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): March 21, 2018

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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communication 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 7.01. Regulation FD Disclosure

On March 21, 2018, the Company posted a copy of its March 2018 Corporate Update in the Presentations page of the Investors tab of its corporate website. A copy of the corporate update is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

All of the information furnished in this Item 7.01 and in Exhibit 99.1 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	March 2018 Corporate Update.

SIGNATURES

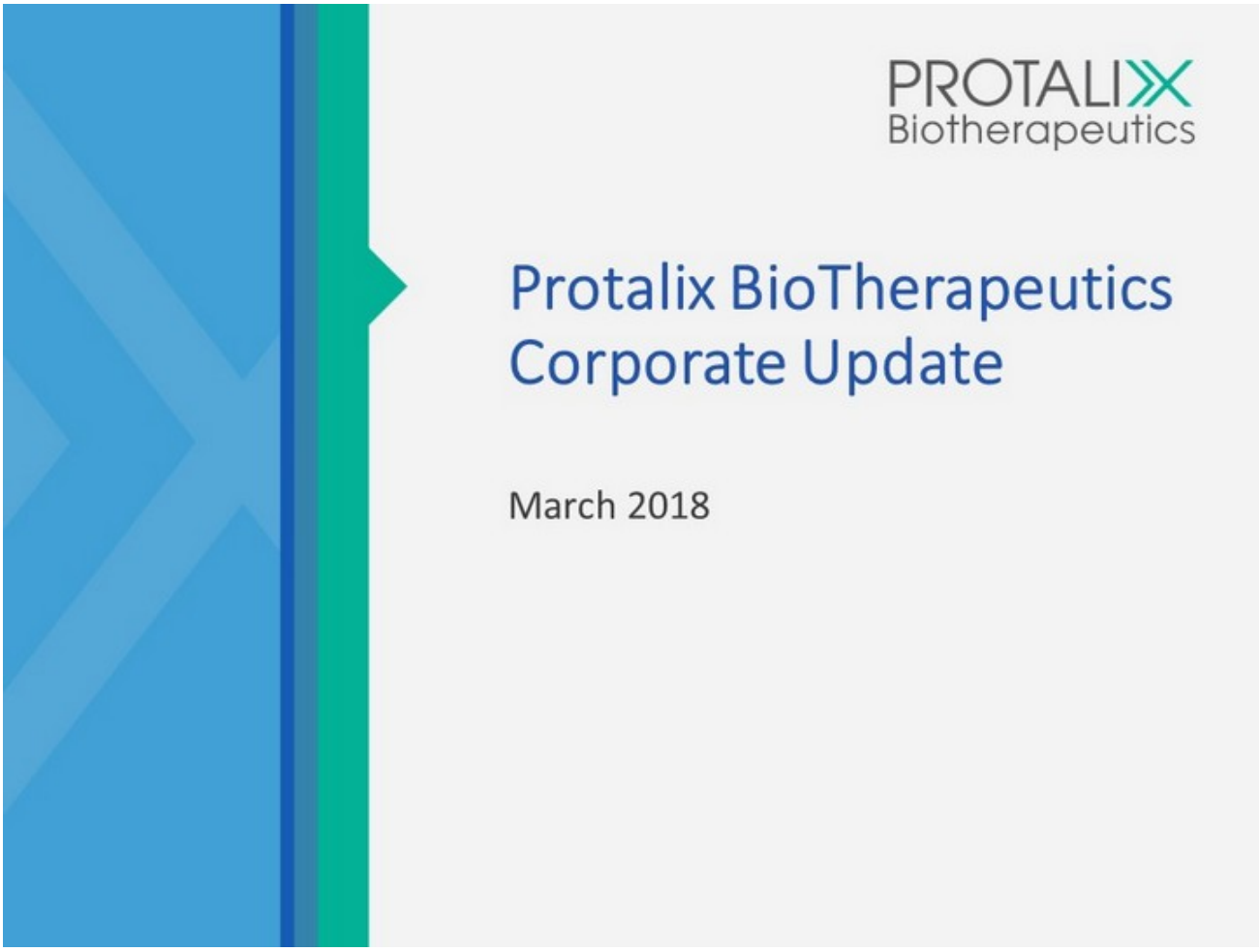
Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 21, 2018

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Yossi Maimon
Name: Yossi Maimon
Title: Vice President and
Chief Financial Officer

Exhibit 99.1


PROTALIX
Biotherapeutics
Protalix BioTherapeutics
Corporate Update
March 2018

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 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-based expression system
  - FDA multi-product and EMA approved manufacturing facility in Israel
- Pegunigalsidase alfa in Phase III for Fabry disease ~$1.4B growing market; potential to be best-in-class with a superiority claim:
  - Ex -US license to Chiesi
  - Fast Track Designation -FDA
  - Orphan Drug Designation (ODD) –EMA
- Two Phase II candidates with business development opportunities
- 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.

Corporate Strategy

- **Execution** of Phase III Fabry clinical trial program and key data read-outs and potential global approvals
- **Focus on additional partnering** opportunities for assets in development
- **Generate revenue** through sales of alfataliglicerase in Brazil
- **Advancement** of early pipeline products into clinical development

Pipeline Overview

pegunigalsidase alfa
(PRX -102) Fabry Disease

alidornase alfa
(PRX -110) Cystic Fibrosis

Oral anti-TNF-α
(OPRX-106) Ulcerative Colitis/ Inflammatory Bowel Disease

PROTALIX Biotherapeutics

pegunigalsidase alfa

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

for Fabry Disease

Fabry disease

- Rare genetic lysosomal storage disorder caused by deficiency in the enzyme α-galactosidase A. Lipids accumulate in key organs (kidney, heart, CNS) leading to a progressive and potentially life threatening disease.
- Disease characterized by:
  - Progressive kidney disease which can lead dialysis or transplant
  - Cardiovascular and cerebrovascular complications
  - Severe symptomology including pain, abdominal discomfort and poor quality of life
- ~$1.4B growing market (CAGR ~10%); ~5,000 patients treated worldwide.

Key Players

Fabrazyme®, Sanofi	Enzyme Replacement Therapy (ERT) bi-weekly infusions	• Approved Worldwide
Replagal®, Shire		• Approved ex-US only
Galafold™, Amicus	pharmacological chaperone	• Applicable only for patients with amenable mutations (~30%)

Fabry disease remains a high unmet need - Learnings:

Treating Physicians

- **Limited effect of ERT** due to:
  - Little functional enzyme every second week and incomplete tissue penetration of the infused protein[1]
  - Presence of antibodies to infused enzyme[1]
  - Renal function continues to decline even for patients on long term ERT[2]

Patients

- Lack of symptom relief on the second week
- Infusion reactions
- High burden of treatment with bi-weekly infusions

FDA

- Current product approved conditionally based on non-established surrogate markers
- Evidence based improvement in clinical parameters has not been established to date

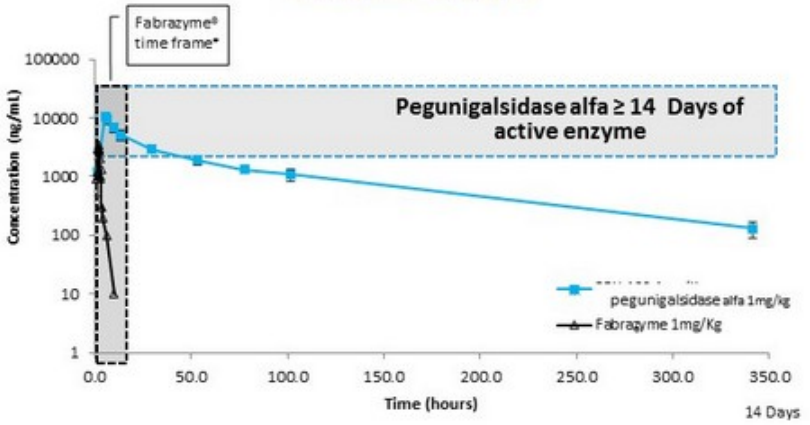
1. Fabry Expert Panel Consensus: Kidney Disease: Improving Global Outcomes (KDIGO) Conference, Oct 2016
2. Rombach, et al 2013

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

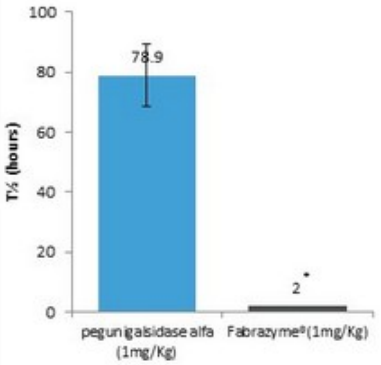
Substantially greater enzyme exposure than current ERTs

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

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



Half life 40 times greater than Fabrazyme®

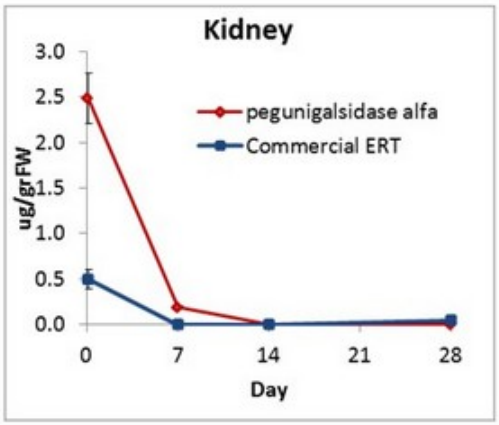


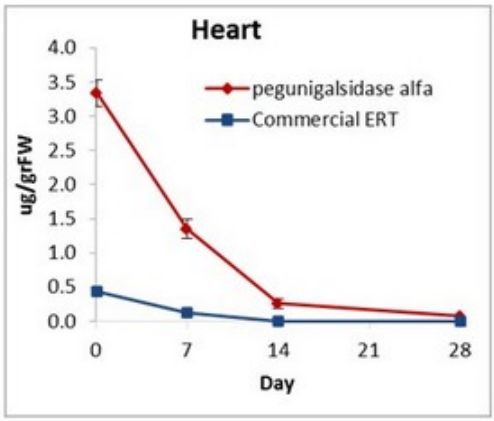
Higher levels of active available enzyme → potentially more efficacious

PROTALIX Biotherapeutics

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

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

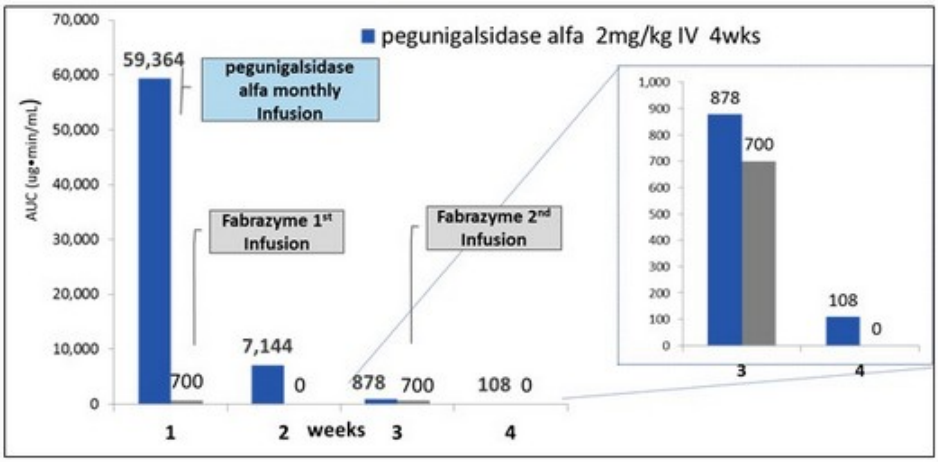
Kizhner T. et al (2015), A- Molecular Genetics and Metabolism 114: 259–267

PROTALIX Biotherapeutics

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

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

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

Efficacy & safety seen over 24 months

- ☑ Positive impact on kidney function

	Pegunigalsidase alfa (eGFR BL 82.4-156.3)	Fabrazyme® (eGFR BL 49-170) [2]
eGFR slope[1]	-2.2*	-3.8

- ☑ Stable cardiac parameters
- ☑ Improvement in gastro-intestinal symptoms
- ☑ Excellent safety and tolerability profile throughout ~35 patient years
- ☑ 19% formation of anti-drug antibodies (ADAs) in pegunigalsidase alfa with all negative in the second year vs. 74% ADAs with Fabrazyme®

*n=7 classic Fabry patients

1. eGFR = estimated Glomerular Filtration Rate. Measured as annualized rate of Estimated GFR Change (mL/min/1.73 m^2/year) – 24 months
2. Germain et al 2015

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

Clinical advantages recognized by regulatory bodies

- Orphan Drug Designation (ODD) granted by European Commission for significant and plausible clinical advantages compared to authorized therapies
  - Clinical data demonstrating the stabilization of kidney function
  - Reduced immunogenicity and peripheral neuropathy
  - Reduced accumulation of toxic metabolites in relevant tissues

EMA

- Fast Track Designation granted by FDA
  - Acknowledgement of potential to address unmet medical needs such as prevention of renal failure and better quality of life
  - Eligibility for accelerated approval and priority review

FDA

PROTALIX Biotherapeutics

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

Ex-US exclusive collaboration with Chiesi Farmaceutici S.p.A.

- Chiesi, an international privately-held company, strong presence outside US, with focus on the development and commercialization of innovative medicines
- In exchange for ex-US commercialization rights for pegunigalsidase alfa:
  - Upfront payment of $25 million and additional payments of up to $25 million in development costs
  - Eligibility for an aggregate of $320 million in regulatory and commercial milestone payments as well as tiered royalties ranging from 15% to 35%
- Protalix remains the manufacturer for clinical development and commercial product.

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

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

Robust phase III pivotal clinical program

	balance **1mg/kg 2 weeks** Head to Head vs. Fabrazyme® in Switch Patients	bright **2mg/kg 4weeks** Switch-over from Fabrazyme® and Replagal®	bridge **1mg/kg 2 weeks** Switch-over from Replagal®
FDA	24 mos Superiority	12 mos Safety and efficacy	12 mos Supportive
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+26)	30	22

Enrollment expected to be finalized in 2018

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)

1 mg/kg /2 weeks
Potential superiority in efficacy

	Fabrazyme®	pegunigalsidase alfa
eGFR slope	-3.8	-2.2*
Half life	2 hours	~80 hours
Active enzyme	½ day	>14 days
Antibody presence	74%	0%**

Once monthly 2 mg/kg
50% less infusions

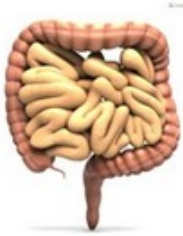
↓

- One month of active enzyme
- Clinical efficacy maintained
- Enhanced quality of life
- Lower treatment burden

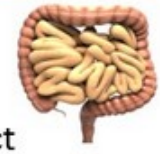
*N=7 classic Fabry patients , 24 months
**19% formation of anti-drug antibodies (ADAs)/ All ADAs turned negative in the second year following treatment, leaving 0% of present anti-drug antibodies

PROTALIX Biotherapeutics

Oral anti-TNF-α OPRX-106 for Inflammatory Bowel Disease

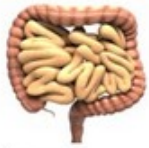


Inflammatory Bowel Disease (IBD)



- IBD are autoimmune inflammatory diseases of the digestive tract including Ulcerative Colitis (UC) and Crohn's Disease (CD)
  - Debilitating: severe diarrhea, abdominal pain, fatigue and weight loss
  - Affects > 2.5 million people across US and Europe
- UC market ~ $5.5B; CD market ~ $3.0B
- Key players include:
  - Infused or injectable anti-TNFα : Remicade (J&J), Humira (Abbvie), Simponi (J&J)
  - Infused Anti-Integrin: Entyvio (Takeda)
  - Infused IL-12, Oral JaK inhibitor – in development

Inflammatory Bowel Disease remains an area of high unmet need



Despite the wide array of available treatments, there are major drawbacks:

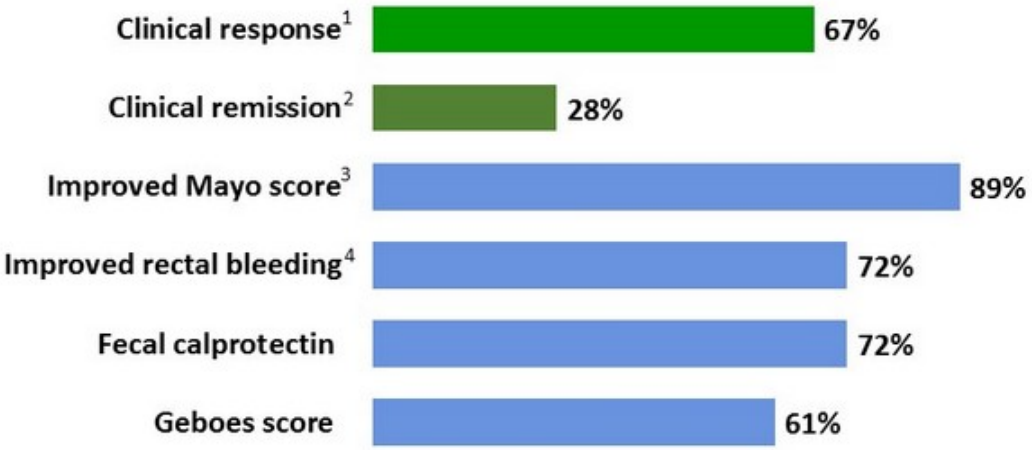
- Loss of response to anti –TNF α drugs
  - Clinical efficacy is lost in ~25-45% of all patients who were primary responders
  - Most likely attributed to the high level of neutralizing antibodies
- Safety risks
  - Black box warnings for serious infections and malignancy for anti-TNF-α and Jak –Inhibitors
  - Precaution for risk of Progressive Multifocal Leukoencephalopathy (PML) in integrin inhibitors
  - Precautions for serious infections and malignancy for anti –IL 12 drugs

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 with no anti-drug antibody formation and without systemic absorption. This can potentially result in:
  - A safe therapy
  - Long term response
- OPRX-106 completed 2 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



- Safe and well-tolerated. Adverse events (AEs) were mild to moderate and transient
- **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. Any improvement in Mayo Score
4. Rectal bleeding sub-score = 0 or 1 point

OPRX-106

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

- Inflammatory Bowel Disease market >$8.0B
- High clinical response and remission rates in patients with moderate disease
- No formation of anti-drug antibodies
- No systemic absorption
- Will potentially not carry the safety risks of current therapies.
- Overcomes the drawbacks of injected or infused anti-TNF-α while demonstrating good clinical results via the proven mechanism of TNF alfa blockage

PROTALIX Biotherapeutics

alidornase alfa

(PRX-110)

for Cystic Fibrosis

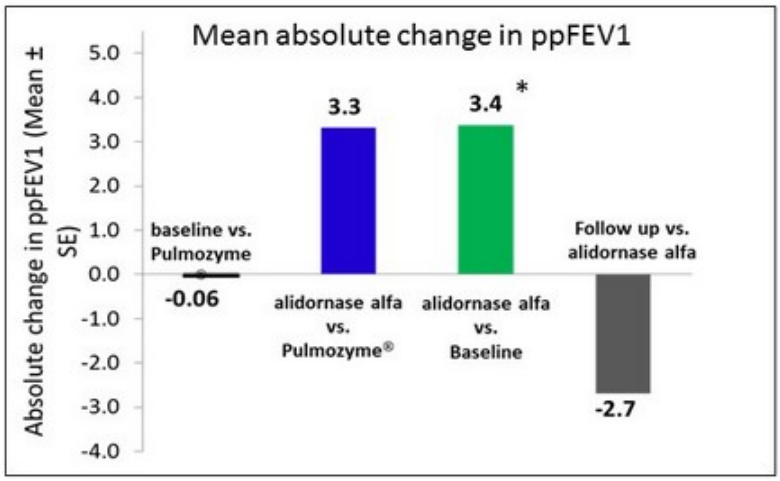
alidornase alfa
(PRX-110)

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 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



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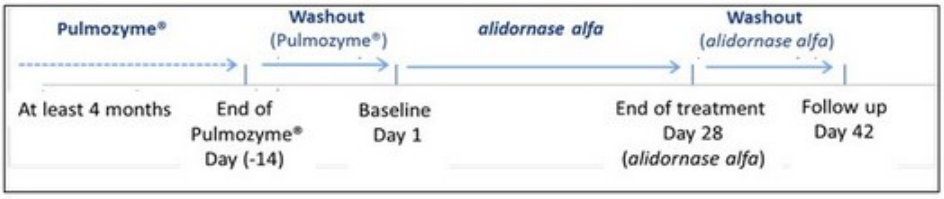

PROTALIX Biotherapeutics

alidornase alfa
(PRX-110)

Advances the treatment of Cystic Fibrosis

- Clinically meaningful lung function improvement as a result of effective mucociliary clearance
- Extraordinary reduction of the presence of Pseudomonas aeruginosa (P.sa) infections as a result of alidornase alfa treatment - All P.sa positive patients showed an >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
- While Cystic Fibrosis Foundation (CFF) acknowledged the need and potential of PRX-110, it declined funding for current proposed protocol
- Ongoing discussions with potential partners
- Amended protocol to be adopted and resubmitted to CFF with the potential partner

Financial Overview

- ~145M shares outstanding, as of December 31, 2017
- Dual listed on NYSE American and TASE
- Cash position: ~$51M as of December 31, 2017
- Cash level currently projected to fund operations into 2020
- $5.9M convertible note due by September 2018, ~$59M convertible note due by November 2021
- 10 years of 0% tax after using up NOL (currently ~$180M)

Protalix had significant achievements to date

- ✓ Strong positive two year data for pegunigalsidase alfa
- ✓ Promising results for OPRX-106 and alidornase alfa
- ✓ Clinical development pipeline targeting markets ~$10B
- ✓ R&D focus to advance early pipeline with attractive opportunities for proteins designed for superior clinical profiles

and multiple near term catalysts expected in the next 12 months

1. Finalize enrollment in all Phase III pegunigalsidase alfa studies
2. Continue seeking and signing partnership transactions
3. Introduce new pipeline (currently in preclinical)

PROTALIX Biotherapeutics

Thank You

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