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): January 4, 2019

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 Snunit Street **Science Park, POB 455** **Carmiel, Israel** **(Address of principal executive offices)**	**20100** **(Zip Code)**

Registrant's telephone number, including area code +972-4-988-9488

(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))

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 2.02. Results of Operations and Financial Condition

On January 4, 2019, Protalix BioTherapeutics, Inc. (the "Company") released its January 2019 Corporate Update which includes certain financial information for the fiscal year ended December 31, 2018. A copy of the update will be posted in the Presentations page of the Investors tab of the Company's corporate website and is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

All of the information furnished in Item 2.02 and 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 7.01. Regulation FD Disclosure

The information set forth in Item 2.02 of this Current Report on Form 8-K is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	January 2019 Corporate Update.

SIGNATURES

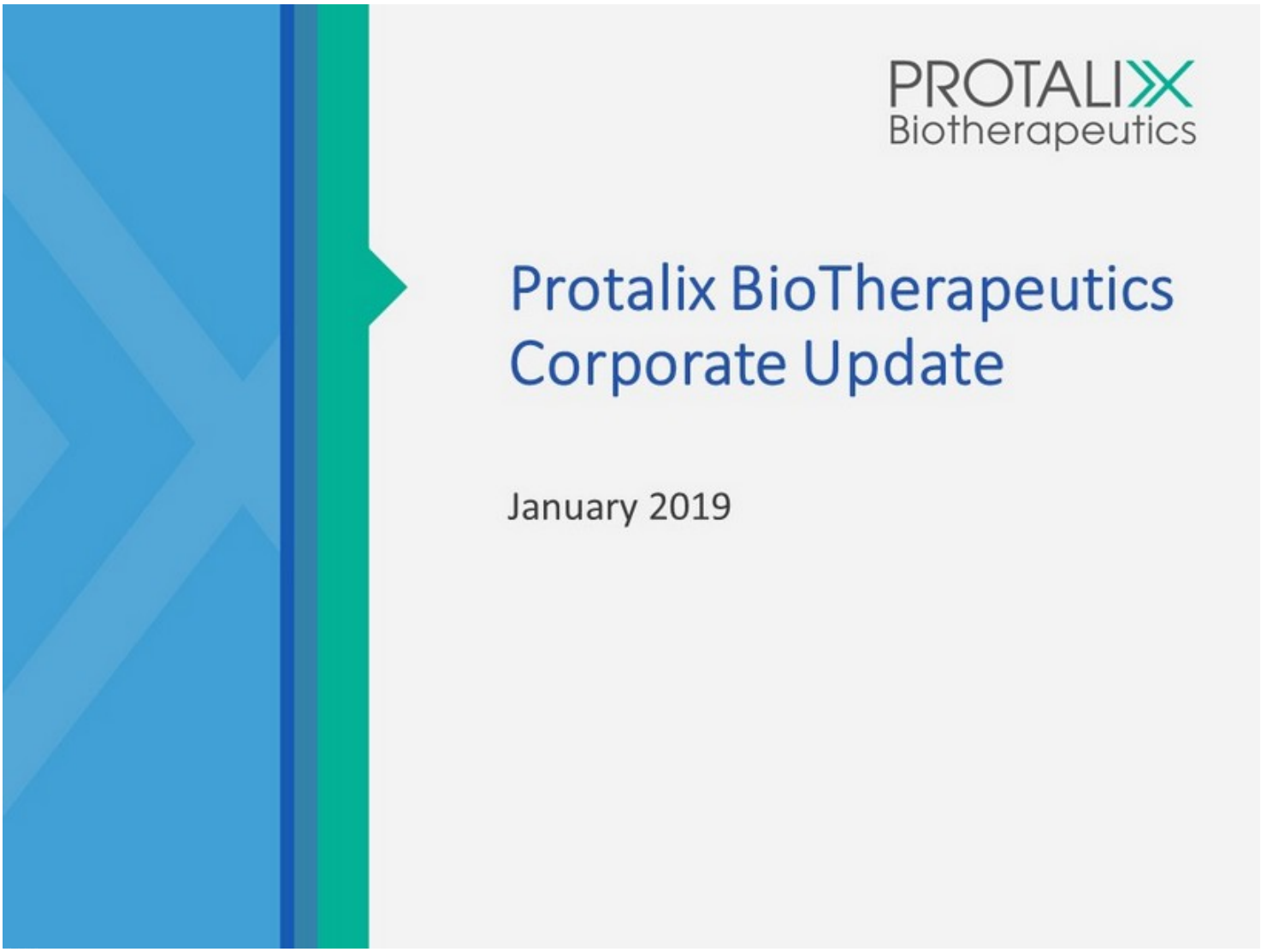
Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 4, 2019

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Moshe Manor
Name: Moshe Manor
Title: President and
Chief Executive Officer

Exhibit 99.1


PROTALIX
Biotherapeutics
Protalix BioTherapeutics
Corporate Update
January 2019

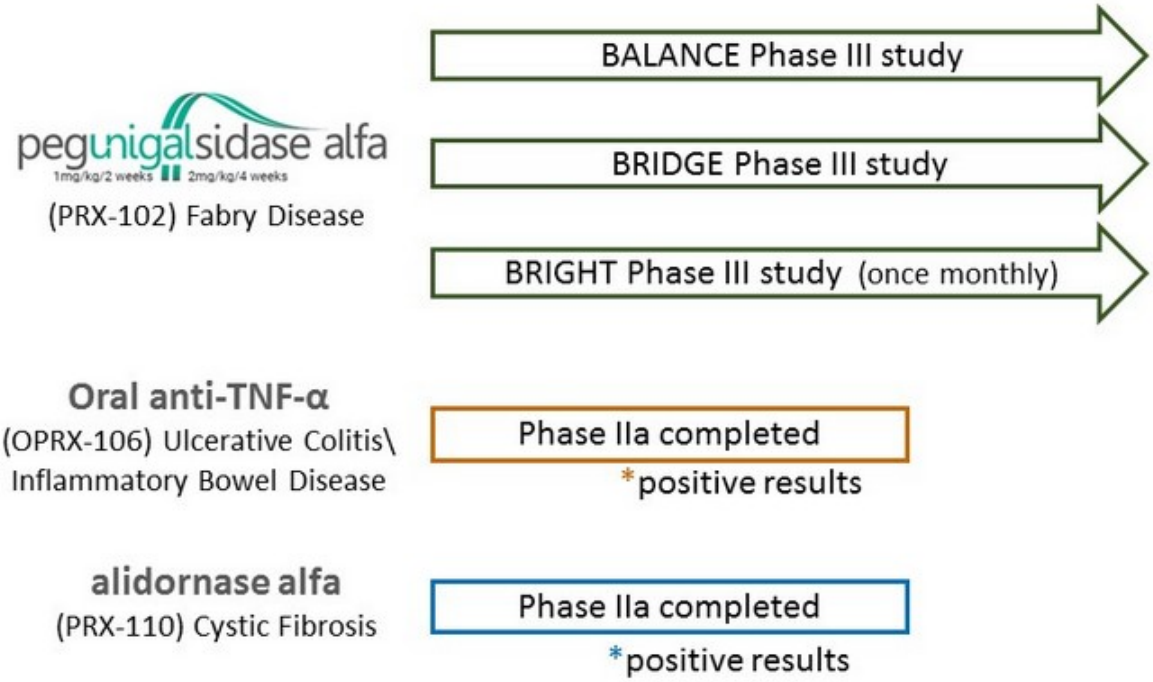
Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, 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: failure or delay in the commencement or completion of the Company's preclinical 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 monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow the Company's clinical protocols; and lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of the Company's product candidates will not support the Company's claims of superiority, 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 our ability to manage our relationship with Chiesi Farmaceutici S.p.A. and any other collaborator, distributor or partner; risks related to the amount and sufficiency of the Company's cash and cash equivalents; risks related to the amount of the Company's future revenues, operations and expenditures; risks relating to the Company's ability to make scheduled payments of the principal of, to pay interest on or to refinance its outstanding notes or any other indebtedness; 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; delays in the approval or potential rejection of any applications we file with the FDA or other health regulatory authorities, and other risks relating to the review process; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies and 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.

Company highlights

- Clinically differentiated and improved recombinant therapeutic proteins
  - FDA approved ProCellEx® plant cell culture based expression system
  - FDA multi-product and EMA approved manufacturing facility in Israel
- Elelyso® (taliglucerase alfa) approved and commercialized for Gaucher disease; Protalix retains rights in Brazil, with rights in the rest of the world held by Pfizer
- Pegunigalsidase alfa in Phase III for Fabry disease, an ~$1.4B growing market; potential to be best-in-class with a superiority claim:
  - Global license to Chiesi Farmaceutici S.p.A.
  - Fast Track Designation - FDA
  - Orphan Drug Designation (ODD) – EMA
- Two Phase II candidates with business development opportunities

Protalix pipeline overview



PROTALIX Biotherapeutics

pegunigalsidase alfa

1mg/kg/2 weeks || 2mg/kg/4 weeks

for Fabry Disease

Fabry disease remains a high unmet need

- Rare genetic lysosomal storage disorder caused by enzyme deficiency; potentially life threatening disease characterized by progressive kidney disease, cardiovascular and cerebrovascular complications and severe pain
- ~$1.4B growing market (CAGR ~10%); ~5,000 patients treated worldwide

Enzyme Replacement Therapy (ERT) Bi-weekly infusions		Pharmacological Chaperone- Oral
Fabrazyme®, Sanofi	Replagal®, Shire (ex-US)	Galafold™, Amicus

• **Renal function declines even for patients on long term ERT[1]**
• **Limited effect due to:[2,3]**
  • Little functional enzyme and incomplete tissue penetration
  • Presence of anti-drug antibodies, mainly neutralizing antibodies
• **Poor Quality of Life:**
  • Lack of symptom relief on the second week
  • Infusion reactions
  • High burden of treatment
		Applicable only for certain amenable mutations (~30%)

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

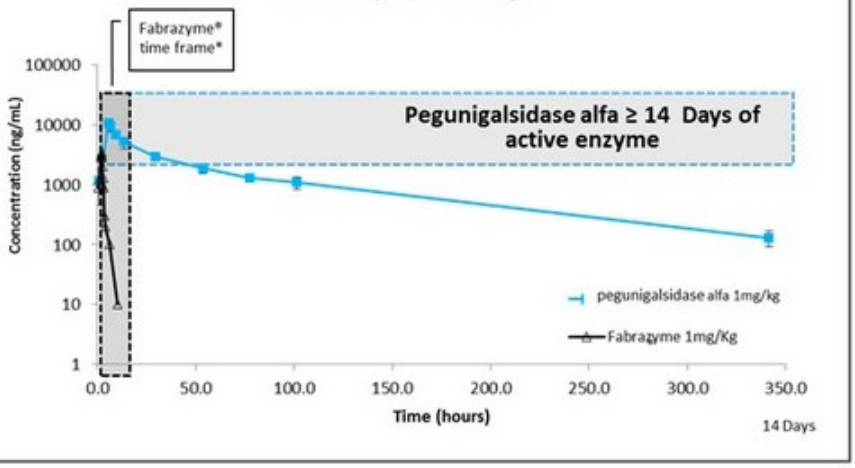
PROTALIX Biotherapeutics

pegunigalsidase alfa
1mg/kg/2 weeks 2mg/kg/4 weeks

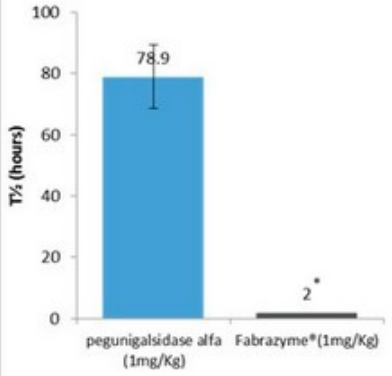
Substantially greater enzyme exposure than current ERTs

A chemically modified plant cell derived PEGylated covalently bound homodimer
→ active and stable enzyme throughout infusion interval

Higher levels of pegunigalsidase alfa in the blood at day 14 than Fabrazyme® at day 1



Half-life 40 times greater than Fabrazyme®



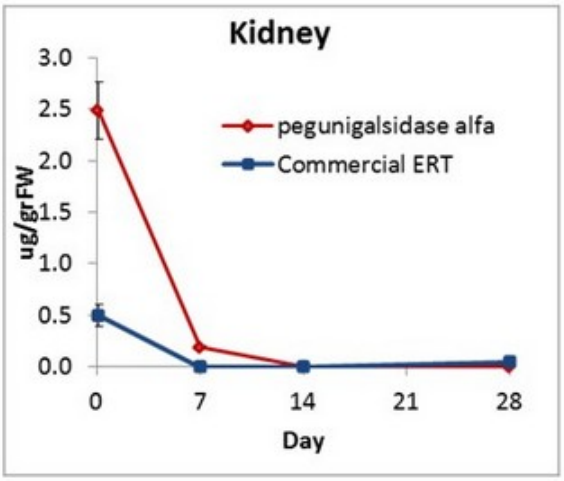
Higher levels of active available enzyme → potentially more efficacious

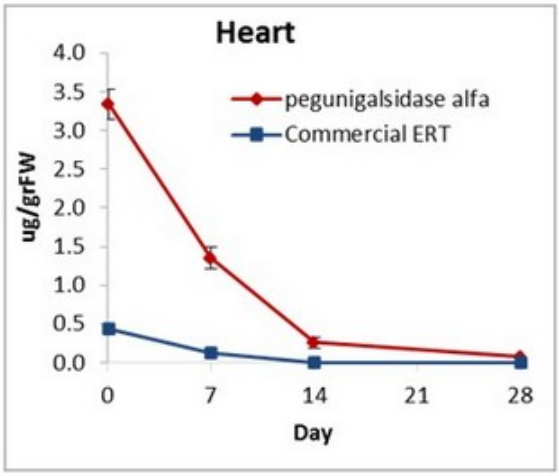
* Fabrazyme® (agalsidase beta) – USPI

PROTALIX Biotherapeutics

pegunigalsidase alfa

Higher uptake and prolonged activity in target organs





Fabry mice model

Higher levels of active enzyme in target organs → potentially more efficacious

µg/gr FW = amount of enzyme [µg] per gr of tissue fresh weight [FW], assessed by activity

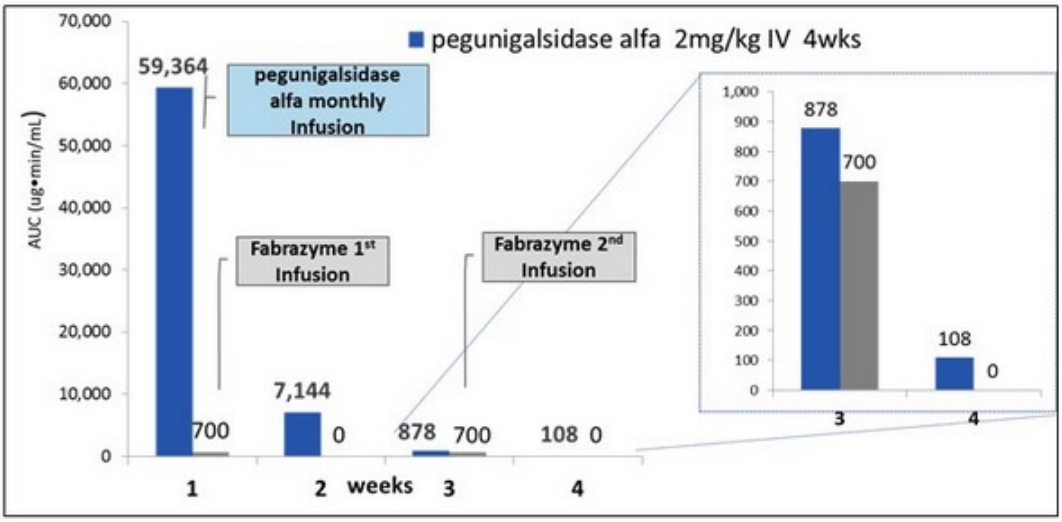
Kizhner et al (2015), Molecular Genetics and Metabolism 114: 259–267

PROTALIX Biotherapeutics

pegunigalsidase alfa

First-in-class, once-monthly administration

PK modeling shows greater AUC in a single infusion of 2 mg/kg pegunigalsidase alfa vs. two bi-weekly infusions of Fabrazyme® over a 4-week time frame.



Greater AUC → potential for clinical stability with half the infusions

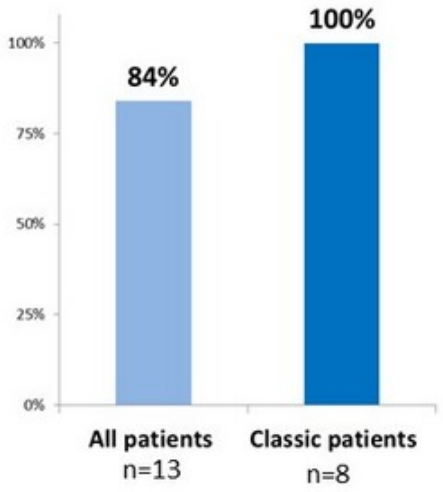
PROTALIX Biotherapeutics

pegunigalsidase alfa
1mg/kg/2 weeks || 2mg/kg/4 weeks

Positive results from completed phase I/II study

Reduction in GB_3 burden in kidney biopsies

% of patients with ≥50% reduction in BLISS score



Efficacy & safety seen over 24 months

- ☑ Positive impact on kidney function
- ☑ Stable cardiac parameters
- ☑ Improvement in gastro-intestinal symptoms
- ☑ 19% formation of anti-drug antibodies (ADAs) vs. 74% s with Fabrazyme®*
  - ➢ All pegunigalsidase alfa patients were ADA negative in year 2
- ☑ Excellent safety and tolerability profile throughout ~35 patient years
  - ➢ Patients currently in their 4th year of treatment

*Fabrazyme prescribing information

PROTALIX Biotherapeutics

pegunigalsidase alfa

Robust phase III pivotal clinical program

	balance	bright	bridge
	1mg/kg 2 weeks Head-to -Head vs. Fabrazyme® in Switch Patients	**2mg/kg 4weeks** Switch-over from Fabrazyme® and Replagal®	**1mg/kg 2 weeks** Switch-over from Replagal®
FDA*	24 mos Superiority	12 mos Safety and efficacy	12 mos Safety and efficacy
EMA Rest of World	12 mos Comparability (potential for superiority)	12 mos Safety and efficacy	12 mos Safety and efficacy
Number of patients to be enrolled	78 (52 pegunigalsidase alfa 26 Fabrazyme) ~70% enrolled	30 ~95% enrolled	22 Enrollment completed

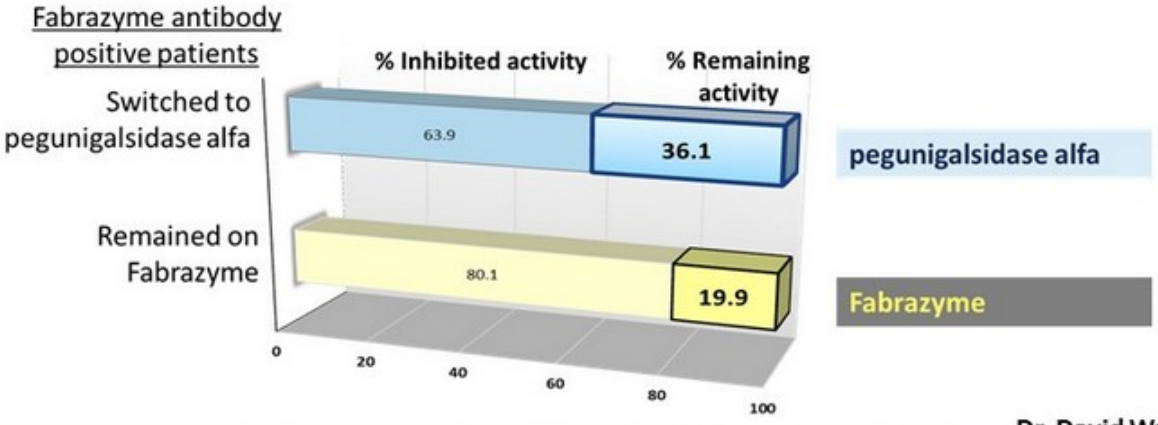
* Based on recent FDA guidelines, there may be a faster path for BLA filing.
A meeting with the agency is planned for first quarter 2019.

pegunigalsidase alfa
balance

Twice the enzyme activity for antibody positive Fabrazyme patients if switched to pegunigalsidase alfa

Substantially less inhibited by Fabrazyme neutralizing antibodies (nAbs)

Analysis of baseline characteristics of the BALANCE study: Ex-vivo immunogenicity testing of blood samples:



"Given pegunigalsidase alfa is less inhibited by preexisting neutralizing antibodies than Fabrazyme, coupled with its significantly longer half-life, **there is the potential for pegunigalsidase alfa to control proteinuria and/or stabilize renal function in patients who have not had an optimal clinical response to agalsidase beta (Fabrazyme)"**

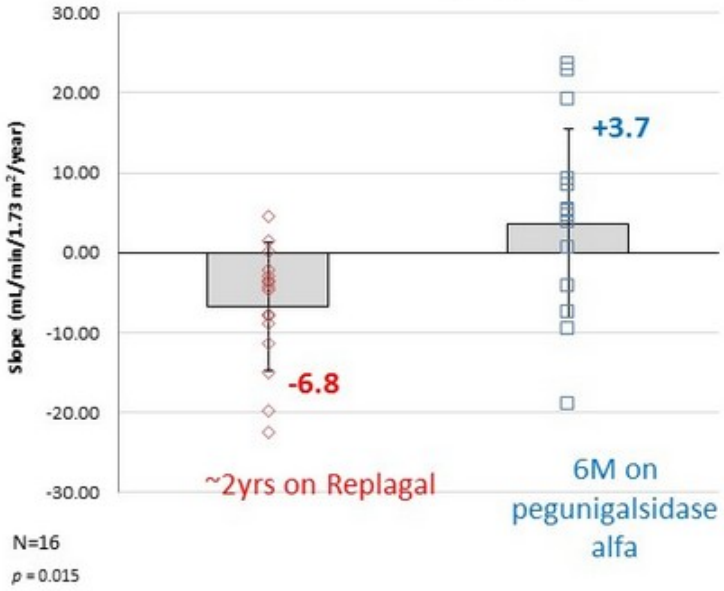
Dr. David Warnock, Director of the Division of Nephrology , Professor of Medicine & Physiology, Univ. of Alabama Birmingham

PROTALIX Biotherapeutics

pegunigalsidase alfa
1mg/kg/2 weeks 2mg/kg/4 weeks
bridge

Preliminary results of BRIDGE study: Improved kidney function following switch to pegunigalsidase alfa

Mean annualized eGFR slopes "pre" vs. "post" switch to treatment with pegunigalsidase alfa



N=16

$p = 0.015$

Based on available historical serum creatinine for approximately 2 years

eGFR mL/min/1.73 m^2 is calculated using CKD-EPI formula

eGFR Slope - mL/min/1.73 m^2/year

$eGFR_{CKD-EPI}$- Mean BL (range): 80 (49-100)

PROTALIX Biotherapeutics

pegunigalsidase alfa

Evidence for potential superiority

Phase I/II - Naïve

24 month follow-up

	pegunigalsidase alfa	Fabrazyme®
eGFR slope	-2.2[1]	-3.8
Half-life	~80 hours	2 hours
Active enzyme	>14 days	½ day
Antibodies (ADA)	0%[3]	74%[2]

1. N=7 classic Fabry patients, 24 months
2. Fabrazyme prescribing information
3. 19% formation of anti-drug antibodies (ADAs). All ADAs turned negative in the second year following treatment, leaving 0% of present anti-drug antibodies

Phase III - Switch: Preliminary Results

bridge

Improved kidney function with pegunigalsidase alfa

Negative eGFR slope **reversed** to positive eGFR slope following switch from Replagal

balance

Twice the enzymatic activity with pegunigalsidase alfa

Less inhibited from Fabrazyme neutralizing ADA following switch from Fabrazyme

pegunigalsidase alfa
1mg/kg/2 weeks || 2mg/kg/4 weeks

Potential to be gold standard therapy

Peak Sales Potential over $1B Annually (>50% market share)

› Unique proposition for addressing significant unmet needs

Two dosing regimens: potential for better efficacy and lower treatment burden

1mg/kg/2weeks	2mg/kg/4weeks
Superior ERT for patients with progressing impaired renal function	**Better** quality of life by maintaining clinical stability with 50% less infusions

- ✓ Treatment flexibility for patients
- ✓ Two independent paths for product superiority

pegunigalsidase alfa
1mg/kg/2 weeks || 2mg/kg/4 weeks

Global partnership with Chiesi Farmaceutici S.p.A

Ex-US partnership now expanded to include exclusive rights in the United States

The combined two agreements reflect:

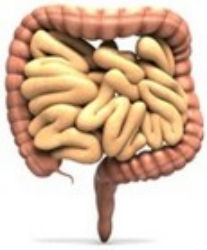
- Investment of $95M in upfront payments and development cost reimbursement
- Up to $1 billion in potential milestone payments
- Tiered royalties of 15-35% ex-US; 15-40% US

- Validates Protalix's Fabry program
- Secures funding for clinical program
- A focused and effective commercialization partner

PROTALIX Biotherapeutics

Oral anti-TNF-α OPRX-106

for Inflammatory Bowel Disease



Inflammatory Bowel Disease (IBD) – High unmet need despite the wide array of available treatments

- IBD are autoimmune inflammatory diseases of the digestive tract including Ulcerative Colitis (UC) and Crohn's Disease (CD); debilitating disease characterized by severe diarrhea, abdominal pain, fatigue and weight loss
- >$12B market; >2.5 million patients across US and Europe

Anti TNF biologics (infused and injected)			Anti-Integrin (Infused)	JAK inhibitors (oral)	IL-12 (infused)
Remicade (J&J)	Humira (Abbvie)	Simponi (J&J)	Entyvio (Takeda)	Xeljanz (Pfizer)	Stelara (Jannsen)
Loss of response - up to 40% of patients - most likely attributed to neutralizing antibodies **"Black Box" Safety warnings** Infections and Malignancies			**Safety precautions** include infections and risk of PML (Progressive Multifocal Leukoencephalopathy)	**"Black Box" Safety warnings** Infections and Malignancies	**Safety precautions** include infections, malignancies and risk of RPLS (Reversible Posterior Leukoencephalopathy Syndrome)

OPRX-106

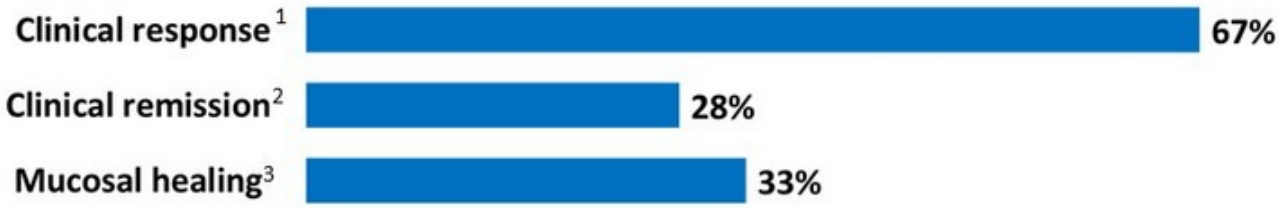
A plant cell expressed anti –TNF- α fusion protein administered orally with local activity in the gut

- Developed via Protalix's platform for orally delivered proteins whereby the plant cell wall protects the protein and serves as a natural oral administration vehicle
- Administered orally, OPRX-106 is biologically active in the gut
- OPRX-106 completed two clinical trials in Ulcerative Colitis:
  - Phase I – Healthy Volunteers: Safe and well tolerated
  - Phase IIa: Positive results from 18 patients who completed the study*
    - Two doses explored for induction of remission by week 8
    - 89% of patients had a Mayo score of ≥6 (moderate disease category)

*24 patients were enrolled, 6 patients withdrew, none related to adverse events. Drop out rate consistent with other UC trials reported in similar populations.

OPRX-106

Positive clinical results in 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
- Safe and 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

1. Reduced Mayo score of >3 points and decrease in the rectal bleeding sub-score of >1 point from baseline, or a rectal bleeding sub-score of 0 or 1
2. Mayo score of ≤ 2 with no sub-score reaching >1 point
3. Mayo endoscopy score of 0 or 1

PROTALIX Biotherapeutics

OPRX-106

Oral anti-TNF-α biologically locally active in the gut

- Inflammatory Bowel Disease market >$12B
- High clinical response and remission rates and meaningful mucosal healing in Ulcerative Colitis patients with moderate disease

OPRX-106 Advantages

- 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 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

PROTALIX Biotherapeutics

alidornase alfa

(PRX-110)

for Cystic Fibrosis

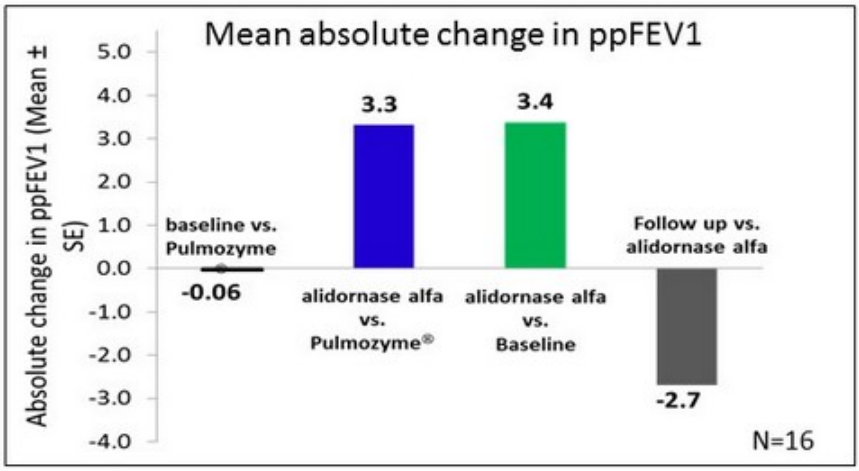
alidornase alfa (PRX-110)

More effective mucus clearance for Cystic Fibrosis patients

- Cystic Fibrosis (CF) is a rare genetic disease characterized by a highly viscous mucus most prominently leading to severe lung damage and loss of respiratory function; over 70,000 CF patients world-wide
- Leading product, Pulmozyme®, DNase enzyme, ~$700M annual sales with significant growth potential
- Alidornase alfa (PRX-110) was designed as a recombinant DNase resistant to actin inhibition to enhance enzyme activity
- In human sputa samples, alidornase alfa exhibits superior activity compared to Pulmozyme® in breaking down extracellular DNA and lowering sputum viscosity which translates to more effective mucociliary clearance and potentially improving lung function
- Can potentially lower incidence of respiratory tract infections

alidornase alfa (PRX-110)

Phase II trial demonstrates clinically meaningful lung function improvement



- Pulmozyme treated patients following 14-day washout
- 28-day alidornase alfa treatment
- 14-day follow-up without treatment

- Extraordinary reduction of the presence of Pseudomonas aeruginosa (P.sa) infections as a result of alidornase alfa treatment - All P.sa positive patients showed a >75% reduction of which 60% experienced **total** eradication
  - potential for lowering respiratory tract infections
  - potential for reduction in CF exacerbations
- Safe, tolerable and shorter inhalation time

Financial Overview

- ~148M shares outstanding as of December 31, 2018
- Dual listed on NYSE American and TASE
- Cash position: ~$37.5M as of December 31, 2018
- Cash level projected to fund operations through read outs of all Fabry trials and potential major regulatory milestones
- ~$58M convertible note due by November 2021 ($0.85 strike)
- 10 years of 0% tax after using up NOL (currently ~$190M)

Protalix had significant achievements to date

- ✓ Strong positive two-year data for pegunigalsidase alfa and positive interim data from the BRIDGE study (Phase III) reversing eGFR slope after switch to pegunigalsidase alfa
- ✓ Global partnership for pegunigalsidase alfa with significant upfront, R&D investment, and regulatory and commercial milestones
- ✓ Promising results for OPRX-106 and alidornase alfa
- ✓ Clinical development pipeline targeting markets of ~$15B

and multiple near term catalysts expected in the next 12 months

- Finalize enrollment in BALANCE and BRIGHT studies
- Engage with the FDA to explore the potential of gaining accelerated approval path with pegunigalsidase alfa
- Continue seeking and signing partnership transactions
- Advance early pipeline with attractive opportunities for proteins designed with superior clinical profiles

PROTALIX Biotherapeutics

Thank You

Moshe Manor
President and CEO
Protalix BioTherapeutics
moshe.manor@protalix.com