#### 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): September 11, 2013

Protalix BioTherapeutics, Inc. (Exact name of registrant as specified in its charter)

Florida (State or other jurisdiction of incorporation) 001-33357 (Commission File Number) 65-0643773 (IRS Employer Identification No.)

20100

2 Snunit Street Science Park, POB 455 Carmiel, Israel (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))

D 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 September 11, 2013, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that it intends, subject to market conditions, to offer and sell \$60 million principal amount of its convertible senior notes due 2018 (the "Notes") through a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The Company expects to grant the initial purchaser an option to purchase up to an additional \$9 million principal amount of Notes, exercisable for 30 days after the pricing date of the notes offering. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering. A copy of the press release is furnished as Exhibit 99.1.

A copy of the Company's Management Presentation is furnished as Exhibit 99.2 to this Item 7.01.

The information contained in Item 7.01 of this report and in Exhibits 99.1 and 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

#### Item 9.01. Financial Statements and Exhibits

#### (d) Exhibits

- 99.1 Press release dated September 11, 2013.
- 99.2 Investor Presentation.

#### 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: September 11, 2013

By:/s/ David Aviezer, Ph.D.Name:David Aviezer, Ph.D.Title:President and Chief Executive Officer



#### Protalix BioTherapeutics Announces Proposed \$60 Million Offering of Convertible Notes

CARMIEL, Israel, September 11, 2013 //GlobeNewswire - Protalix BioTherapeutics, Inc. (NYSE MKT:PLX, TASE:PLX) announced today that it intends, subject to market conditions, to offer and sell \$60 million principal amount of its convertible notes due 2018 (the "notes") through a private offering. The Company expects to grant the initial purchaser an option to purchase up to an additional \$9 million principal amount of notes, exercisable for 30 days after the pricing date of the notes offering. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

The notes will be unsecured, unsubordinated obligations of the Company, and interest will be payable semi-annually. The interest rate, initial conversion rate and other terms and conditions of the notes will be determined by the Company and the initial purchaser of the notes at the time of pricing of the notes. The notes may be converted at the option of holders into shares of the Company's common stock at any time prior to the close of business on the business day immediately preceding the stated maturity date of the notes.

The Company intends to use the net proceeds from this offering to fund clinical trials for its product candidates, to fund its research and development activities, to enhance its manufacturing capacity and for working capital and general corporate purposes.

The offering is being made to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). This announcement is neither an offer to sell nor a solicitation of an offer to buy any of these securities and shall not constitute an offer, solicitation, or sale in any jurisdiction in which such offer, solicitation, or sale is unlawful. Any offer of the securities will be made only by means of a private offering memorandum. The notes and the shares of common stock issuable upon conversion of the notes, if any, will not be registered under the Securities Act or any state securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act and applicable state laws.

#### 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, by Israel's Ministry of Health in September 2012, by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013, by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in April 2013, and by the regulatory authorities of other countries. Marketing applications for taliglucerase alfa have been filed in additional territories as well. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of taliglucerase alfa, excluding Israel and Brazil, where Protalix retains full rights. Protalix's development pipeline also includes the following product candidates: PRX-102, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; PRX-105, a pegylated recombinant human acetylcholinesterase in development for several therapeutic and prophylactic indications, a biodefense program and an organophosphate-based pesticide treatment program; an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, also for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel®) for the treatment of Cystic Fibrosis; PRX-107 for the treatment of emphysema due to hereditary alpha1-antitrypsin deficiency; 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 "anticipate," "believe," "estimate," "expect," "plan" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. Drug discovery and development involve a high degree of risk. Factors that might cause material differences include, among others: risks relating to our ability to complete the proposed offering in a timely manner, if at all; risks relating to the sufficiency of the funds raised in the proposed offering, if any; risks relating to our use of the net proceeds from the proposed offering; risks related to the commercial sales of taliglucerase alfa in jurisdictions where it has been granted marketing approval; failure or delay in the commencement or completion of our preclinical studies and clinical trials which may be caused by several factors, including: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; 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 the clinical trials; the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy, that our product candidates will not have the desired effects or will include undesirable side effects or other unexpected characteristics; 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; 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; risks related to the potential infringement of a third party's patents or other intellectual property rights; the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third parties; risks of securing adequate levels of product liability and clinical trial insurance coverage; and other factors described in our filings with the U.S. Securities and Exchange Commission. These forward-looking statements are based on current information that may change and you are cautioned not to place undue reliance on these forward-looking statements. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information. All forward-looking statements are qualified in their entirety by this cautionary statement.

#### **Investor Contact**

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



## Protalix BioTherapeutics Roadshow Presentation

September 2013

David Aviezer, Ph.D., MBA President & Chief Executive Officer Yossi Maimon, CPA, MBA Chief Financial Officer

### PROTALIX 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 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.

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### **Protalix Investment Thesis**

Approved Biologic Drug	<ul> <li>FDA approval of ELELYSO<sup>™</sup> – May 1, 2012</li> <li>Israel MOH approval – September 27, 2012</li> <li>Brazil ANVISA approval – March 18, 2013</li> </ul>	rew eleiyso (talglucerase alfa) for injection Plant based. People focused.			
Strong Commercial Partners	<ul> <li>Collaboration with <i>Ppzer</i> for ELELYSO<sup>™</sup> commercialization</li> <li>Rights for Israeli and Brazilian market fully owned by Protalix</li> <li>Long-term commercial agreement with Brazilian Government</li> </ul>				
Attractive Platform	<ul> <li>Plant cell-based protein expression system – <i>ProCellEx</i><sup>®</sup></li> <li>Significant advantages over existing expression systems</li> </ul>				
Promising Pipeline	<ul> <li>PRX-102 Fabry disease – IND approved – Phase I/II ongoing</li> <li>PRX-112 Gaucher Oral treatment – Phase I ongoing</li> <li>PRX-110 for Cystic Fibrosis</li> <li>PRX-107 for AAT deficiency</li> <li>Oral Anti-TNF (PRX-106) for the treatment of various inflammatory diseases</li> </ul>				
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### **Protalix Pipeline**

Compound	Indication	Research	Pre clinical	Phase I	Phase	Phase Ⅲ	Approved	Partner	Market
taliglucerase alfa (i.v.)	Gaucher Disease						$\rightarrow$	Pfizer	>\$1.25B
PRX-105 (Acetyl Cholinesterase)	Biodefense & CNS								>\$700M
PRX-102 (Alpha Galactosidase)	Fabry Disease			*					~\$900M
PRX-112 (Oral Glucocerebrosidase)	Gaucher Disease			•					>\$1.25B
PRX-110 (DNase I)	Cystic Fibrosis		->						>\$570M
PRX-107 (Alpha 1 Anti Trypsin)	AAT deficiency		$\rightarrow$						>\$600M
PRX-106 Oral (Anti-TNF fusion protein)	Autoimmune Inflammatory		-						~\$8B
PRX-111	Enzyme Replacement	$\rightarrow$							>\$600M
PRX-113	Enzyme Replacement	$ \rightarrow $							~\$500M

\* Phase I/II study 4
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### **ProCellEx®** Proprietary Technology Platform

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### **Key Advantages**

- Cost effectiveness and scalability
  - · Flexible polyethylene bioreactors, low initial capital investment
  - · Rapid, horizontal scalability at low cost in compliance with cGMP
  - Requires less costly "hands-on" maintenance
- Safety and potency
  - · Free of any mammalian components
  - No risk of mammalian viral transmission or infection
  - Hundreds of patients have been treated worldwide
- Potentially enables penetration of certain patent protected markets
  - May avoid infringement on method-based patents of other proteins developed with mammalian cell expression systems







# PROTALIX Biotherapeutics Current Market Dynamics

Growing Market	Lucrative Market	Competition*
• Approximately 12,000 patients worldwide	<ul> <li>Orphan disease supports premium pricing</li> </ul>	• Cerezyme® (Sanofi- Genzyme) is the major
<ul> <li>Approximately 6,000 patients are being treated</li> </ul>	<ul> <li>Chronic therapy</li> <li>Concentrated group of prescribers</li> </ul>	recombinant GCD on the market and is made in mammalian CHO cells
<ul> <li>~50% global market penetration</li> </ul>	<ul> <li>Annual treatment cost is ~\$250,000 per year</li> <li>Growing market with estimated annual \$1.25 billion of enzyme sales</li> </ul>	• VPRIV® (Shire), a recombinant GCD produced in human cancer cells, approved in US and EU

\*Zavesca @ (Actelion) is a small molecule drug approved for the treatment of Gaucher disease, however usage is extremely limited due to significant side effects

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### **ELELYSO:** Approval Status

### **United States**

- U.S. FDA approved enzyme replacement therapy for the long-term treatment of adults with a confirmed diagnosis of type 1 Gaucher disease
- Priced in the U.S. 25% below the cost of Cerezyme®

### Israel

- September 27, 2012 Approved by Israeli Ministry of Health
- January 2013 Added to the national health basket for 2013
- The Company is currently marketing ELELYSO in Israel at a competitive price compared to other products

### Brazil

- August 2010
  - Pfizer entered into a \$30 million short-term supply agreement with the Ministry of Health of Brazil.
     Protalix and Pfizer have provided ELELYSO to the Ministry of Health of Brazil for the treatment of Gaucher patients
- March 18, 2013
  - Approved by ANVISA in Brazil
- June 2013
  - Agreement signed in which Brazilian government will purchase Elelyso from Protalix in return for technology
  - At the end of a 7-year technology transfer, Protalix will transfer the production technology to Fiocruz (arm of Brazilian Ministry of Health)
  - In return, Brazil MOH is required to buy at least \$40 million of the drug each year during the agreement's 7-year term
  - The arrangement can be extended for an additional 5 more years if the tech-transfer is not complete



### ELELYSO: Commercialization Agreement with Pfizer

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### Terms

 Pfizer and Protalix share net profit and net loss of ELELYSO on a 60% / 40% basis. Only certain limited capped expenses allowed

### Territories

- · Pfizer retains exclusive worldwide rights outside of Israel and Brazil
- Protalix retains exclusive commercialization rights in Israel and in Brazil

### Manufacturing

Protalix manufactures ELELYSO Drug Substance

### **Oral Gaucher treatment**

Protalix retains full global rights to oral GCD program



### **ELELYSO**

### **Gaucher Personal Support**

- Reimbursement support
  - Help with benefit verification and pre-authorization for treatment
  - \$0 out-of-pocket costs for eligible patients
- · Infusion support
  - Assists with administration of at-home infusions
  - · Schedules transportation to and from infusions and helps coordinate infusions while traveling
- Ongoing support
  - Designated case manager
  - Nurses and pharmacists are available 24/7 to answer questions
  - Pfizer dedicated patient affairs liaison

### **Supply Continuity Program**

- To help minimize supply disruptions, Pfizer plans to maintain a rolling 24 months of supply at various stages of production around the world for US patients prescribed ELELYSO
- This program was developed to help fill a need within the Gaucher community
- Pfizer regularly verifies patient demand as part of the monthly planning process for ELELYSO and can rapidly scale production





### ELELYSO: Approved in Israel

- Approved by Israeli Ministry of Health September 27, 2012
- Approved for reimbursement via the national health basket as

### of January 2013

- Agreements in place with payers
- Currently, for the first quarter of commercial sales in Israel, ELELYSO has generated \$1.0M and for the second quarter, \$1.4M
- Additional patients are still being treated in clinical trials
- The Company is marketing ELELYSO in Israel at a competitive price compared to other products



## PROTALI ELELYSO / UPLYSO<sup>™</sup>: Brazil

- Protalix and Brazil's Ministry of Health enter into supply and technology transfer agreement for UPLYSO (Marketing name in Brazil)
- Fiocruz (an arm of the Brazilian Ministry of Health) is required to complete purchase of at least ~\$280 million worth of UPLYSO to reach the final stage of the transfer of Protalix technology

### **Deal Terms**

- Fiocruz is committed to purchase ~\$40M of UPLYSO over the first 2 years
- Each subsequent year a minimum purchase of ~\$40M of UPLYSO is required or Protalix has the right to terminate the agreement
- Fiocruz is obligated to purchase
   ~\$280M of UPLYSO before Protalix is
   obligated to complete the technology
   transfer

### **Financial Benefits**

- · Creates partnership with one of world's growing economies
- · Lucrative economics and steady cash flow for Protalix
- Ability to generate visible, meaningful revenues on limited operational expenses
- · Relatively short penetration period into the market
- · Eliminates the need to participate in bids
- · Secures prices over a long period

### Drug Supply / Technology Transfer Description

- Throughout the entire agreement, Fiocruz and MOH will support and distribute UPLYSO in Brazil
- Upon completing all four stages which include performing a clinical study, Fiocruz will be able to produce UPLYSO for the Brazil market on its own
- After the technology transfer is complete, Protalix will receive mid-single digit royalties on net sales by Fiocruz



### **PRX-102 for Fabry Disease**



### **Fabry Overview**

### **Disease Overview**

- · Fabry Disease
  - Second most common lysosomal storage disease
  - Accumulation of Gb3 (α-Galactosidase-A substrate) causes multiple system disorders
  - Main target organs affected heart, kidney and brain
- α-Galactosidase-A
  - A non-covalently linked Homo-dimer of 404aa each (~96 KDa)
  - A lysosomal hydrolase that cleaves a terminal Glactose from glycolipids/glycoproteins

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### **Market Dynamics**

- Annual cost of treatment ~\$200,000/patient
- Diagnosis rate is rapidly growing (CAGR = 12.8%)
- 2012 Market : ~\$900M
- · Fabrazyme approved in US and EU
- · Replagal approved only in EU



### PRX-102: Potential Best-in-Class Fabry Treatment

### Enzyme Kinetics - Michaelis Menten Kinetics



Sample	<i>К</i> м (µМ)	V <sub>max</sub> (µM/min)	k <sub>cat</sub> (sec <sup>-1</sup> )	<i>k</i> <sub>cat</sub> / <i>K</i> <sub>M</sub> (sec <sup>-1*</sup> mM <sup>-1</sup> )
Replagal®	4443	3.31	52.96	0.011
PRX-102	3285	3.72	59.53	0.018

PRX-102 exhibits somewhat better kinetic properties compared to commercial enzyme

#### Improved Pk

#### Enhanced Circulatory Half-life



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### PRX-102: Potential Best-in-Class Fabry Treatment

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Bio-distribution and efficacy of PRX-102 in Fabry mice following repeat dosing

### Experiment

Four injections once every two weeks with either  $2_{mg/kg}$  of PRX-102 or placebo



Gb3 clearance from tissues following repeated administration of PRX-102 or placebo



### PRX-102: Potential Best-in-Class Fabry Treatment

### Improved In-vivo Activity: PRX-102 vs. Replagal



### PRX-102 exhibits higher activity levels in target organs over time in Fabry mice after a single injection





PROTALIX PRX-102: Clinical Perspectives

### **Clinical Development Progress**

- Aug 2012 Protalix Received FDA clearance of Investigational New Drug (IND) application
- · Multi-center submissions to IRBs -Ongoing
- Phase I/II trial in Fabry Patients Initiated under IND
- Ongoing phase I/II trial in Fabry patients
- · Patients currently being treated and/or recruited in sites in the United States. South America, United Kingdom and Australia

### **Clinical Plan Outline**

- Phase I/II
  - 18 patients (6/group), IV infusion once every two weeks
  - 3 doses (0.2mg/Kg, 1 mg/Kg, 2 mg/Kg)
  - Duration: 12 weeks (7 infusions, 3 months)
- Extension study
  - 18 patients, IV infusion once every two weeks, at same doses as in Phase I/II
  - Duration Total: 38 weeks (20 infusions, 9 months)
- Study evaluation
  - Skin and kidney biopsies + cardiac MRI (after 6 months)







### **PROTALI** Biotherapeutics

## GCD Enzyme Oral Delivery

### Protein Oral Delivery Advantages

- · Oral delivery of therapeutic proteins
  - Long-time goal of the biopharmaceutical industry
  - Currently only very limited success
- · The plant cell advantage
  - The concept: plant cell wall (cellulose) serves as protective agent against the gastric environment and can serve as an oral administration vehicle

### **PK Experiments in Rodents**





### PROTALI PRX-112: Plant Cell Expressed GCD for Oral ERT

### Overview

- · Edible carrot cells expressing recombinant human glucocerebrosidase (prGCD)
- ٠ Same genetically modified carrot plant root cells from which the approved drug ELELYSO (taliglucerase alfa) is purified
- · Carrot cells contain "ready to use" enzyme
- Once in blood, enzyme is expected to act like approved IV administered ELELYSO
- PRX-112 carrot cells are prepared as a drink . for "patient friendly" administration

### **Development Status**

- · Study conducted under Israeli MOH approval
- Study performed in Shaarei Zedek (Jerusalem) and Rambam (Haifa) medical centers in Israel
- Scheduled study completion Q3 2013
- Study Report Q4 2013

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### Phase | Study

Design - An exploratory, open-label study to evaluate the safety of PRX-112 and pharmacokinetics of oral prGCD in Gaucher patients

Study Main Aim - Detection of prGCD in circulation after oral administration Strategy:

- · Evaluation in Gaucher patients
- Inclusion criteria no detection of prGCD in plasma .
- Collection of blood samples at short intervals over 30hrs .
- · Assessment of prGCD in plasma
- Assessment of prGCD in circulating mononuclear cells

### Initial Observations

- No drug related safety events
- Good compliance
- Initial detection of orally-administered active enzyme in the circulation



### PRX-106: Overview

### **Anti-TNF Protein**

Enbrel® (etanercept) product overview:

- Mode of action: a competitive inhibitor of TNF
- · Expression platform: CHO
- · Indications: Rheumatoid Arthritis and multiple autoimmune indications
- Market: ~\$8 billion

PRX-106

- Amino acid sequence and MOA is identical to Enbrel<sup>®</sup>
- Promising pre-clinical efficacy data in arthritis (CIA) model

### Plant recombinant Soluble TNFRII

Enbrel® Overview

- Main function: TNFα "trap" for anti-inflammatory indications
- Target protein: Tumor Necrosis Factor (TNF)
- Composition: Chimera of human sTNFRII and Fc (lgG1)
- · Proof-of-Concept study: Collagen induced Arthritis

Anticipated Advantages of Oral delivery of PRX-106:

- Potential of new indications
- · Opens new markets
- · IP advantage
- · Higher patient compliance





### **Colon Pathology**

- · Project Highlights:
  - Oral Plant Cell platform
  - Targets disease site
  - IP advantage
- Expressing PRX-106
- Experiment: TNBS animal model of colitis
  - Induction of inflammation with tri-nitrobenzene-sulfonic acid (TNBS)
  - Mice were fed with plant cells expressing PRX-106
  - Colon damage was assessed on day 4

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### Oral Administration Of Plant Cells Expressing Anti-TNF Fusion Protein (PRX-106) For The Treatment Of Colitis



673+ 5VA PR.S.104

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### PROTALIX Biotherapeutics A

### Orally Administered Plant Cell PRX-106 Alleviates ConA Immune-Mediated Hepatitis

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### **Experiment: ConA liver inflammation model**

- · Mice were fed plant cells expressing PRX-106
- · Mice were then injected with ConA to induce liver inflammation
- · Liver damage was assessed 14 hour after ConA injection
- · ALT and AST Liver enzymes that are markers of inflammation



PROTALIX Oral PRX 106 anti-TNF Summary

### Positive results from two models:

Hepatitis (Con-A model) - Two consecutive experiments (~50 animals)

- Oral PRX-106 reduced inflammation(INFγ and liver enzymes depletion)
- Oral PRX-106 reduced necrosis in the liver

Colitis (TNBS model) – Two consecutive experiments (~60 animals)

- Oral PRX-106 reduced pro-inflammatory Markers (TNFα)
- Oral PRX-106 elevated anti-inflammatory markers (IL10)
- Oral PRX-106 reduced weight loss

### Ongoing experiment:

- Fatty liver (High fat diet model)
- Every two weeks the mice are evaluated for various metabolic markers

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Blood glucose, Body weight, Serum ALT Serum triglyceride





### **Financial Overview and Upcoming Milestones**



### **Financial Status**

\$ in millions		
	Six months ended 6/30/2013	Six months ended 6/30/2012
~ 93.5M Shares Common Stock 0/S 9/15/2013	Unaudited	Unaudited
Cash & Cash Equivalents	\$33.1	\$59.3
Total Revenues	7.0	3.9*
R&D Expenses, net	11.8	15.7
G&A Expenses	4.3	5.1
Net Loss	\$11.2	\$21.3*

\* Excludes \$25M milestone payment received from Pfizer in connection with FDA approval for ELELYSO.





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- ~93.5M shares outstanding (6.30.2013)
- US, Israeli and EU institutional holders
- Publicly traded on NYSE MKT and TASE
- Substantial tax benefits



### Upcoming Milestones Next 12 months

- Receive additional marketing approvals for ELELYSO
- Report data from clinical trial of oral prGCD for Gaucher disease
- Complete recruitment for Phase I/II trial of PRX-102 in Fabry patients

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- Report data from Phase I/II trial of PRX-102 in Fabry patients
- File IND and initiate Phase I clinical trial for additional programs including: Oral anti-TNF, DNAse and AAT

