
**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): June 7, 2016

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33357
(Commission File Number)

65-0643773
(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 communications 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))
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Item 7.01. Regulation FD Disclosure

On June 7, 2016, Moshe Manor, the President and Chief Executive Officer of Protalix BioTherapeutics, Inc., presented a corporate overview at the Jefferies 2016 Global Healthcare Conference. A copy of the slide presentation used in Mr. Manor's presentation is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

An archived webcast of the presentation is available at www.protalix.com, on the event calendar page.

All of the information furnished in Item 7.01 and Exhibit 99.1 hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and unless expressly set forth by specific reference in such filings, shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, whether made before or after the date hereof and regardless of any general incorporation language in such filings.

Item 9.01. Financial Statements and Exhibits**(d) Exhibits**

99.1 Slide Presentation entitled "Protalix BioTherapeutics Corporate Update – June 2016."

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.

PROTALIX BIOTHERAPEUTICS, INC.

Date: June 7, 2016

By: /s/ Moshe Manor

Name: Moshe Manor

Title: President and Chief Executive Officer



Protalix BioTherapeutics Corporate Update

June 2016

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 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; 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.

Protalix Snapshot



- FDA approval for plant cell culture based production of a protein - Elelyso®



- Protein production site approved by FDA, EMA and other major regulatory bodies world-wide

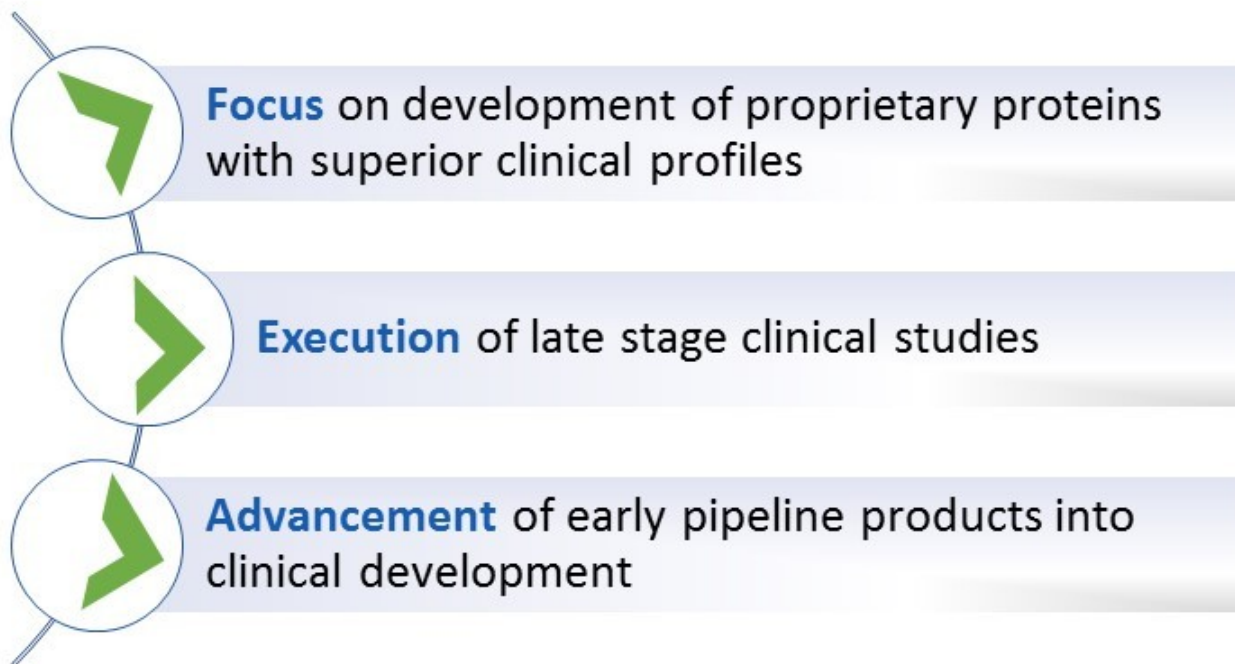


- Phase III clinical program testing the superiority of drug candidate for Fabry Disease

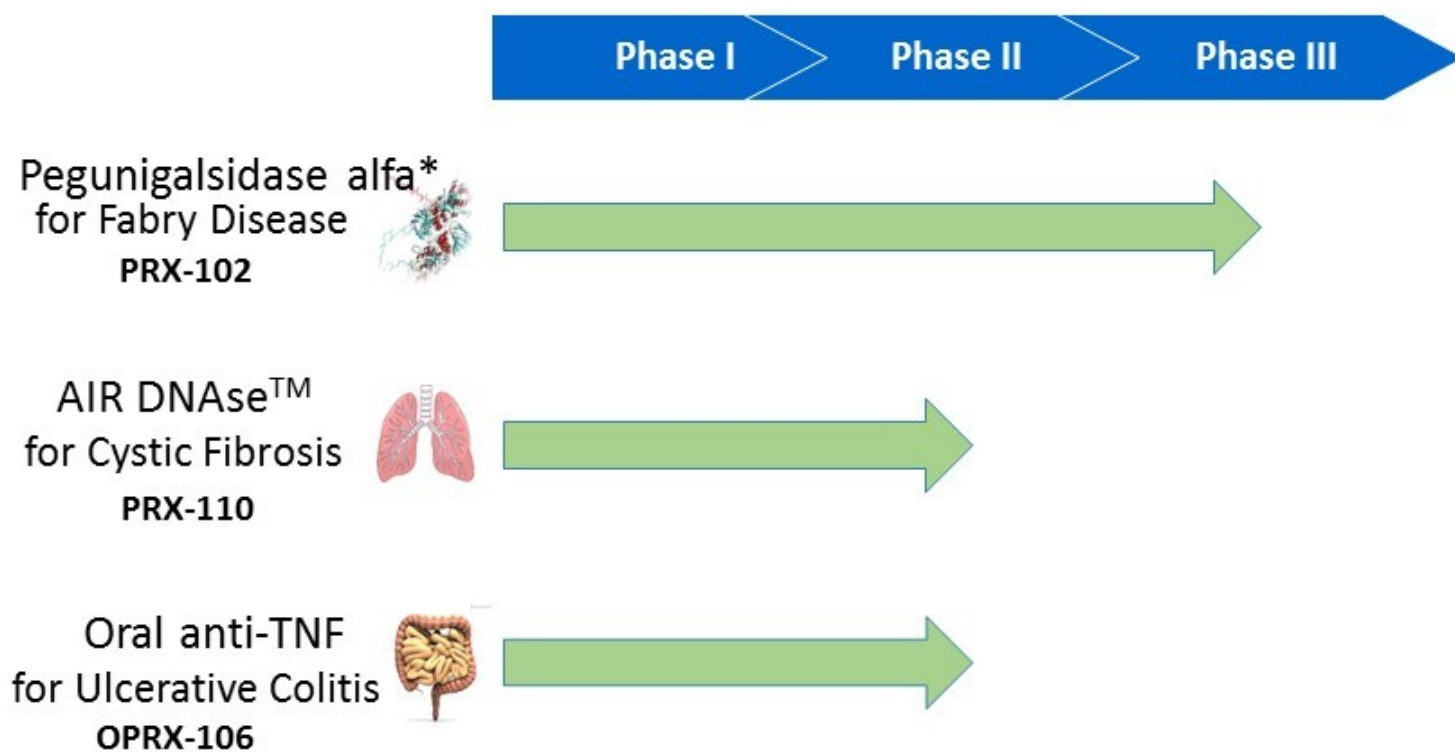


- Phase II candidates:
 - Inhaled protein for Cystic Fibrosis
 - Oral protein for inflammatory diseases

Strategy Highlights



Pipeline Overview

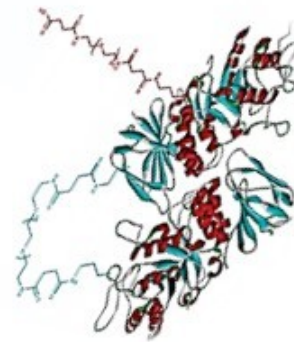


*pending WHO publication



Pegunigalsidase alfa (PRX-102)

for Fabry Disease



Fabry Disease

- Rare genetic lysosomal storage disorder caused by deficiency in the enzyme α -galactosidase A. ~5,000 patients treated worldwide
- Lipids accumulate in key organs (kidney, heart, CNS) leading to a progressive and potentially life threatening disease.
- Renal and Cardiac failures are the most predominant causes for morbidity
- ~\$1.2B growing market (CAGR ~10%)

Key Players

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

Fabry Disease Remains a High Unmet Need



**Renal
insufficiency and
renal failure**



**Hypertension and
cardiomyopathy**



**Impact on pain and
gastrointestinal
function**

Renal function continues to decline even for patients on long term Enzyme Replacement Therapy (ERT)

Rombach et al 2013

Most pronounced
4-7 days prior to
next infusion

Pegunigalsidase alfa (PRX102): A Chemically Modified Plant Cell Derived Recombinant Human α -galactosidase-A



- > PEGylated covalently bound homodimer → active and stable enzyme
- > Designed to be superior to the currently approved ERTs

Proven Advantages

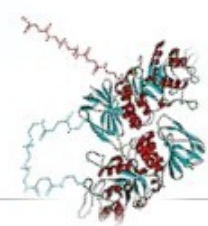
- Larger amounts and longer duration of active enzyme
- Enhanced uptake and activity in target organs
- Lower formation of antibodies



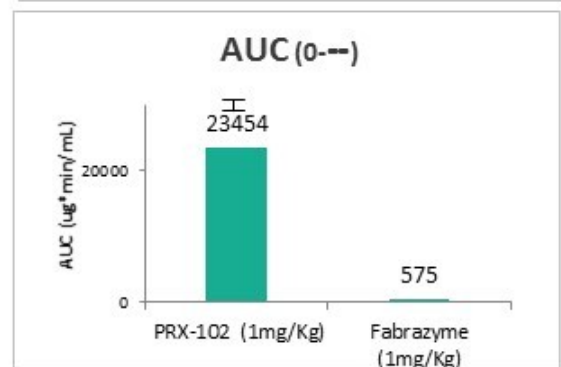
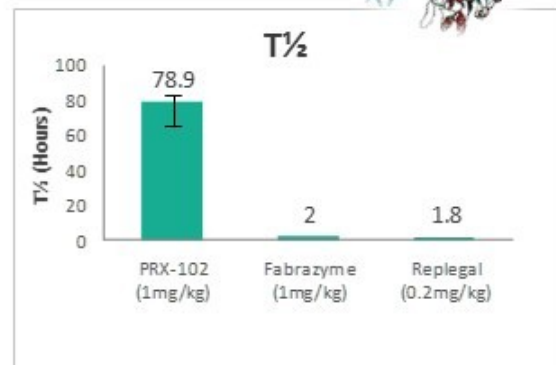
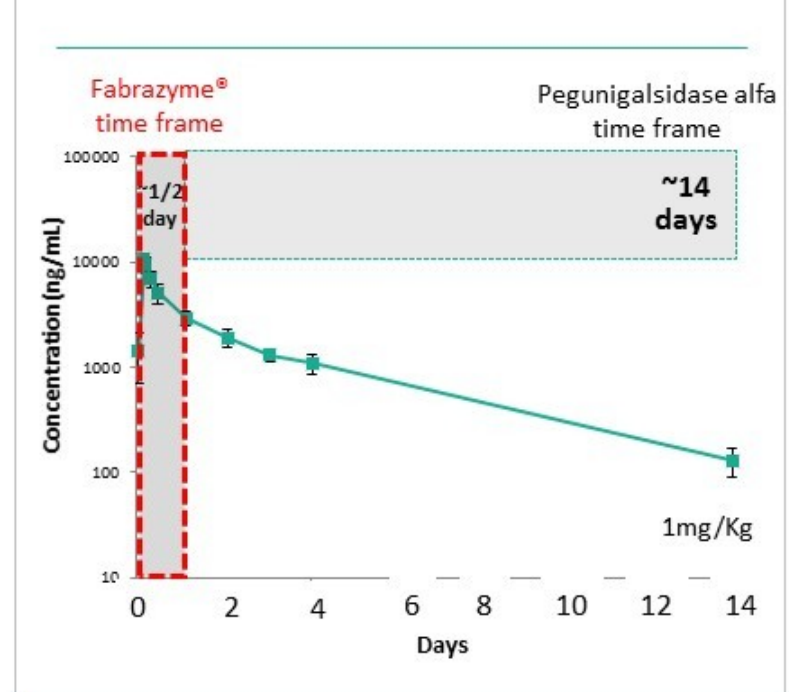
Results In

- ✓ Better clinical efficacy
- ✓ Improved Safety profile

Pegunigalsidase alfa (PRX 102): 14 Days of Active Enzyme

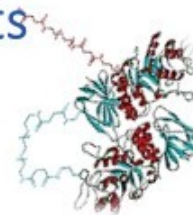


Plasma pegunigalsidase alfa concentration vs. time

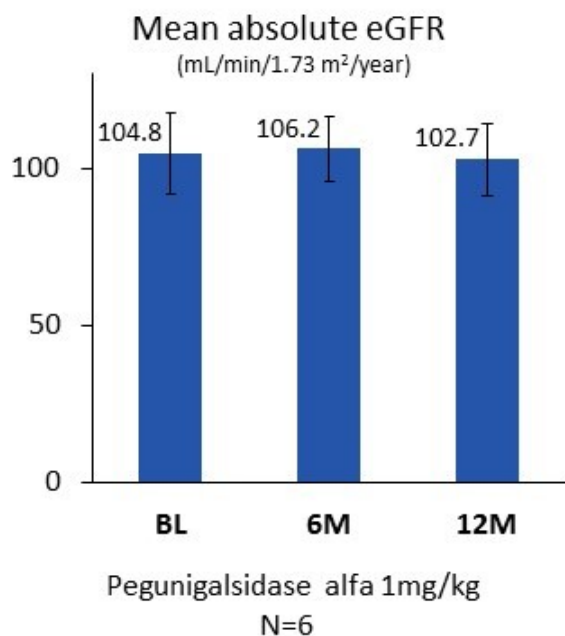


Higher levels of active available enzyme than current ERTs

Pegunigalsidase alfa (PRX102): Results from Phase I/II Clinical trial Fabry patients



Positive impact on Kidney Function



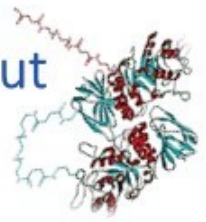
| Treated Populations | eGFR slope* |
|---|-------------|
| Fabrazyme (eGFR BL 85-160) n=32** | -1.89 |
| Pegunigalsidase alfa (eGFR BL 70-160) n=16*** | -0.32 |

*measured as Annualized Rate of Estimated GFR Change (mL/min/1.73 m²/year)

** Germain et al 2015

*** Phase I/II Doses 0.2, 1, 2 mg/kg ; For pegunigalsidase alfa 1mg/kg dose (n=6). eGFR slope was -0.30

Pegunigalsidase alfa (PRX 102) : : Favorable safety and tolerability observed throughout ~15 patient years



- Pegunigalsidase alfa was well tolerated, with 98% of events being mild and moderate
- Only 3 patients (19%) tested positive for treatment-induced anti-drug antibodies

| | % antibodies |
|----------------------|--------------|
| Pegunigalsidase alfa | 19% |
| Fabrazyme | 74%* |

“As PRX-102 has a different PK profile, which is probably the cause for the very low formation of antibodies, it has the potential for reduced immunogenicity.”

* Fabrazyme® Prescribing Information

Professor Raphael Schiffmann,
Director, Institute of Metabolic Disease at the
Baylor Research Institute, Dallas, Texas

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PROTALIX
Biotherapeutics

Pegunigalsidase alfa (PRX102): Phase III pivotal trial initiated



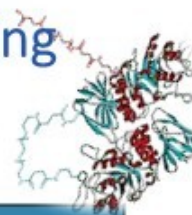
- Randomized, double blind, active control study of PRX-102 (pegunigalsidase alfa) compared to Fabrazyme® in Fabry patients previously treated with Fabrazyme®
- Number of patients to be enrolled: 78
 - 52 to be switched to pegunigalsidase alfa
 - 26 to remain on Fabrazyme®
- Objective: Demonstrate superiority to Fabrazyme® in renal function over 24 months with interim results at 12 months - 30% improvement
- Primary Endpoint: Comparison of eGFR slope (mean annualized change) between treatment groups
- Other Endpoints: LVMI, pain, plasma lyso GB3, safety, immunogenicity, Quality of Life




Pegunigalsidase alfa (PRX102): Supportive Clinical Trial

A Fabry clinical study
bridge

- Open label, single arm switch over study to assess the efficacy and safety of PRX-102 (pegunigalsidase alfa) in Fabry patients currently treated with Replagal®
- Number of patients to be enrolled: 22
- Objective: Efficacy and safety data of patients switched from Replagal® to PRX-102 over 12 months with interim results at 6 months
- Endpoints: Safety, mean annualized change (slope) in eGFR , pain, plasma lyso GB3, immunogenicity, Quality of Life

Pegunigalsidase alfa (PRX102): Summary of Global Clinical Program to Support Filing



| | | Pivotal Randomized Controlled Study vs Fabrazyme® | Open Label Switch-Over from Replagal® |
|---------------|---|--|---------------------------------------|
| FDA |  | 24 mos Superiority | Supportive – 12 mos |
| EMA |  | 12 mos Interim non-inferiority (potential for superiority) | Supportive – 12 mos |
| Rest of World |  | | |

- Ongoing follow-up of Phase I/II naïve patients
- Pediatric plan in place

Pegunigalsidase alfa (PRX102): Peak Sales Potential of \$1B Annually

- At current rate, market is projected to grow from \$1.2B to \$1.7B in the next 5 years
- Target – Worldwide Naïve & Switch patients
- Potential superiority in efficacy based on:

| | Fabrazyme® | Pegunigalsidase alfa |
|-------------------------|------------|----------------------|
| eGFR slope | -1.89 | -0.32 |
| Half life | 2 hours | ~80 hours |
| Active available enzyme | ½ day | 14 days |
| Antibody formation | 74% | 19% |



Potential to
be gold
standard
therapy



AIR DNase™ (PRX-110)

For Cystic Fibrosis



Cystic Fibrosis (CF)



- Rare genetic disease characterized by a highly viscous mucus most prominently leading to severe lung damage and loss of respiratory function
- ~70,000 CF patients worldwide. Growth in number of patients and increase in life expectancy

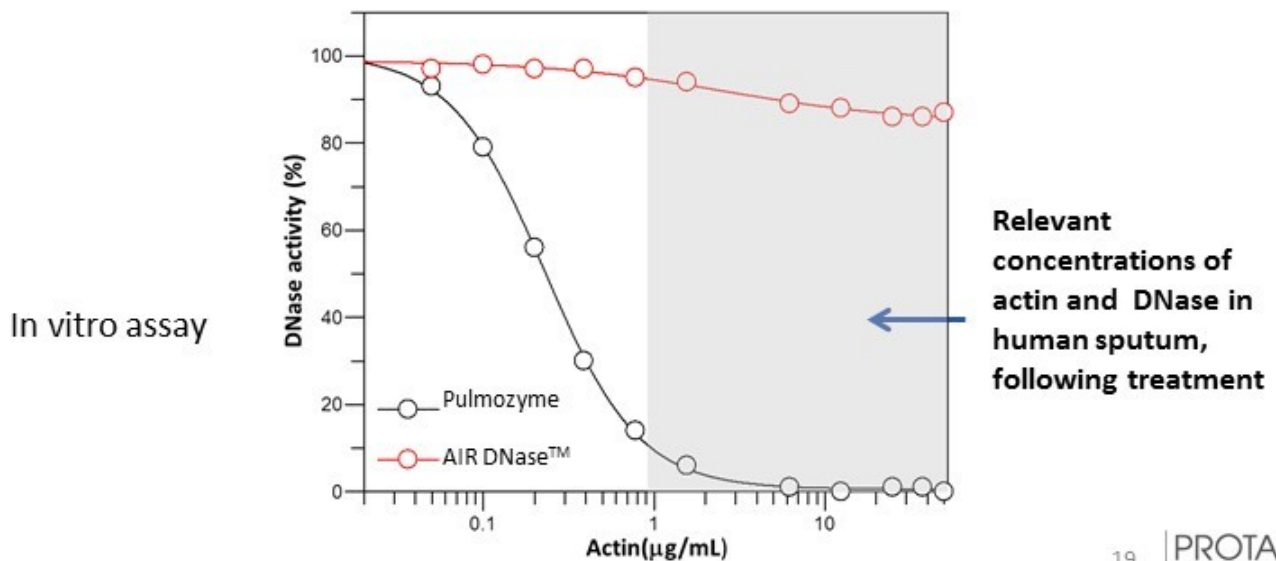
Top Selling Drugs

| Target | Product | 2015 Sales |
|---|---------------------------|------------|
| Reduce mucus viscosity | Pulmozyme® | \$678M |
| CFTR protein potentiation <ul style="list-style-type: none">• Applicable to ~30% of patients• Given on top of all other treatments | Kalydeco® and Orkambi® | \$983M |

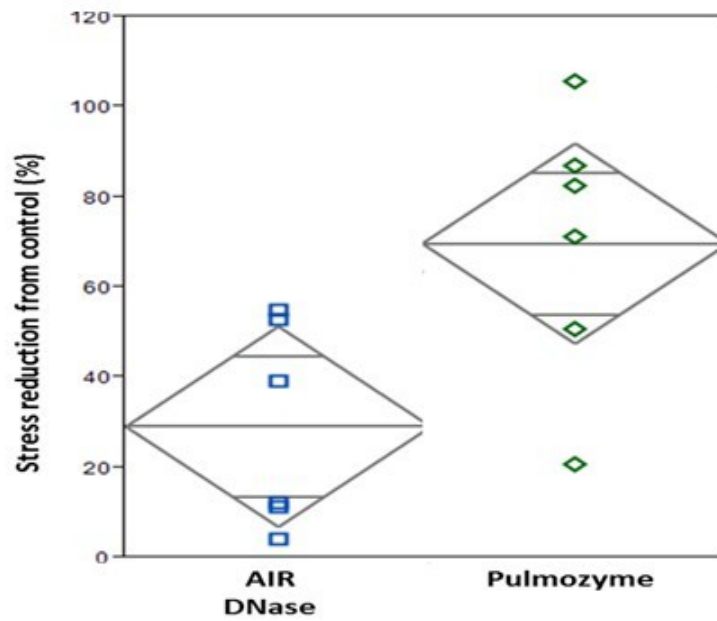
AIR DNase™ Plant cell derived chemically modified recombinant DNase with Actin Inhibition Resistance



- Chemically modified DNase enzyme **resistant to inhibition by actin** thus **designed to enhance the enzyme's efficacy in CF patients' sputa**.
- Actin, a potent inhibitor of DNase, found in high concentrations in CF patients' sputum, interferes with the effectiveness of the currently available DNase, Pulmozyme®



AIR DNase™: Demonstration of reduction of mucus viscosity in human sputum samples



N=6

Rheology Data Analysis

AIR DNase™ Clinical Development Plan for Cystic Fibrosis



- Phase I – 18 healthy volunteers: Completed
 - AIR DNase™ found to be safe and tolerable
- Phase II in CF patients – Initiated
 - Switch-over study for 15 patients previously treated with Pulmozyme®
 - Study duration: 28 days
 - Efficacy endpoint: FEV1
 - Safety and immunogenicity



Oral anti-TNF (OPRX-106)

For Ulcerative Colitis



Oral Delivery of Therapeutic Proteins

Requirements for oral delivery of protein therapeutics

- Protein must survive the gastric environment
- Protein must be released from within the cells into the intestine
- Protein must be able to act within the intestine

The plant cell advantage:

- Plant cell wall (cellulose) serves as protective agent against the gastric environment
- Can serve as a natural oral administration vehicle

Anti-tumor Necrosis Factor Alpha (anti-TNF α) for Inflammatory Diseases

- Anti-TNF market >\$30B with multiple blockbuster products (injections and IV infusions)
- Multiple indications:
 - **Ulcerative Colitis (~\$5.5B)**
 - Rheumatoid Arthritis (~\$17B)
 - Psoriasis (~\$5.7B)
 - Crohn's Disease (~\$3.6B)

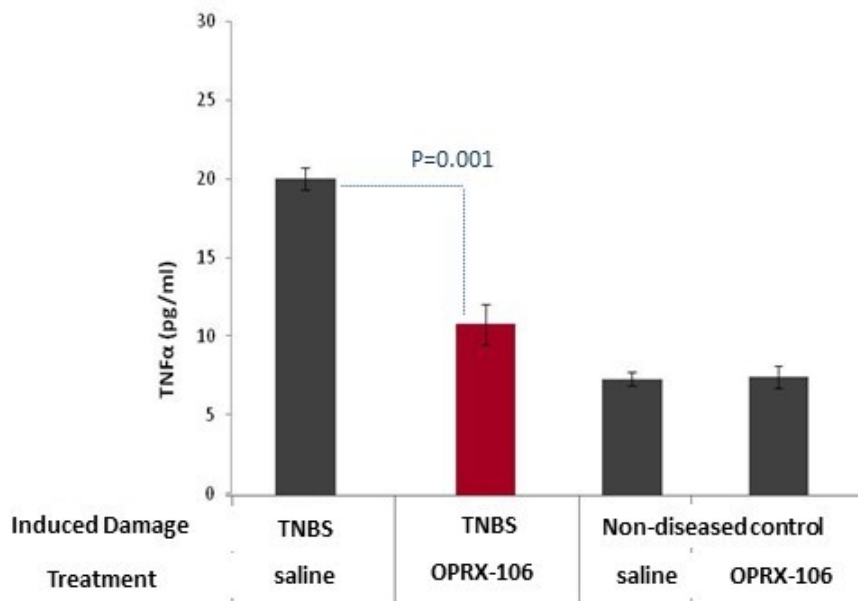


Oral Anti-tumor Necrosis Factor Alpha (anti TNF α) OPRX-106 for Inflammatory Diseases



- Potential to locally deliver higher doses with fewer side effects in an oral formulation

OPRX-106 Inflammatory Bowel Disease Animal Model



OPRX-106 Phase I Healthy Volunteers- complete



- Safe and well tolerated.
- Immunomodulation: Regulatory T cell activation showed biological activity in the gut: CD4/CD25, CD4/Foxp3/CD25, CD8/CD25, CD8/Foxp3/CD25)
- Alteration of systemic immune system ***without significant systemic absorption***
- Serum cytokine levels remained stable

“The results demonstrated in the Phase I trial are very exciting and encouraging. As T regulatory cells have a central role in the immune system, PRX-106 has the potential to be an effective agent for numerous immune-mediated indications.”

”
Prof. Yaron Ilan

Director, Gastroenterology and Liver Units, Department of Medicine , Hebrew University Hadassah Medical Center , Jerusalem.

OPRX-106 Phase II



- Expected to commence by July 2016
- Study design:
 - 15 mild to moderate untreated ulcerative colitis patients
 - Oral once daily administration - 8 week treatment duration
 - Evaluating two doses for:
 - Safety and Tolerability
 - Pharmacokinetics
 - Efficacy parameters: Mayo score, rectal bleeding, CRP levels, fecal calprotectin level

Financial Overview

- ~100M shares outstanding, as of March 31, 2016
- Dual listed on NYSE MKT and TASE
- Strong cash position: ~\$67M as of March 31, 2016
- Cash level currently projected to finance the company into 2018, through significant milestones
- \$69M convertible note due by September 2018
- 10 years of 0% tax after using up NOL (currently ~\$120M)

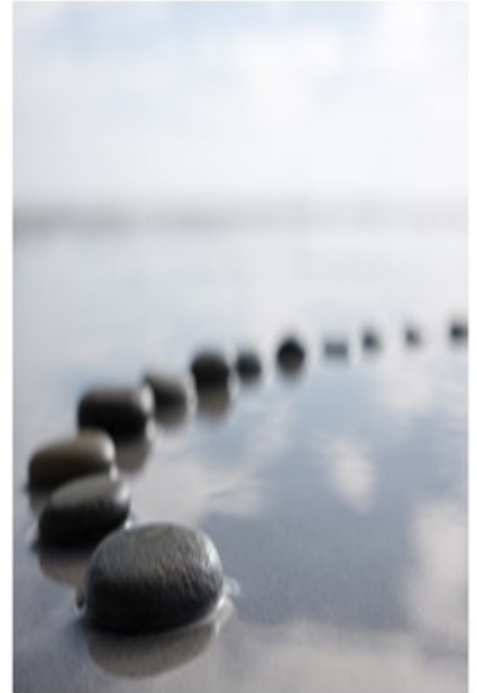
Protalix has an exciting road ahead...

- ✓ Promising results for flagship product for Fabry disease
- ✓ Three molecules in clinical development
 - Phase III with pegunigalsidase alfa
 - Phase II with AIR DNase™
 - Phase II with Oral anti-TNF
- ✓ Clinical stage pipeline targeting markets that are >\$8 billion
- ✓ R&D focus to advance early pipeline with attractive opportunities for proteins designed for superior clinical profiles



...and multiple near term catalysts in the next 12 months

- Finalize enrollment in Phase III pegunigalsidase alfa (PRX-102) studies in Fabry
- Enroll patients in Phase II study for AIR DNaseTM (PRX-110) in Cystic Fibrosis
- Initiate Phase II study for oral anti TNF (OPRX-106) in Ulcerative Colitis
- Report results from Phase II for AIR DNaseTM
- Report results from Phase II for oral anti TNF





Thank You

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