
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 27, 2011

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.)

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

Attached as Exhibit 99.1 to this Item 7.01 is a presentation that is being used by the management of Protalix BioTherapeutics, Inc. (the “Company”) in meetings describing the Company.

The information contained in Item 7.01 of this report and in Exhibit 99.1 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 of 1933, as amended, 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. 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: January 27, 2011

By: /s/ David Aviezer

Name: David Aviezer, Ph.D.

Title: President and Chief Executive Officer

Protalix BioTherapeutics January 2011

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 our product candidates, goals as to product candidate development and timing of our clinical trials, are based on Protalix'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, the Company's 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. Protalix undertakes no obligation to update or revise the information contained in this announcement whether as a result of new information, future events or circumstances or otherwise.

Late Stage
Biologics Program
Targeting a
Significant Market

- Lead Product taliglucerase alfa indicated for Gaucher disease
- Completed PIII trial and notified of NDA acceptance in July 2010
 - Open-label extension trial ongoing
 - Successful Switchover trial , first stage completed
- Filed for regulatory approval in US (NDA submission completed 4/10), Israel (6/10) Europe (11/10) and Brazil (11/10)
- PDUFA date of February 25, 2011 in US

Best-In-Class
Commercial
Partner

- Collaboration with Pfizer for commercialization of taliglucerase alfa
 - Protalix retains rights in Israel
- Attractive economics with significant potential regulatory milestones

Promising Pipeline

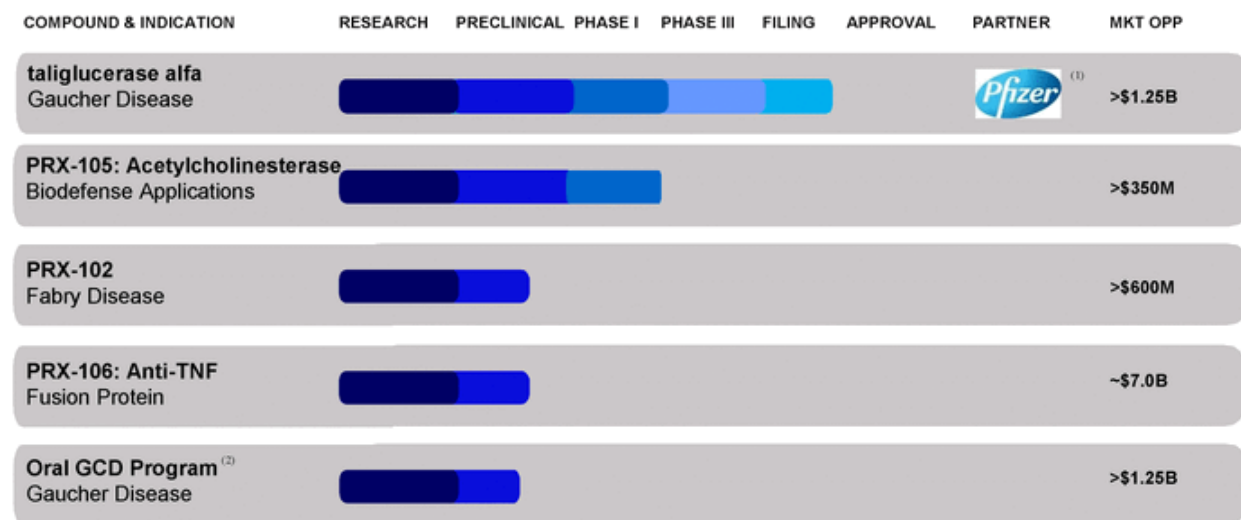
- PRX-105 completed preliminary Phase 1 for potential biodefense and other applications
- PRX-102 for Fabry's disease
- Oral GCD program for Gaucher disease
- PRX-106 for rheumatoid arthritis and other autoimmune indications

Attractive Platform
Technology

- Plant cell-based expression system ProCellEx™
- Offers significant advantages over existing expression systems including cost and safety
- Potentially permits an entry into certain patent protected markets

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Substantial Value in the Pipeline



(1) Protalix retains Israel rights, with Pfizer retaining rights ex-Israel

(2) Protalix retains global rights to oral GCD program

Proprietary Technology Platform: ProCellEx™

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
 - No risk of mammalian viral transmission or infection to cells
 - Hundreds of patients on drug world wide
 - Free of any mammalian components
- Potentially enables penetration of certain patent protected markets
 - May avoid infringement on method-based patents of other proteins developed with mammalian cell expression systems

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Key Milestones and Goals

2010	Expected for 2011
<input checked="" type="checkbox"/> Received Orphan Drug designation in Europe	<input type="checkbox"/> Receive US FDA approval for taliglucerase alfa
<input checked="" type="checkbox"/> Completed FDA submission for taliglucerase alfa	<input type="checkbox"/> Receive marketing approval for taliglucerase alfa from Israeli Ministry of Health
<input checked="" type="checkbox"/> Received PDUFA date for taliglucerase alfa	<input type="checkbox"/> Receive marketing approval for taliglucerase alfa in Europe and Brazil
<input checked="" type="checkbox"/> Completed preliminary PRX-105 Phase 1 study	<input type="checkbox"/> Continue enrollment of patients for taliglucerase alpha in compassionate use programs
<input checked="" type="checkbox"/> Granted temporary authorization for use (ATU) for taliglucerase alfa in France	<input type="checkbox"/> IND and Initiate clinical trials for PRX-102
<input checked="" type="checkbox"/> Preliminary top-line data from taliglucerase alfa Switchover Trial	<input type="checkbox"/> IND and Initiate clinical trials for PRX-106
	<input type="checkbox"/> Advance oral delivery of GCD for Gaucher's disease towards clinical trials

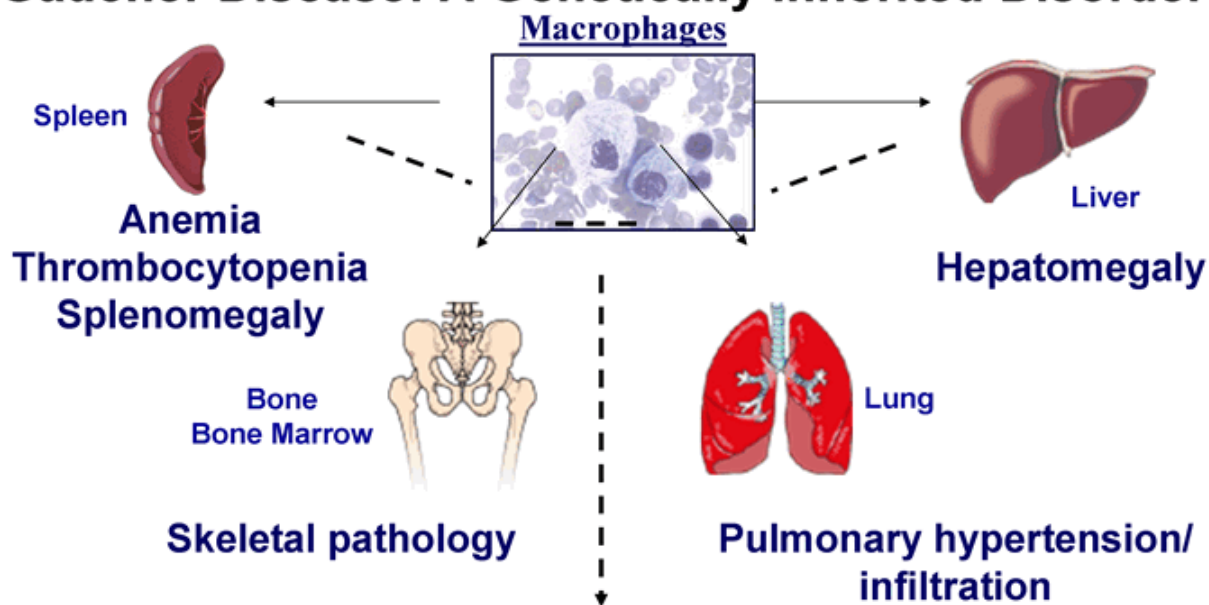
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Taliglucerase alfa

Gaucher Disease Background

- Autosomal recessive disorder caused by mutations in the GBA gene which result in a deficiency of the lysosomal enzyme beta-glucocerebrosidase
- Patients accumulate large quantities of glucocerebroside in the spleen, liver, lungs and bone marrow that prevent these organs from functioning properly
- Enzyme replacement therapy is the current standard of treatment. If untreated, patients experience a poor quality of life and death can occur prematurely
- Higher prevalence among Jews from European origin and occurs at any age in life

Gaucher Disease: A Genetically Inherited Disorder



Outcome: Death - Poor quality of life

Gaucher Disease: Current Market Dynamics

Growing Market

- ~10,000 patients worldwide
- Around ~5,500 patients are being treated
- ~50% global market penetration

Lucrative Market

- Orphan disease supports premium pricing
- Chronic therapy
- Concentrated group of prescribers
- Annual treatment cost is ~\$250,000 per year
- Growing market with annual \$1.25 billion of enzyme sales

Competition*

- Cerezyme® (Genzyme) is the major recombinant GCD on the market and is made in mammalian CHO cells
- Velaglucerase (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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Phase III Pivotal Trial Under SPA with FDA

Design

- Multicenter, world-wide, randomized, double blind, parallel groups, dose-ranging study in 31 untreated patients with significant symptoms of Gaucher disease
- Patients randomized to one of two dose arms, 30 U/Kg or 60 U/kg, bi-weekly dosing for 9 months

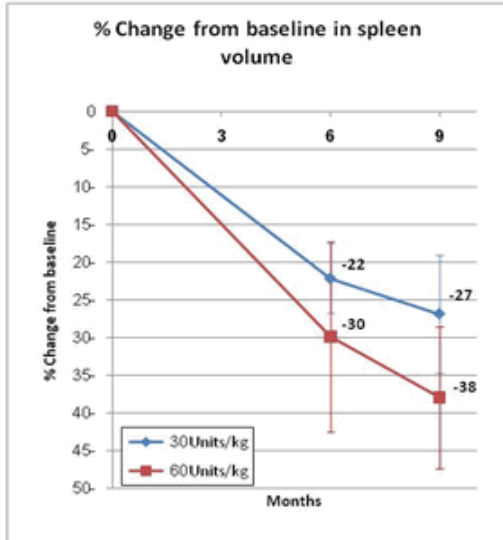
Endpoints

- Primary: Mean decrease in spleen volume
- Secondary: Decrease in liver volume, increase in hemoglobin, increase in platelet count

Met Primary Endpoint of % Change in Spleen Volume

MRI validated method-2 blinded readers

Intra-reader variability $\leq 0.5\%$; Inter-reader variability $\leq 1.00\%$



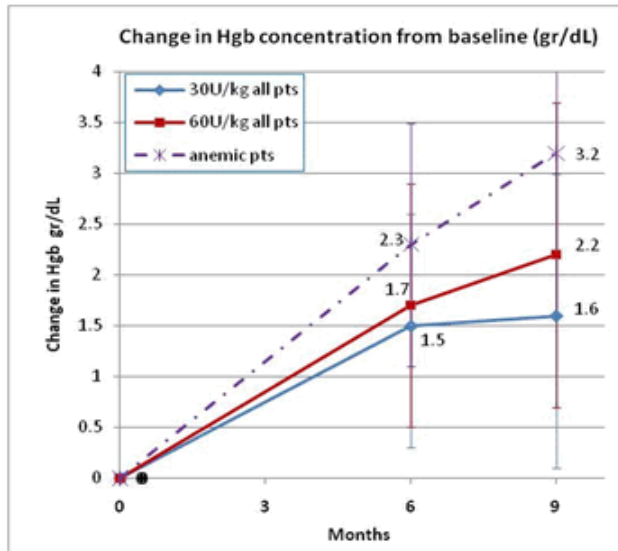
		30 Units/kg	60 Units/kg
		N=15	N=16
9 Months	Mean	-26.91% \pm 7.79*	-38.01% \pm 9.38*
	Median	-27.85	-37.63
	Range	-42.60 to -15.58	-56.30 to -20.04
Baseline	Mean	15.4X	16.6X
X Normal			
9 Months	Mean	11.3X	10.9X
X Normal			

Range of Spleen volume at baseline 8X – 54X

* P-value < 0.0001

End point was achieved after 6 months in both dose groups

1st Major Secondary endpoint: Change in Hemoglobin (g/dL) From Baseline - ITT vs. Anemic patients



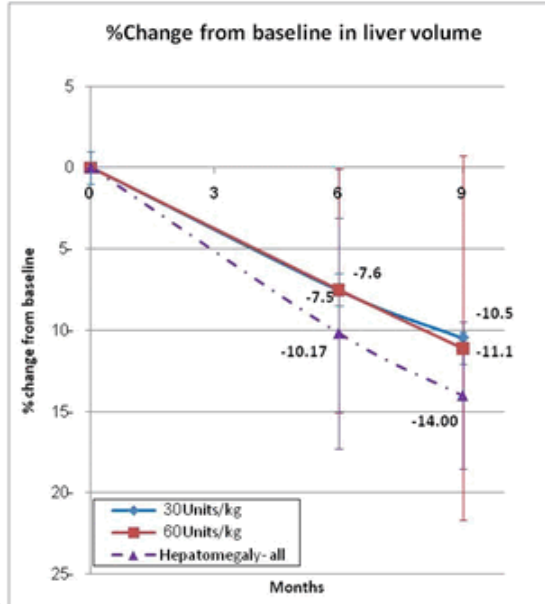
	ITT n= 31	30 Units/kg n = 15	60 Units/kg n = 16
9 months	Mean g/dL	1.6 ± 1.4	2.2 ± 1.4
	Median	1.3	1.6
	P-value	0.0010*	<0.0001*
9 months	% change	14.8%	22.2%

	ITT n = 31	30 U/kg n = 15	60 U/kg n = 16	Anemic pts n = 10
9 months	Mean g/dL	12.4 ± 1.7	11.4 ± 2.6	9.5 ± 1.6
	Median	12.7	10.7	10.2
9 months	% change	14.8%	22.2 %	36%

Both anemic and non anemic patients showed an increase in Hb

2nd Major Secondary Endpoint: Liver Volume % Change from Baseline

MRI validated method-2 blinded readers
Intra-reader variability $\leq 0.5\%$; Inter-reader variability $\leq 1.00\%$

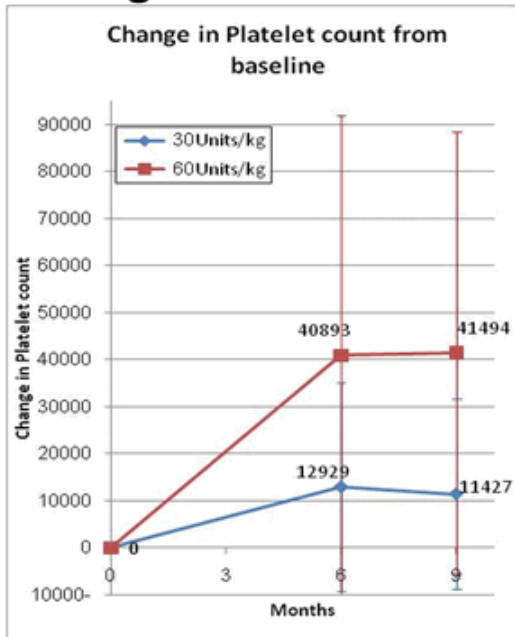


		30 Units/kg	60 Units/kg
9 Months (absolute values)	Mean	2564.07	2190.99
	SD	559.57	376.70
	Median	2473.19	2098.13
	Range	2000.33 - 4121.94	1654.07 - 2894.12
9 Months (%change from baseline)	Mean	-10.48%	-11.11%
	SD	11.27	6.68
	Median	-13.87	-12.25
	P-value	0.0041*	<0.0001*

16 (52%) of the patients who presented hepatomegaly showed a reduction of 14% on liver volume

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3rd Major Secondary Endpoint: Platelet Counts Change from Baseline



Baseline range 27,000/ ml – 163,000/ml

		30 Units/kg	60 Units/kg
9 Months	Mean	N=15	N=16
(change	SD	11427	41494
from	Median	20214	47063
baseline)	Range	10000	38000
	P-value	-25000 to 59000	-15000 to 186000
		0.0460*	0.0031*
9 Months	% change	13.7%	72.1%

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Phase III Safety Results

- No serious adverse events
- All AEs were mild or moderate in intensity and the majority of the events spontaneously resolved
 - Headache; hypersensitivity; dizziness; muscle spasm; chest discomfort; nausea; skin irritation; arthralgia
- No neutralizing antibodies to taliglucerase were detected
- 6% of the patients developed IgG antibodies to taliglucerase alfa
 - These patients completed the study and are being treated in the extension study
- 6% of the patients developed hypersensitivity reaction
- No anti-taliglucerase antibodies detected in the patients who experienced hypersensitivity

Switchover Study

Overview

- Multicenter, open-label, switchover trial of taliglucerase alfa
- To assess the efficacy, safety, and lack of deterioration in Gaucher patients currently treated with Cerezyme®
- After 9 months of treatment, patients are enrolling in the extension study
- First stage of study is completed. Data lock on October 2010
- The trial remains open to a few pediatric patients
- Preliminary Results to be presented at the WORLD conference, Las Vegas, NV in February by Dr. Greg Pastores, NYU medical Center.

Results

- Patients switched from imiglucerase (doses ranging from 10-60 U/kg every other week) to equivalent dose using same number of units of taliglucerase alfa
- Data from first 15 patients demonstrate maintenance of efficacy achieved over a nine month period with no increased safety concerns.
- Hemoglobin and platelet counts remained stable demonstrating hematological stability
 - As measured by MRI, mean spleen volume and liver volume also remained stable
- No evidence of increased safety concerns in patients switched from Cerezyme® to taliglucerase alfa
- No drug-related serious adverse events or hypersensitivity reactions
 - One patient developed non-neutralizing IgG antibodies to taliglucerase at the end of the study

Regulatory Status

- Rolling NDA submission filed with FDA
 - February 25th, 2011 PDUFA date
- Submission to Ministry of Health in Israel
 - Information dossier submitted
 - GMP audit of manufacturing facility performed
- Submission of MAA to EMEA in Europe November 2010
- Submission to ANVISA in Brazil November 2010
- Additional submissions in Rest of World in process

Expanded Access Program Overview

- FDA requested submission of a treatment protocol allowing expanded access to taliglucerase alfa in adult patients with Gaucher disease resulting from the shortage of Cerezyme
 - Protocols approved by FDA and EMEA
 - Patient enrollment on-going in clinical centers around the world
 - Under a treatment protocol (US and Israel); and
 - Compassionate use program (EU, Brazil, ROW)
- Patients treated in France under ATU program (temporary approval) – Paid by French Government
- Hundreds of patients on taliglucerase world wide

Brazil Program

- Total estimate of around 600 Gaucher patients previously treated in Brazil
- On 8/10/2010, Pfizer entered into a \$30 million short-term supply agreement with the Ministry of Health of Brazil
 - Protalix and Pfizer have provided taliglucerase alfa to the Ministry of Health of Brazil for the treatment of patients with Gaucher disease
- In addition, we and the Ministry of Health of Brazil are in discussions relating to a possible long-term supply agreement that contemplates, among other matters, providing certain components of Protalix's manufacturing technology to the Ministry of Health of Brazil for implementation by it in Brazil
 - At this time, we are unable to assess whether these discussions will result in an agreement

Commercialization Strategy: Collaboration

- **Terms**

- Upfront payment of \$65 million
- Additional near-term regulatory milestone payments of up to \$50 million
- Pfizer and Protalix to share net profit and net loss of taliglucerase alfa on a **60% / 40 %** basis to Protalix. Certain limited capped expenses

- **Territories**

- Pfizer retains exclusive worldwide rights outside of Israel
- Protalix retains exclusive commercialization rights in Israel ⁽¹⁾

- **Manufacturing**

- Protalix to manufacture taliglucerase alfa

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(1) Protalix retains global rights to oral GCD program.

Manufacturing and Capacity

- Completed GMP Manufacturing Audits by FDA and Israel's Ministry of Health during, 2010
- EMEA and ANVISA audits are prerequisite for approval
- Current facility can supply over 1000 patients
- Currently building up launch inventory
- Expansion of manufacturing facility in process with an estimated cost of ~\$25M

Taliglucerase Milestones Over the Next 12 Months

- PDUFA in US (February 25, 2011)
- Potential approval in Israel
- Potential approval in Europe
- Potential approval in Brazil
- Additional data from Switchover study
- Filing for Approval in additional territories around the world

Pipeline Overview

PRX-105: Biodefense

Overview of Acetylcholinesterase

- An enzyme present within the synaptic cleft that hydrolyses acetylcholine to choline and acetic acid
- Protalix has expressed this enzyme and confirmed biological activity in several in-vitro and in vivo assays
- In development for highly lucrative biodefense market and several other pharmaceutical clinical applications
- Preliminary phase I Clinical Trial of Acetylcholinesterase for biodefense indications has been performed under FDA and Israeli MOH approval
- Current Status: Ongoing discussions with government agencies

Preliminary Phase I Study Results

- PRX-105 was well tolerated in 10 healthy male volunteers; at doses up to 1.8mg/dose
- No Adverse Events (AEs) were reported
- No Cholinergic reactions were noted
- Pharmacokinetic parameters were established at dose of 1.8mg/dose
- Anti-PRX-105 IgG antibodies were not detected

PRX-102: Fabry's Disease

Overview of Plant rh α -Galactosidase-A

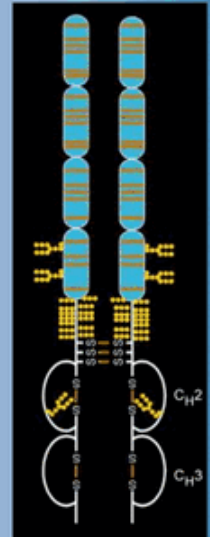
- Prx-102 is a plant cell expressed, **chemically modified and improved** version of the human α -Galactosidase-A enzyme
- Potential Advantages:
 - Enhanced stability
 - Longer circulatory half life
 - Enhanced activity in target organs
 - Reduced immunogenicity
 - Improved kinetics

Development Status

- 2010
 - Advanced R&D development including product characterization and determination of release specification
 - Performed proof of concept in "Fabry mice" knock out model
 - Pre-IND meeting with FDA held end of 2010
- 2011
 - Toxicological studies
 - IND submission to FDA Q4
 - Initiate Phase I/II in Fabry patients

PRX-106: 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: ~\$7.0 billion
- PRX-106
 - Amino acid sequence is identical to Enbrel™
- Current Status: Pre-IND meeting with FDA set for Q1 2011
- Promising pre clinical efficacy data in arthritis (CIA) model



Oral Delivery of prGCD for Gaucher's Disease

- prGCD is stable in lyophilized carrot cells for months
- In animal studies prGCD is found in liver and spleen, Gaucher target organs when prGCD carrot cells are fed to rats
- Active prGCD enzyme is found in target organs following feeding
- Preliminary PK data demonstrates prGCD in the plasma
- Next Steps:
 - Feeding experiments in large animals
 - Pharmacokinetics and toxicology studies of oral prGCD
 - Initiate clinical trials for oral prGCD enzyme

Protein Oral Delivery Advantages

- Oral delivery of therapeutic proteins
 - Long time goal for the bio pharmaceutical 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

Financial Overview

Financial Status

<i>\$ in millions</i>	Quarter Ending 9/30/2010 <i>Unaudited</i>	Last Twelve Months Ended 9/30/2010 <i>Unaudited</i>
[81.2]M Shares Common Stock O/S 9/30/2010		
Cash & Cash Equivalents	\$44.4	\$44.4
Revenues	3.2	5.9
R & D Expenses*	3.5	28.9
G & A Expenses	1.4	7.6
Operating Cash Use	(9.7)	28.7 ⁽¹⁾

(1) Includes upfront payment from Pfizer collaboration

31 *Less grants

Protalix Shareholder Perspectives

>5.0% Holders and Named Executive Officers

Top Holders	Total Holdings	% of Total Outstanding *
Biocell	14.5mm	17.9%
Techno-Rov	6.2mm	7.6%
Baillie Gifford & Co.	5.8mm	7.2%
Named Executive Officers	7.1mm	8.7%

- 1.3mm shares subject to named executive officer 10b5-1 plans
- Triggering Event: Taliglucerase alfa FDA approval at price of either \$10 or market price

* Based on shares outstanding as of 9/30/10 10Q.

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Q&A