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): November 23, 2015

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Florida	**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**	**20100**
(Address of principal executive offices)	**(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 7.01 Regulation FD Disclosure

On November 23, 2015, Protalix BioTherapeutics, Inc. held a meeting with a Key Opinion Leader (KOL) and a select group of investors and analysts entitled "PRX-102 (prh a-Galactosidase-A) Novel Enzyme Replacement Therapy for the Treatment of Patients with Fabry Disease," at which the KOL presented certain potential benefits of the treatment of Fabry patients with PRX-102 and other information and data relating to PRX-102 and Fabry disease. The meeting took place in New York City, NY. A copy of the slide presentation used at the meeting is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

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 "PRX-102 (prh a-Galactosidase-A) Novel Enzyme Replacement Therapy for the Treatment of Patients with Fabry Disease"

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: November 23, 2015

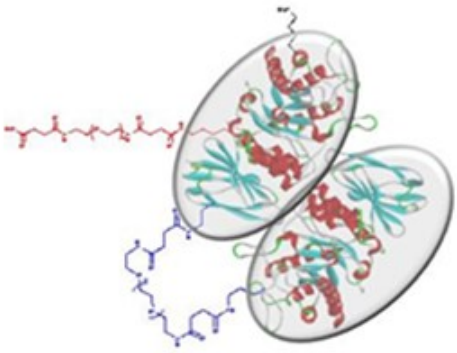
By: /s/ Yossi Maimon
Name: Yossi Maimon
Title: Vice President and
Chief Financial Officer

PROTALIX Biotherapeutics

PRX-102

prh α-Galactosidase-A

Novel Enzyme Replacement Therapy
for the Treatment of Patients
with Fabry Disease



PROTALIX Biotherapeutics

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. Actual results may differ materially from these forward-looking statements because of the Company's unproven business model, its dependence on new technologies, the uncertainty and timing of clinical trials, the Company's ability to develop and commercialize products, its dependence on collaborators for services and revenue, its substantial indebtedness and lease obligations, its changing requirements and costs associated with planned facilities, intense competition, the uncertainty of patent and intellectual property protection, dependence on key management and key suppliers, the uncertainty of regulation of products, the impact of future alliances or transactions and other risks described in the Company's filings with the 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.

PRX-102: A Chemically Modified Plant Derived Human α-galactosidase-A Enzyme

- PRX-102 (prh-alpha-GAL-A) is a chemically modified, recombinant DNA derived protein expressed from tobacco plant cells in suspension
- The enzyme is:
  - Designed to be potentially superior to the currently approved enzymes (stability, half-life, safety immunogenicity→ efficacy)
  - Comprised of two subunits, covalently-linked via a 2 kDa PEG moiety resulting in a stable homo-dimer
  - Order of magnitude longer half-life and greater AUC than the commercially available enzymes, both in plasma and under acidic lysosomal-like conditions
  - Translocated to the lysosome of target cells and hydrolyses accumulated Gb_3 substrate

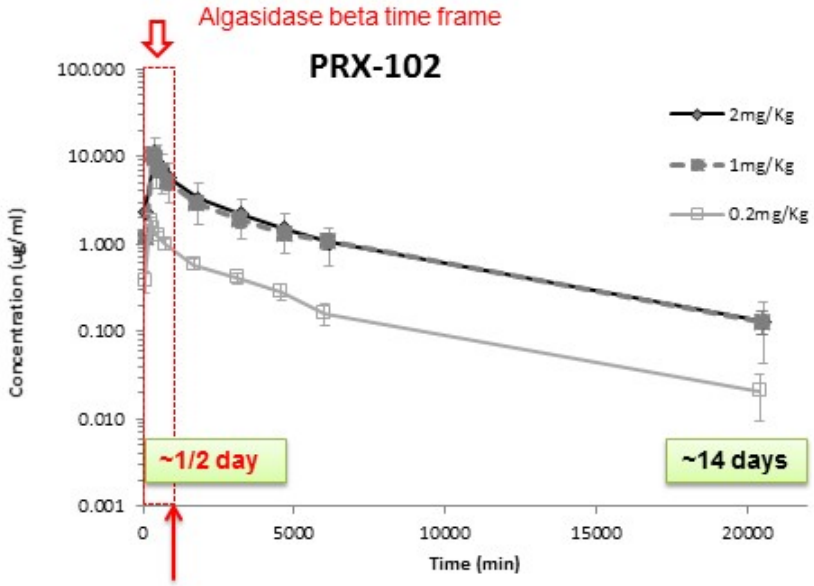
Unique Clinical Benefits Shown in Patients (~15 patients' years)

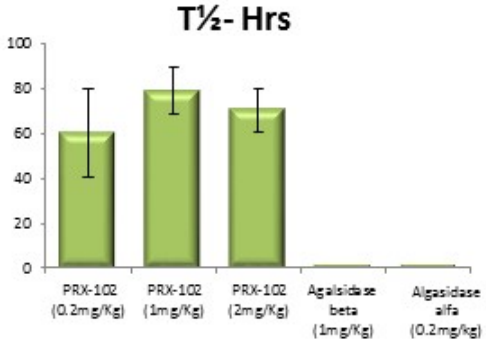
1. PRX-102 has enhanced pharmacokinetic properties including a half-life (T½) of approximately 60 hours and a substantially higher AUC
2. PRX-102 is well tolerated with favorable safety profile
   - The majority of adverse events being mild and moderate in severity
3. Only 19% treatment induced antibody formation
4. Strong indication for immune tolerance
5. Reversal of eGFR slope achieved suggesting improvement in kidney function
6. Translocation to target organ demonstrated by Gb3 inclusion; reduction in kidney peritubular capillaries was substantially reduced

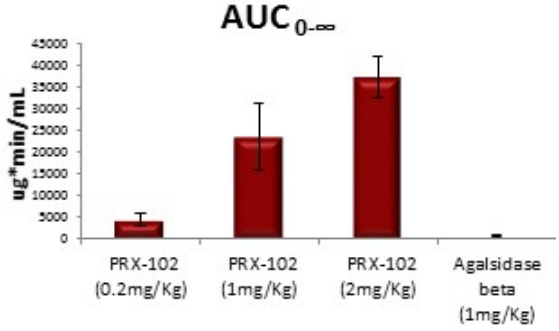
Additional Efficacy Results

- A favorable trend was observed in Gastrointestinal Symptoms Assessment using the Gastrointestinal Symptoms Assessment questionnaire (GSA)
  - Severity and frequency of abdominal pain
  - Frequency of diarrhea
- All patients exhibited stable cardiac function (LVM, LVMI and EF)
- Mean reduction of plasma Gb3 and Lyso-Gb3
- Reduction in the total score of Mainz Severity Score Index (MSSI)
  - General, neurological, cardiovascular and renal systems

Enhanced Pharmacokinetics







Favorable Safety Profile: Very Low Formation of Antibodies

- Adverse Events: (~15 patients' years)
  - 98% AEs mild and moderate
  - 2% severe, 1% was treatment related
  - 27% were considered related or possibly related
  - 2 serious AE: 1 treatment related

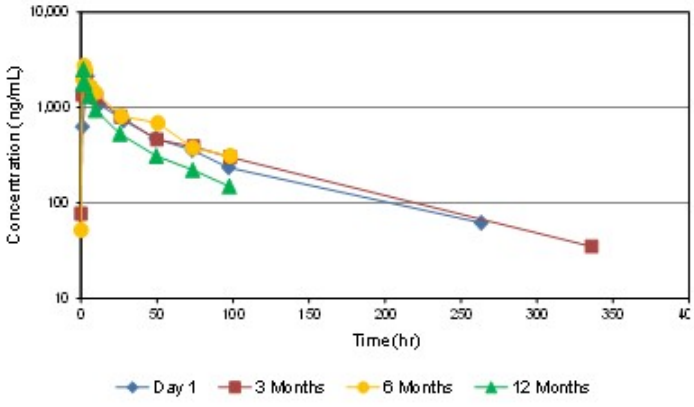
- Antibodies:
  - Low incidence with low titers of antibody formation
  - Only 19% (3 patients) antibody positive had treatment induced ADA
    - 2/3 of the above patients had neutralizing antibodies in some samples

Immune Tolerance

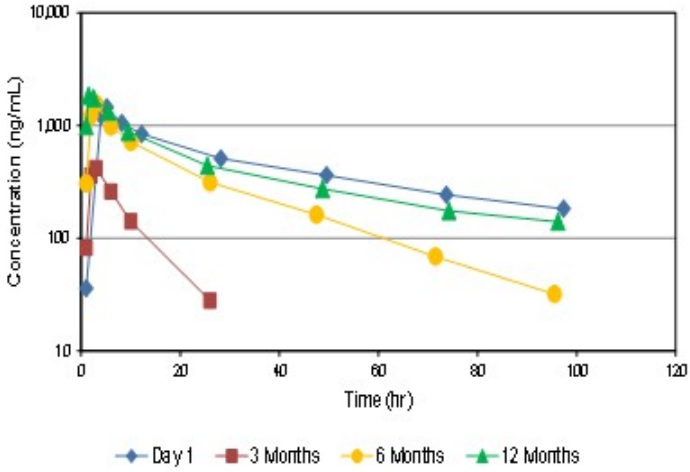
- PRX-102 unique and enhanced PK properties potentially contributing to an immune tolerance phenomenon
- Transient and reversible shift of overall drug availability in antibody positive patients
- Low incidence of antibody formation with low titers which are reduced by 1 year of treatment

Immune Tolerance

Representative of PK of antibody negative patients



Representative PK of ADA positive patients



Reversal in eGFR Slope Achieved Suggesting Improvement in Kidney Function

Population	Annualized Rate of Estimated GFR Change (mL/min/1.73 m^2/year) (95% Confidence Interval)
(*Rombach et al., (2014)*	
Untreated Males, GFR>60	-3.00 (-3.20, -2.80)
ERT Treated Males, GFR>60	-2.57 (-3.21, -1.93)
PRX-102 Phase 1/2	
PRX-102 treated males GFR>60 (0.2mg/kg)	0.16 (-0.18, 0.60)
PRX-102 treated males GFR>60 (1.0 mg/kg)	0.72 (-0.94, 3.08)

Natural course of Fabry disease and the effectiveness of enzyme replacement therapy: a systematic review and meta-analysis Effectiveness of ERT in different disease stages

Saskia M. Rombach & Bouwien E. Smid & Gabor E. Linthorst & Marcel G. W. Dijkgraaf & Carla E. M. Hollak
J Inherit Metab Dis (2014) 37:341–352

PRX-102 Development Plan

Clear Path for BLA submission

- Phase 1/2 - Interim reports to date
- FDA - End of phase II meeting held, minutes received
- Plan to submit SPA for final study design in December 2015

Outlines are developed with lead KOLs including :

D. Warnock, D. Hughes, R. Schiffmann among others

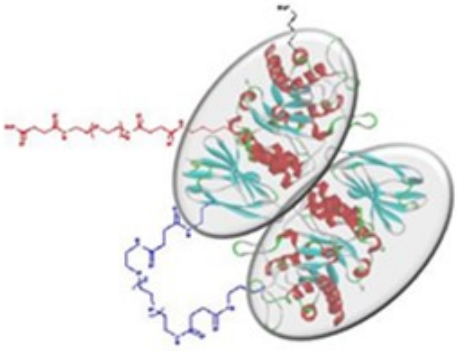
Studies to support BLA per FDA End of Phase II meeting

- On-going naïve study
- Placebo control study in naïve population, ~6 month duration
- Head-to-head superiority study of PRX-102 vs Fabrazyme
  - ~24M study with interim safety analysis to support marketing authorization

The Need for Alternative Treatments for Fabry Disease

Prof. Raphael Schiffmann

Metabolic Disease, Baylor Research Institute, Dallas



Specific Therapy for Fabry Disease

- Currently only one enzyme replacement therapy (ERT), Fabrazyme® (Genzyme), is approved in the US
- A second one, Replagal® (Shire), is approved outside the US
- Randomized controlled trials of either product have not shown a clinical effect

Limited Benefit of Current ERTs for Fabry Disease

Cumulative evidence from open label studies of approved ERTs in adults has shown a limited effect to date

- Limited effect in slowing progression of renal disease
- Decreases gastrointestinal symptoms
- Possibly some stabilization of the peripheral neuropathy
- Diminishing left ventricular hypertrophy – significance unclear
- No other effect on the heart (e.g., rhythm and conduction abnormalities)
- Incidence of stroke is not reduced
- No demonstrated delay or prevention of major clinical events such as death

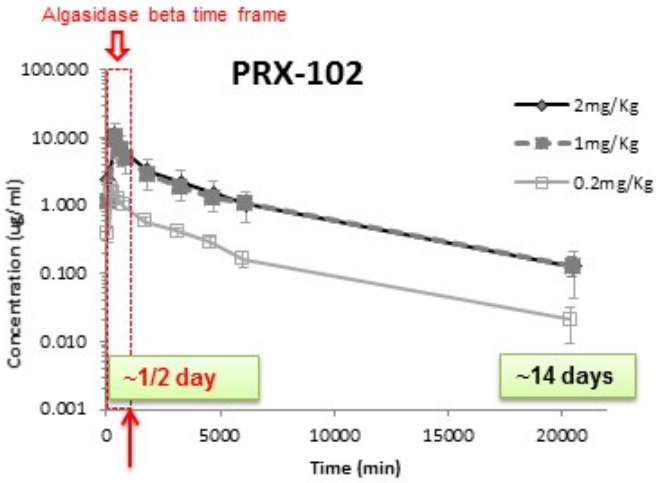
Shortfalls of Current ERT

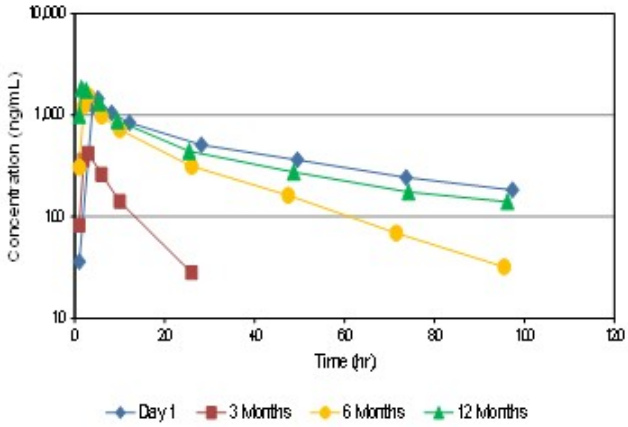
- Not given often enough – patient not protected in the second week due to short half-life
- High incidence of Neutralizing antibodies
- ERT does not gain access to all cells in all relevant organs in sufficient amount
- ERT likely initiated too late in life

Potential Benefits and Improvements of PRX-102 for Fabry Treatment

- Unique PK profile suggesting a better two week coverage to patients and potentially better penetration to target organs
- Excellent safety profile couple with very limited formation of antibodies
- Very promising results across all disease parameters seen from the Phase I/II trial
- Regulatory endorsement to move into Phase III development

Potential Benefits to Patients Derived from PRX-102 Unique Characteristics





Unique PK profile suggesting a better two week coverage to patients and potentially better penetration to target organs

Limited formation of antibodies➔ immune tolerance

Phase III Clinical Trials – Attractive to Patients and Physicians

- Favorable safety and efficacy profile from results to date will encourage patients and doctors to participate
- For naïve study, relatively short-term trial of up to 6 months with a commitment to all patients to be on PRX-102 through approval
- For head to head study, an attractive alternative for patients currently on ERT
- Kidney biopsies - not required
- Little to no alternatives, especially in the US

Summary

- There is a clear need for a better ERT for Fabry patients
- PRX-102 seems to have the potential to meet such demand based on its unique enzyme characteristics including PK profile and clinical results to date
- The company has a clear path forward to support full approval

Conclusion

- Superiority profile of PRX 102 is being built over time in number of layers:
  - Favorable Safety Profile with limited need for pre medication
  - Excellent immunogenicity profile with limited formation of antibodies
  - Favorable trend in kidney function
  - Immune tolerance phenomena is being observed in long-term data, resulting in a transient and reversible shift of overall drug availability
  - Meaningful clinical benefit as measured by change in eGFR data