficacy for monthly administration (2mg / kg 4 week) – BRIDGE (enrollment completed), safety and efficacy (1mg / kg 2 week)	• Fabrazyme®, Sanofi • Replagal®, Shire /Takeda (ex-US) • Galafold®, Amicus, Only applicable to certain amenable mutations	• c. $1.4bn global market (17.5k patients) • No competitor offering 4-week dosing regimen	• Milestone payments of up to c. $1.1bn (in aggregate) • Royalty on net sales of 15-35% (ex-US) / 15-40% (US) (subject to attaining certain sales thresholds)
tulinercept (OPRX-106)	Inflammatory Bowel Disease (IBD)	Completed phase IIa clinical trials in 2018	• Remicade®, J&J • Humira®, Abbvie • Simponi®, J&J • Entyvio®, Takeda • Xeljanz®, Pfizer • Stelara®, Jannsen • Others	• $12bn+ market with 2.5m patients across US and Europe • Non-systemic exposure may potentially provide product advantages • Oral delivery offers more favorable method of administration	In discussions with strategic partners
alidornase alfa (PRX-110)	TBD	• Completed phase IIa clinical trials in 2018 • Previously developed for CF, well tolerated and biologically active. To pursue other indications with unmet medical needs	TBD – dependent on indications pursued	TBD – dependent on indications pursued	n.a.

ProCellEx® System and Manufacturing Facility

cGMP-approved facility with proprietary manufacturing know-how paired with a materially lower sensitivity to environmental changes allows for a dynamic platform with flexibility in scale-up and production of more stable proteins

Regulatory Milestones

March 2010: Facility received a successful cGMP audit from Israeli Ministry of Health

June 2011: Facility passed Brazilian CMP audit

May 2012: Leveraging the ProCellEx® platform, **Elelyso® became the first plant derived protein to receive FDA approval**

January 2014: Health Canada conducted an on-site evaluation and recommended approval of the facility[1]

June 2017: US FDA approval received to convert facility from single-use to multi-product production facility

November 2019: Facility passed FDA cGMP audit

1. In relation to review of taliglucerase alfa (Elelyso®).

Vertical Expansion, rapid horizontal scale-up/down, as required

Per protein tailored modifications of products and candidates, leveraging unique genetic engineering tools and state of the art chemical modifications to produce, for example:

- Enzymes with a favorable circulatory half-life[2] potentially contributing to longer availability in the bloodstream to reach target organs together with potential reduced immunogenicity
- Controlled glycosylation pattern during protein expression without the need for further costly manipulations
- Changes in protein characteristics in accordance with specific unmet needs

2. In relation to PRX-102 (pegunigalsidase alfa)

Summary of IP / Main Patent Families

Protalix positions its intellectual property on the advantageous proprietary modifications of each individual protein product in addition to the unique properties that are derived from the use of the ProCellEx® plant cell culturing technology.

PRX-102 (pegunigalsidase alfa):

- Stabilized alpha-galactosidase and uses thereof (expiry: 2031). Composition of matter (alfa galactosidase with covalently linked monomers); process of production and methods of use
- Nucleic acid construct for expression of alpha-galactosidase in plants and plant cells (expiry: 2031)
- Therapeutic regimen for the treatment of Fabry using alpha-galactosidase (nominal expiry: 2038): Methods of use (2mg every 4 weeks)

PRX-110 (alidornase alfa):

- Modified DNase and uses thereof (expiry: 2036). Composition of matter, process of production and methods of use
- DNase I polypeptides, polynucleotides encoding same, Methods of producing DNase I and uses thereof in therapy (expiry: 2033); Inhalable liquid formulations (expiry: 2033); Dry powder formulations of DNase I (expiry: 2033)

PRX-100 (taliglucerase alfa):

- Production of high mannose proteins in plant culture (expiry: 2024): Composition of matter methods of production and methods of use

OPRX-106 (tulinercept):

- Anti-TNF (expiry: 2034). Family covers composition of matter (plant cells comprising OPRX-106) and method of use (oral delivery of the plant cells containing OPRX-106 for UC/IBD)
- Anti-TNF therapy (expiry: 2034); method of use (oral delivery of the plant cells containing OPRX-106 for liver disease; joint with Hadasit and under license)

ProCellEx® Platform:

- Large scale disposable bioreactor (expiry: 2028). Covers the device (disposable device for culturing and harvesting plant tissue; having a volume of at least 400L; without an impeller); methods for culturing plant cells in the device and plant cell culturing system comprising cells and the device

Note: “Expiry” refers to nominal expiry date of patents originating from this family.