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 9, 2017

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 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))

Item 2.02. Results of Operations and Financial Condition

On January 9, 2017, Protalix BioTherapeutics, Inc. (the "Company") issued a press release providing a review of 2016 and its strategic outlook for 2017. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 7.01. Regulation FD Disclosure

On January 9, 2017, the Company posted a copy of its January 2017 Corporate Update in the Presentations page of the Investors tab of its corporate website. A copy of the corporate update is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

All of the information furnished in Items 2.01 and 7.01, and Exhibits 99.1 and 99.2, 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 Press release dated January 9, 2017.
99.2 January 2017 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.

PROTALIX BIOTHERAPEUTICS, INC.

Date: January 9, 2017

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

Protalix BioTherapeutics Provides Review of 2016 and Strategic Outlook for 2017

Full Switch Plan Initiated and Published by Brazilian Ministry of Health for Gaucher Patients in Brazil Yielding Significant Revenue Stream

Fabry Phase III Clinical Trial Underway with Interim Results Expected in 2018

Phase II Clinical Trial for Cystic Fibrosis Positive Interim Data Reported with Full Results Expected During First Quarter of 2017

Phase II Clinical Trial of Oral anti TNF for Ulcerative Colitis Initiated with Results Expected in Second Half of 2017

New Pipeline Candidates for Indications for which there are Currently No Approved Drugs or that address Significant Unmet Medical Needs anticipated to be announced publicly and to progress into Clinical Development

CARMIEL, Israel, January 9, 2017 — Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX) today announced a review of the Company's clinical and financial highlights for 2016, as well as an outlook for anticipated future strategic milestones.

"2016 was a building year for Protalix. We aggressively pushed our clinical pipeline programs forward, which included high level regulatory agency discussions and the initiation of clinical trials for all three of our disclosed leading assets," said Moshe Manor, Protalix's President and Chief Executive Officer. "Given our recent financing and the projected revenue stream from sales of alfataliglicerase in Brazil, we are well capitalized to deliver on our anticipated, value building milestones. Over the course of 2017 and into 2018, we expect to announce data from our phase III clinical trial on Fabry disease, final results from our phase II clinical trial of alidornase alfa for the treatment of Cystic Fibrosis and results from our phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis. We expect that 2017 will be an extremely important, inflection year for us, with a number of significant commercial and clinical milestones that should bring considerable value to our stockholders."

2016 and Recent Clinical Highlights

- Received purchase order from the Brazilian Ministry of Health for purchase of alfataliglicerase to treat Gaucher patients in Brazil. The order consists of a number of shipments during 2017, in increasing volumes, for a total of approximately $24.3 million. The size of the final shipment of the order represents annual revenues of approximately $42.0 million. The Brazilian Ministry of Health's order was published in the December publication of Brazil's Official Diary of the Union (Diário Oficial).

- Reported positive interim results from the Company's phase II clinical trial of alidornase alfa (PRX-110) for the treatment of Cystic Fibrosis, which results include a clinically meaningful increase in percent predicted forced expiratory volume in one second (ppFEV1).

- Initiated patient enrollment in the Company's phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis. The Company is developing OPRX-106 to be the first ever oral protein treatment, as currently there are no other oral protein treatments available.

- Received regulatory approval of alfataliglicerase in Brazil for children four years old and above with a confirmed diagnosis of Type I Gaucher disease.

- Worked closely with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) to determine the phase III clinical trial program for pegunigalsidase alfa (PRX-102) for the treatment of Fabry disease:

    - Initiated and enrolled patients in a global phase III trial of pegunigalsidase alfa versus Fabrazyme® to support a BLA filing in the United States, with a 12-month non-inferiority interim analysis to support an MAA filing with the EMA.

    - Determined a 12-month switch-over study from Replagal® will also be conducted to support FDA and EMA filings.

- Presented positive 6- and 12-month interim clinical data on pegunigalsidase alfa at the 12th Annual WORLD Symposium™ in March 2016.

- Exchanged $54.1 million principal amount of the Company's $69.0 million 4.50% Senior Convertible Notes due 2018 for $40.2 million principal amount of newly issued 7.50% Senior Secured Convertible Notes due 2021 and approximately 23.8 million shares of common stock. Concurrently, the Company sold, in a private placement, $22.5 million principal amount of 2021 Notes.

- The Company had a strong cash balance of approximately $63.0 million as of December 31, 2016, which is currently projected to fund operations into late 2019.

2017 Outlook and Projected Future Milestones

- Full results for the phase II efficacy and safety study of alidornase alfa expected to be announced during the first quarter of 2017.

- Full results for the phase II efficacy and safety study of OPRX-106 expected to be announced during the second half of 2017.

- Completion of enrollment in the phase III trial of pegunigalsidase alfa for the treatment of Fabry disease expected in 2017; interim data analysis anticipated in 2018 to support EMA and other regulatory filings outside of the United States.

    - If superiority to Fabrazyme is not yet achieved at that time, as shown in the interim data, the trial will continue for an additional year before reporting two-year data to support a U.S. regulatory filing.

- Present, via two key opinion leader (KOL) presentations and a poster, pegunigalsidase alfa clinical data at the 13th Annual WORLD Symposium™ to be held in February 2017.

- Present at the 5th Update on Fabry Nephropathy: Biomarkers, Progression and Treatment Opportunities in April 2017.

- Present, at the 40th European Cystic Fibrosis Conference, full data from the Company's phase II efficacy and safety study of alidornase alfa, in June 2017, and at the North American Cystic Fibrosis Conference in November 2017.

- Potential partnership for alidornase alfa.

- Potential collaboration for alidornase alfa with the Cystic Fibrosis Foundation.

- Potential partnership for oral anti-TNF.

A copy of the Company's January 2017 Corporate Update will be posted in the Presentations page of the Investors tab of its corporate website.

About Protalix BioTherapeutics, Inc.

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®. Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (FDA) in May 2012 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights. Protalix's development pipeline includes the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa for the treatment of Cystic Fibrosis; and others.

Forward-Looking Statements

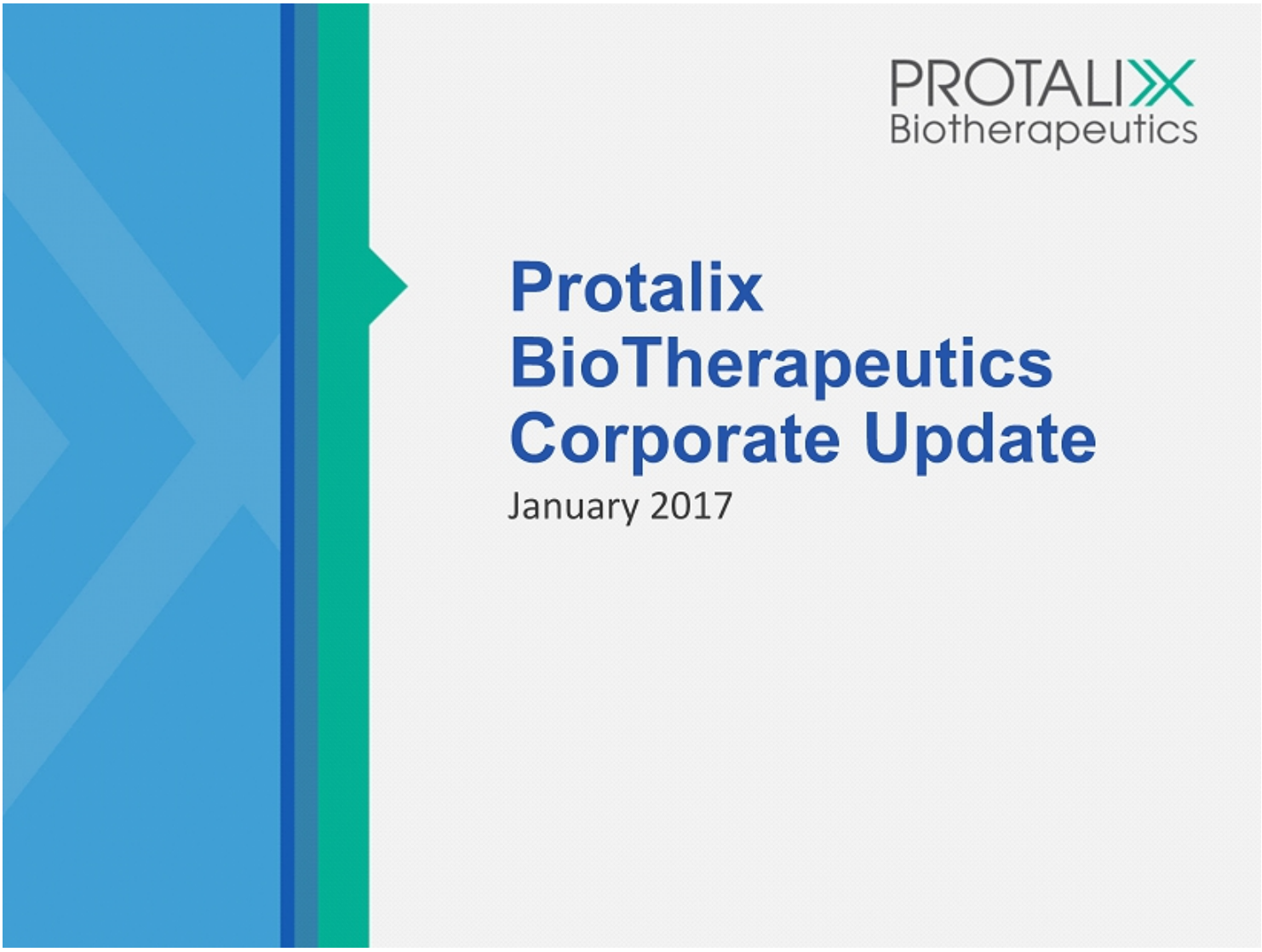
To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms “expect,” “anticipate, “believe,” “estimate,” “project,” “plan,” “should” and “intend” and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause material differences include, among others: risks related to the ultimate purchase by Fundação Oswaldo Cruz of alfataliglicerase pursuant to the stated purchase intentions of the Brazilian Ministry of Health of the stated amounts, if at all; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase generally; risks related to our commercialization efforts for alfataliglicerase in Brazil; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the amount of our future revenues, operations and expenditures; failure or delay in the commencement or completion of our 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 our clinical protocols; and lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of our product candidates will not support our claims of safety or efficacy, that our 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 make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in our 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; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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 our filings with the U.S. Securities and Exchange Commission. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Investor Contact

Marcy Nanus
The Trout Group, LLC
646-378-2927
mnanus@troutgroup.com

Source: Protalix BioTherapeutics, Inc.

Exhibit 99.2

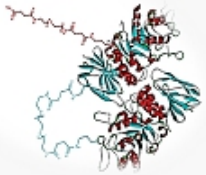

PROTALIX
Biotherapeutics
Protalix
BioTherapeutics
Corporate Update
January 2017

Note Regarding Forward-Looking Statements

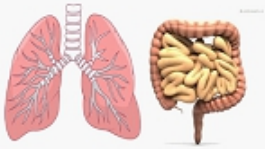
This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements including, among others, statements regarding expectations as to regulatory 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® (afaltaliglicerase)
- 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

- Commercialization of alfataliglicerase in Brazil
- Order of ~ $24M for 2017 was secured

Strategy Highlights

- **Focus** on development of proprietary proteins with superior clinical profiles
- **Execution** of late stage clinical studies
- **Advancement** of early pipeline products into clinical development
- **Significant reduction** of capital consumption through sales of alfataliglicerase in Brazil

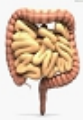
Pipeline Overview

Preclinical | Phase II | Phase III

pegunigalsidase alfa
for Fabry Disease
PRX-102

alidornase alfa
for Cystic Fibrosis
PRX-110

Oral anti-TNF
for Ulcerative Colitis
OPRX-106



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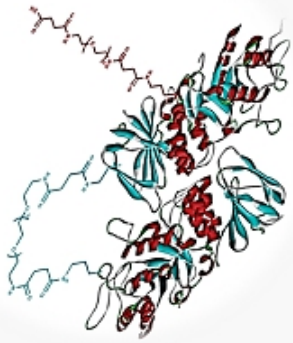
pegunigalsidase alfa (PRX-102)

for Fabry Disease



Fabry Disease

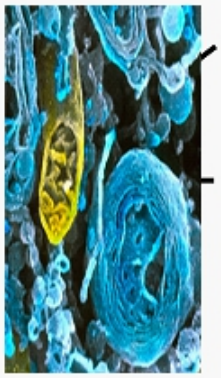
- Rare genetic lysosomal storage disorder caused by deficiency in the enzyme α-galactosidase A. ~5,000 patients treated worldwide
- Lipids accumulate in key organs (kidney, heart, CNS) leading to a progressive and potentially life threatening disease.
- Renal and Cardiac failures are the most predominant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

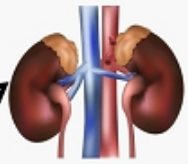
Key Players

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%)

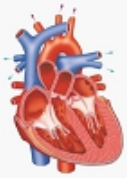
PROTALIX Biotherapeutics

Fabry Disease Remains a High Unmet Need





Renal insufficiency and renal failure



Hypertension and cardiomyopathy

Impact on pain and quality of life

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

Rombach et al 2013

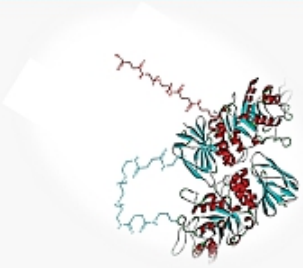
Little functional enzyme every second week and presence of anti-agalsidase antibodies are likely contributors to the limited effect of ERT

Schiffmann, Hughes, Linthorst, Ortiz, Svarstad, Warnock, West Wanner - Conference Participants

Summary of Screening, Diagnosis, and Management of patients with Fabry disease: conclusions from a "Kidney Disease: Improving Global Outcomes" (KDIGO) Controversies Conference, *Kidney International, 2016*

KDIGO is a global organization of experts in kidney disease, developing and implementing evidence based clinical practice guidelines in kidney disease.

pegunigalsidase alfa (PRX-102)



A Chemically Modified Plant Cell Derived Recombinant Human α-galactosidase-A

- PEGylated covalently bound homodimer composes of 2 subunits forming an active and stable enzyme
- Designed to be superior to the currently approved ERTs

Proven Advantages

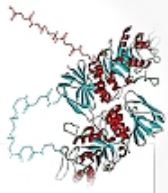
- Larger amounts and longer duration of active enzyme
- Enhanced uptake and activity in target organs
- Lower formation of antibodies

Results In

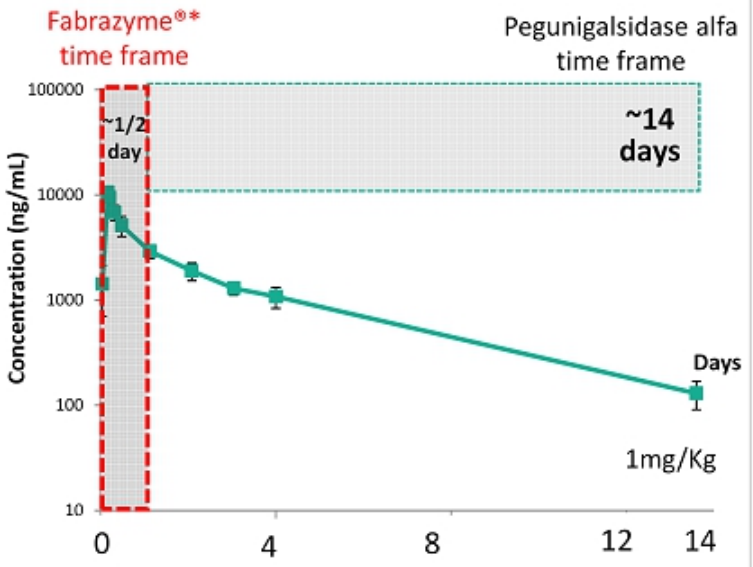
- ✓ Better clinical efficacy
- ✓ Improved Safety profile

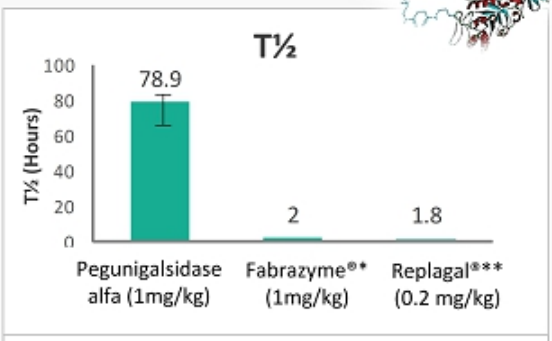
pegunigalsidase alfa (PRX-102)

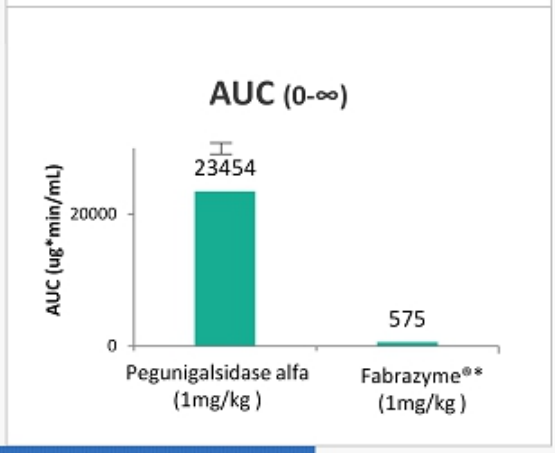
14 Days of Active Enzyme



Plasma pegunigalsidase alfa concentration vs. time







Higher levels of active available enzyme than current ERTs

*Fabrazyme® Prescribing Information ** Replagal® Prescribing Information

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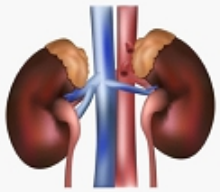
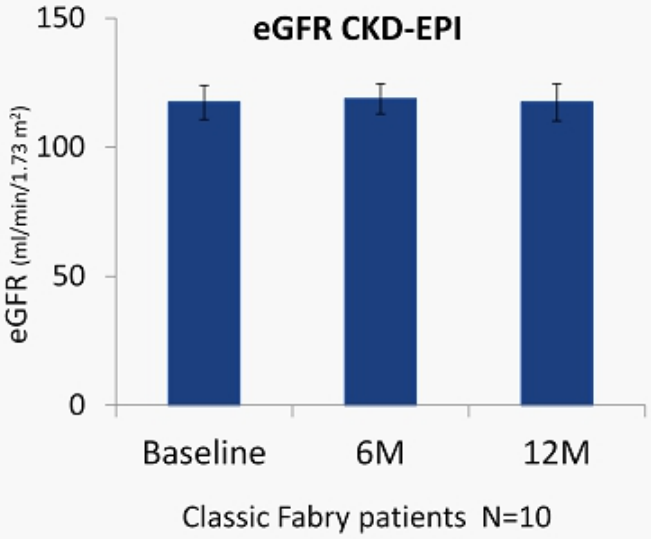
pegunigalsidase alfa (PRX-102)

Results from Phase I/II Clinical trial



Positive impact on Kidney Function



Classic Fabry Patients	eGFR slope[1]
Pegunigalsidase alfa (eGFR BL 82.4-156.3)	-1.8*
Fabrazyme® (eGFR BL 49-170) [2]	-3.8

* 0.01± 1.37 calculated slope for classic Fabry patients excluding 1 male patient who received doxycycline

1. Measured as Annualized Rate of Estimated GFR Change (mL/min/1.73 m²/year)
2. Germain et al 2015

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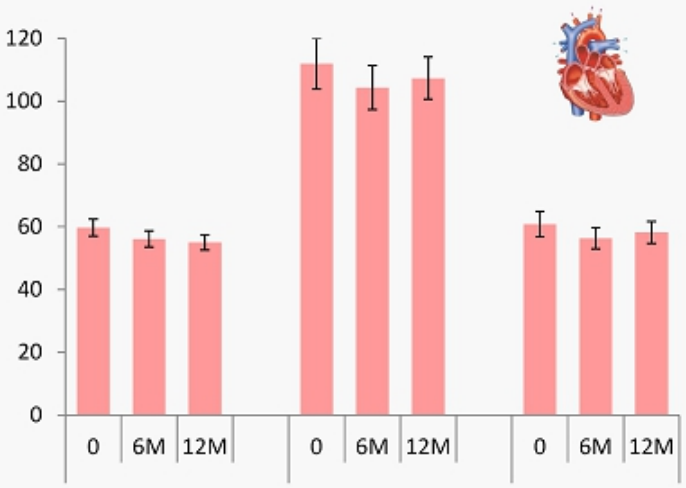
pegunigalsidase alfa (PRX-102)

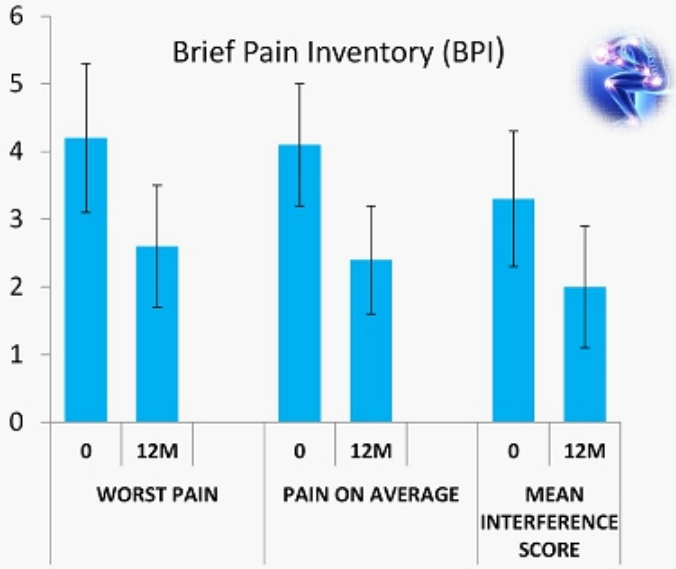
Results from Phase I/II Clinical trial

Positive impact on cardiac function



Classic Fabry patients N=10

Meaningful Reduction in Pain



Classic Fabry patients N=10

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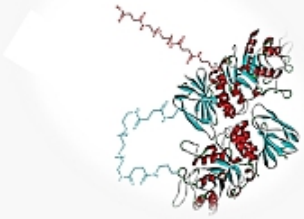
pegunigalsidase alfa (PRX-102)



Favorable safety and tolerability observed throughout ~16 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 – all of whom are sero-negative after one year of treatment

	% 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 ."

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

* Fabrazyme® Prescribing Information

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pegunigalsidase alfa (PRX-102) balance a Fabry clinical study

Phase III pivotal trial initiated

- Randomized, double blind, active control study of pegunigalsidase alfa (PRX-102) 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
- 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 (PRX-102) bridge a Fabry clinical study

Supportive Clinical Trial

- Open label, single arm switch over study to assess the efficacy and safety of pegunigalsidase alfa (PRX-102) in Fabry patients currently treated with Replagal®
- Number of patients to be enrolled: 22
- Objective: Safety and Efficacy 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 (PRX-102)

Summary of Global Clinical Program to Support Filing

	balance (Head to Head vs. Fabrazyme® in Switch Patients)	bridge (Switch-over from Replagal®)
FDA 	24 mos Superiority	Supportive – 12 mos
EMA  Rest of World 	12 mos Comparability (potential for superiority)	Supportive – 12 mos

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

pegunigalsidase alfa (PRX-102)

Peak Sales Potential of $1B Annually

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

	Fabrazyme®	pegunigalsidase alfa
eGFR slope	-3.8	-1.8*
Half life	2 hours	~80 hours
Active enzyme	½ day	14 days
Antibody formation	74%	19%

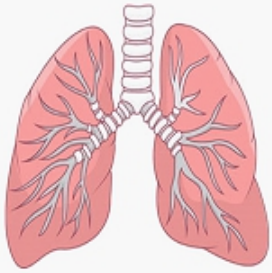
Potential to be gold standard therapy

*0.01± 1.37 calculated slope for classic Fabry patients excluding one male patient who received doxycycline

PROTALIX Biotherapeutics

alidornase alfa
(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
- More than 70,000 CF patients worldwide. Growth in number of patients and increase in life expectancy

Top Selling Drugs

Target	Product	Annual Sales
Reduction of mucus viscosity	Pulmozyme®	$678M (2015)
CFTR protein modulation • Applicable to ~40% of patients • Given on top of all other treatments	Kalydeco® and Orkambi®	$1.6B (4Q15-3Q16)

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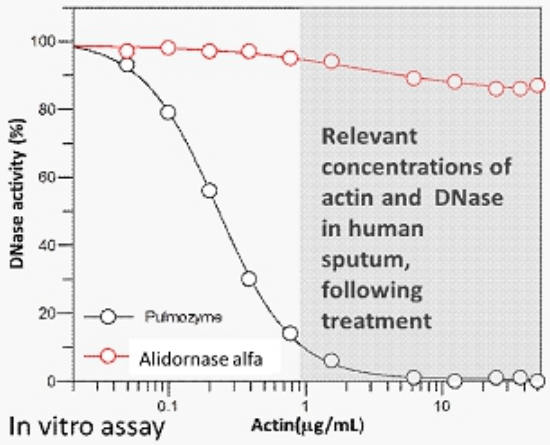
alidornase alfa (PRX 110) with Actin Inhibition Resistance

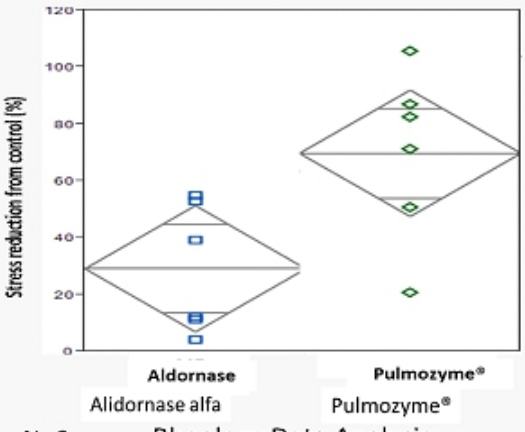
- Plant-cell derived, chemically modified DNase enzyme **resistant to inhibition by actin** thus **designed to enhance the enzyme's efficacy in CF patients' sputa.**
- Actin, a potent inhibitor of DNase, found in high concentrations in CF patients' sputum, interferes with the effectiveness of the currently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

DNAse activity



In vitro assay

Sputum Viscosity



N=6 Rheology Data Analysis

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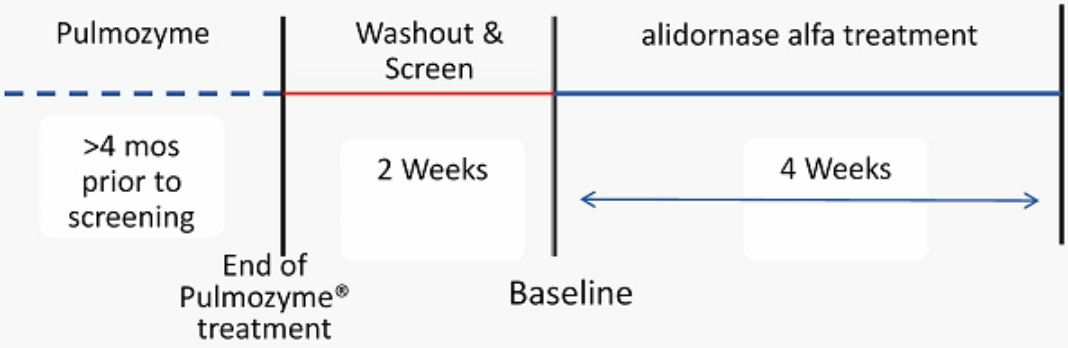
alidornase alfa -Clinical Development Plan for CF

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

Phase II Study Outline



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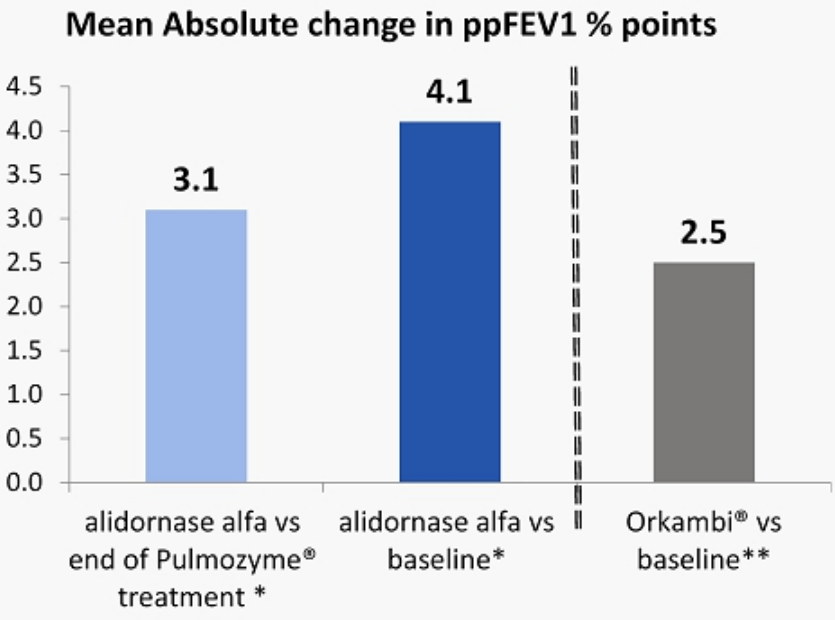
Top Line Results from Interim Analysis of Phase II trial

- alidornase alfa (PRX 110) was found to be safe and well-tolerated
- **Clinically meaningful** improvement in lung function
  - Mean absolute improvement in ppFEV1 compared to baseline of 4.1 points



"The preliminary efficacy results of alidornase alfa are very encouraging, even when compared to past trials of approved drugs for the treatment of CF. Although the study was performed on a small number of patients, the data is very encouraging since it shows clinically meaningful results,"

Prof. Eitan Kerem,
Chairman of Pediatrics
Head of CF Center, Hadassah Medical Center, Jerusalem;

* n=13 **Orkambi® phase III trial

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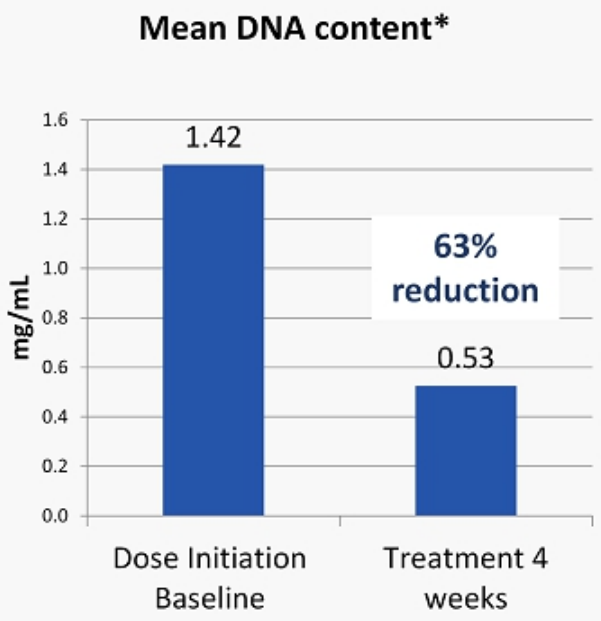
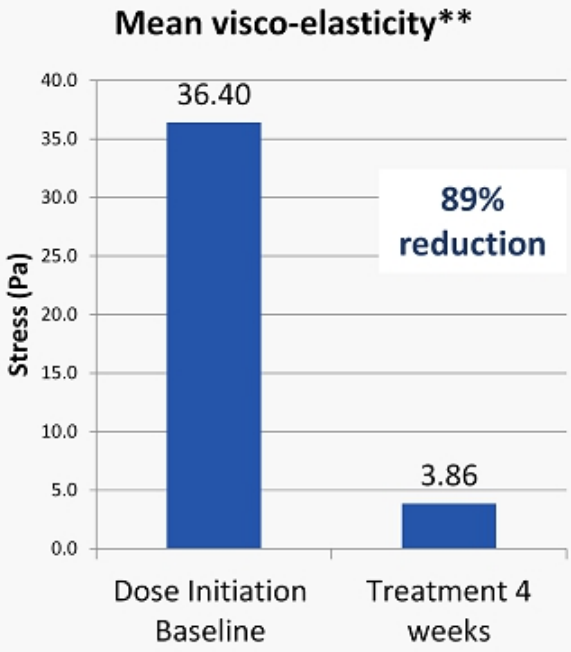
Decrease in Sputum DNA Content and Sputum Viscosity upon alidornase alfa Treatment Initiation





* n=7
**n=5

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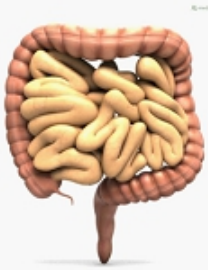
Oral anti-TNF
(OPRX-106)

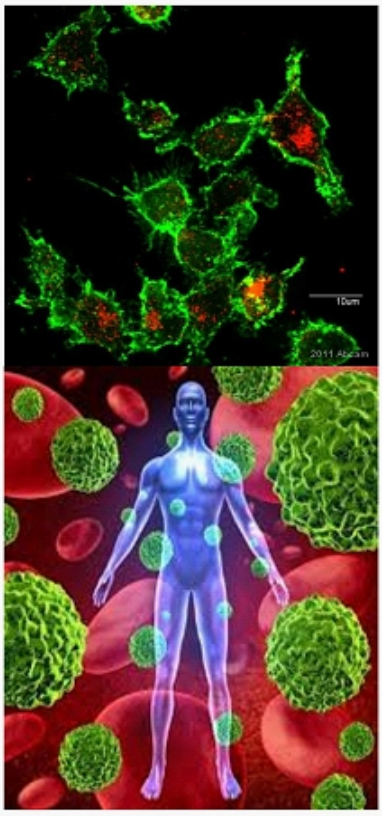
For Ulcerative Colitis



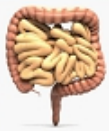
Anti-tumor Necrosis Factor Alpha (anti -TNF α) for Inflammatory Diseases

- 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)

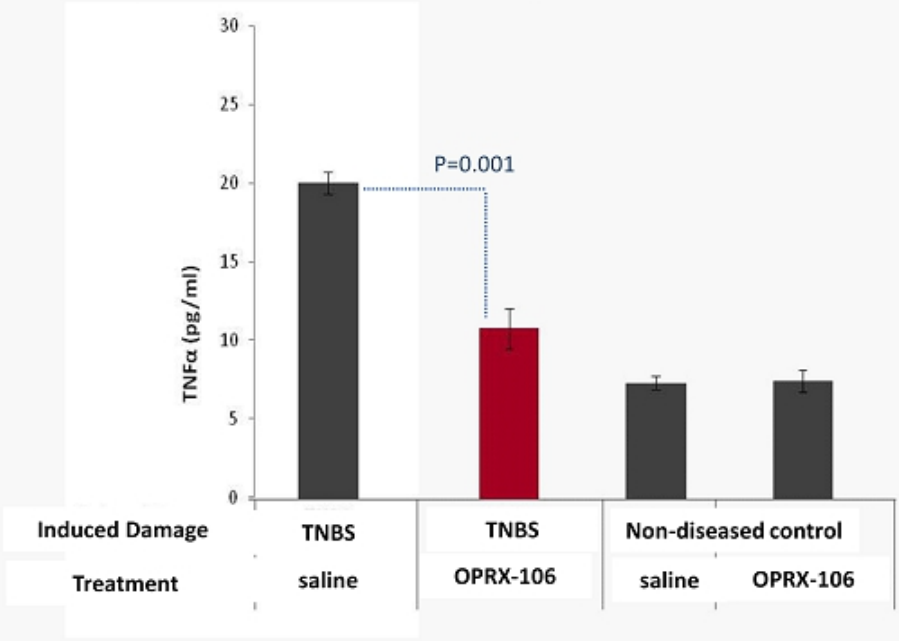


Oral Anti-tumor Necrosis Factor Alpha (anti TNF α) OPRX-106 for Inflammatory Disease



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

OPRX-106 Inflammatory Bowel Disease Animal Model



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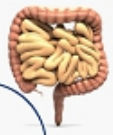
OPRX-106 Clinical Program



Phase I –COMPLETED

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

Phase II –ONGOING

- 15 mild to moderate untreated ulcerative colitis patients
- Oral once daily administration - 8 week follow-up
- Evaluating two doses for:
  - Safety and Tolerability
  - Pharmacokinetics
  - Efficacy parameters: Mayo score, rectal bleeding, CRP levels, fecal calprotectin level

"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.

Sales of Alfataliglicerase in Brazil

- Negotiations held with the newly elected government officials in the Brazilian Ministry of Health regarding the potential of alfataliglicerase to become the preferred enzyme replacement therapy for the approximately 700 Gaucher patients treated in Brazil
- Brazilian Ministry's order consists of 3 product shipments to start in mid 2017 and reach approximately $24.3M this year
- Size of the last shipment of this order in Q4-17 represents annual revenues of approximately $42 million.
- Sales to Brazil significantly reduce Protalix's cash consumption rate and close to breakeven in 4Q 2017
- Protalix owns full rights to alfataliglicerase in Brazil

Financial Overview

- 124M shares outstanding, as of December 31, 2016
- Dual listed on NYSE MKT and TASE
- Strong cash position: ~$63M as of December 31, 2016
- Cash level currently projected to fund operations into late 2019
- $14.9M convertible note due by September 2018, $62.7M convertible note due by November 2021
- 10 years of 0% tax after using up NOL (currently ~$150M)

Protalix has an exciting road ahead…

- ✓ Promising results for pegunigalsidase alfa and alidornase alfa
- ✓ Clinical development pipeline targeting markets >$8B
- ✓ R&D focus to advance early pipeline with attractive opportunities for proteins designed for superior clinical profiles
- ✓ Sales in Brazil significantly reduce cash consumption rate

and multiple near term catalysts in the next 12 months

1. Report phase II full results on alidornase alfa (PRX-110)
2. Report results from Phase II for oral anti TNF (OPRX -106)
3. Finalize enrollment in Phase III pegunigalsidase alfa (PRX-102) studies
4. Introduce new pipeline (currently in preclinical)

PROTALIX Biotherapeutics

Thank You

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