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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**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 2, 2007**

**Protalix BioTherapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Florida**  
(State or other jurisdiction of incorporation)

**000-27836**  
(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)

**+972-4-988-9488**  
Registrant's telephone number, including area code:

\_\_\_\_\_  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 7.01. Regulation FD Disclosure**

On November 2, 2007, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that the Company would present at the CIBC World Markets 18th Annual Healthcare Conference being held at the Waldorf-Astoria Hotel in New York City on Monday, November 5, 2007 at 3:00 p.m. EST. The full text of the press release is set forth in Exhibit 99.1 to this Report.

A copy of the Company's presentation materials for the conference, appearing in Exhibit 99.2, is furnished and not filed pursuant to Regulation FD.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

- |      |   |
|------|---|
| 99.1 | Press release dated November 2, 2007, titled "Protalix BioTherapeutics to Present at CIBC World Markets 18th Annual Healthcare Conference." |
| 99.2 | Slide Presentation to be used at the CIBC World Markets 18th Annual Healthcare Conference on November 5, 2007.                              |

## **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 2, 2007

By: /s/ David Aviezer

Name: David Aviezer, Ph.D.

Title: President and  
Chief Executive Officer

**Protalix BioTherapeutics to Present at  
CIBC World Markets 18th Annual Healthcare Conference**

**CARMIEL, Israel – November 2, 2007** – Protalix BioTherapeutics, Inc. (Amex: PLX), today announced that Dr. David Aviezer, Ph.D., its President and Chief Executive Officer, will present at the CIBC World Markets 18th Annual Healthcare Conference. Dr. Aviezer's presentation will take place at 3:00 EST on Monday, November 5th at the Waldorf-Astoria Hotel in New York City.

Dr. Aviezer's presentation may be heard live via a simulcast link at <http://www.veracast.com/webcasts/cibcwm/healthcare07/84112115.cfm>. Following the live presentation, the archived webcast will be available for a period of 90 days after the presentation.

**About Protalix BioTherapeutics, Inc.**

Protalix is a biopharmaceutical company. Its goal is to become a fully integrated biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins to be expressed through its proprietary plant cell based expression system. Protalix's ProCellEx™ presents a proprietary method for the expression of recombinant proteins that Protalix believes is safe and scalable and will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins. Protalix has initiated enrollment and treatment of patients in its pivotal phase III clinical trial in the United States of its lead product candidate, prGCD, for its enzyme replacement therapy for Gaucher disease, a lysosomal storage disorder in humans, and has reached an agreement with the United States Food and Drug Administration on the final design of the pivotal phase III clinical trial through the FDA's Special Protocol Assessment (SPA) process. Protalix is also advancing additional recombinant biopharmaceutical drug development programs.

**Safe Harbor Statement:**

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. 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 such a material difference include, among others, uncertainties related to the ability to attract and retain partners for our technologies and products under development, the identification of lead compounds, the successful preclinical development of our products, the completion of clinical trials, the review process of the FDA, foreign regulatory bodies and other governmental regulation, and other factors described in our filings with the Securities and Exchange Commission. The statements are valid only as of the date hereof and we disclaim any obligation to update this information.

**For additional information, contact Protalix BioTherapeutics at:**

[investors@protalix.com](mailto:investors@protalix.com)

**AMEX IR Alliance for Protalix BioTherapeutics**

Lee Roth / David Burke

212-896-1209 / 1258

[lroth@kcsa.com](mailto:lroth@kcsa.com) / [dburke@kcsa.com](mailto:dburke@kcsa.com)

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**CIBC Healthcare Conference  
November 5<sup>th</sup>, 2007**

**Dr. David Aviezer  
President and CEO**



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# Company Highlights

## prGCD for Gaucher Disease

- **Lead product candidate targeting a large, growing market**
  - Similar to Cerezyme, the only approved enzyme replacement therapy
  - Currently in Phase III trials under SPA for treating Gaucher Disease
  - Gaucher Disease, a growing \$1 billion market, is a severe and chronic condition

## Proprietary Protein Expression System

- **Proprietary ProCellEx™ plant cell-based expression system offers significant advantages over existing expression systems**
  - New paradigm for developing recombinant proteins with equivalent activity and structure to their naturally-produced human counterparts
  - Enables penetration of patent-protected markets
  - Greater cost-effectiveness and Safety

## Targeting Commercially Viable Proteins

- **Biologically equivalent of superior versions of proteins with known biological mechanisms of action, validated markets and clearer regulatory path**
  - Substantially less development and regulatory risk
  - Pipeline focused on complex therapeutic proteins, including Fabry disease and female infertility disorders and other novel and biogeneric indications

## World Class Management & Board

- **Experienced board and management team**
  - Mr. Eli Hurvitz, Chairman of the Board, Chairman of the Teva
  - Dr. Phillip Frost, former Chairman and CEO of IVAX
  - Dr. David Aviezer, Director, President and CEO

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# Experienced Management and World Class Board and Advisors

Name	Title	Experience
<b>KEY MANAGEMENT</b>		
<b>Dr. David Aviezer</b>	President & CEO	ProChon Biotech, American Cyanamid, Ph.D. in Molecular Biology and Biochemistry, M.B.A
<b>Yossi Maimon</b>	CFO	Colbar LifeScience, Way2Call Communications, C.P.A., M.B.A
<b>Dr. Yoseph Shaaltiel</b>	Executive VP, R&D	MIGAL Technological Center, Rutgers U., Berkley U., Biological Center of IDF, Ph.D. in Plant Biochemistry
<b>Dr. Einat Almon</b>	VP, Product Dev	Biogenics, Ph.D. in molecular biology of cancer research
<b>Iftah Katz</b>	VP, Operations	Taro Pharmaceutical Industries, M.Sc. in Biotechnology and Food Engineering
<b>KEY BOARD MEMBERS</b>		
<b>Mr. Eli Hurvitz</b>	Chairman	Chairman and former CEO of TEVA, former director Bank Leumi
<b>Dr. Phillip Frost</b>	Director	TEVA, Chairman and former CEO of Ivax, Ladenburg Thalman, Key Pharmaceuticals
<b>Dr. Jane Hsiao</b>	Director	Ivax, DVM Pharmaceuticals
<b>SCIENTIFIC ADVISORY BOARD</b>		
<b>Prof. Ernest Beutler</b>	Advisor	Chairman, Dept. of Molecular and Experimental Medicine, Scripps Research Institute, La Jolla, CA. <i>World leader in Hematology and genetic diseases</i>
<b>Prof. Aaron Ciechanover</b>	Advisor	Director of the Institute for Research in Medical Sciences at the Technion, Israel. <i>Laureate of the Nobel Prize in Chemistry. World opinion leader in the field of protein trafficking.</i>
<b>Prof. Gad Galili</b>	Advisor	Chairman, Dept. of Plant Biology, Weizmann Institute of Science, Israel. <i>Scientific opinion leader in the field of plant molecular and cell biology</i>
<b>Prof. Ari Zimran</b>	Advisor	Director of the Gaucher clinic, Shaarei Zedek Medical Center, Jerusalem. <i>World opinion leader in Gaucher Disease</i>

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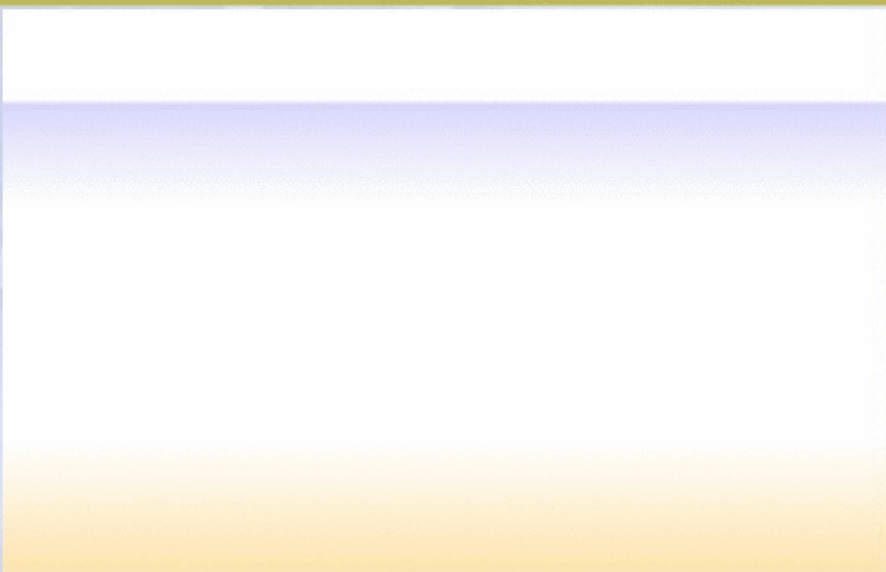
# Company Snapshot

**Advanced clinical stage biopharmaceutical company focused on development and commercialization of recombinant therapeutic proteins**

- Proprietary ProCellEx™ protein expression system based on plant cell-based expression technology
- Lead product prGCD - plant expressed Glucocerebrosidase for Gaucher Disease currently in Phase III clinical trials
- Deep pipeline focused on complex therapeutic proteins for novel and biogeneric indications
- Publicly traded PLX: AMEX.
- Executive offices, R&D and manufacturing facility in Carmiel, Israel
- Collaboration agreement with TEVA for the development of two biological drugs
- 90 employees of which 40% earned Ph.D., M.D. or M.Sc. Degrees
- Approved Enterprise status granting 0% tax for a period of 10 years



# ***Technology Demonstration***



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# ProCellEx™ Protein Expression System



## Technology Platform

- Proprietary plant cell-based protein expression system
- Comprehensive set of technologies and capabilities for the development of recombinant proteins from initial nucleotide cloning to large scale protein production
- Enables expression of proteins with similar amino acid, glycan and three dimensional structure as compared to their naturally-produced human counterparts
- Demonstrated feasibility through expression of many complex therapeutic proteins belonging to different drug classes:
  - Enzymes, cytokines, monoclonal antibodies, hormones, vaccines.
  - Have shown biological and structural equivalence to the naturally-produced human protein

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# Key Advantages of the ProCellEx System

## Enables Penetration of Patent Protected Markets

- Avoids infringing on the method-based patents of other proteins developed with mammalian cell-based expression systems, allowing penetration of certain patent-protected markets.
- Expect to obtain method-based patent protection for proteins developed using our ProCellEx system and in some cases, will seek composition patents as well.

## Cost Effectiveness and Scalability

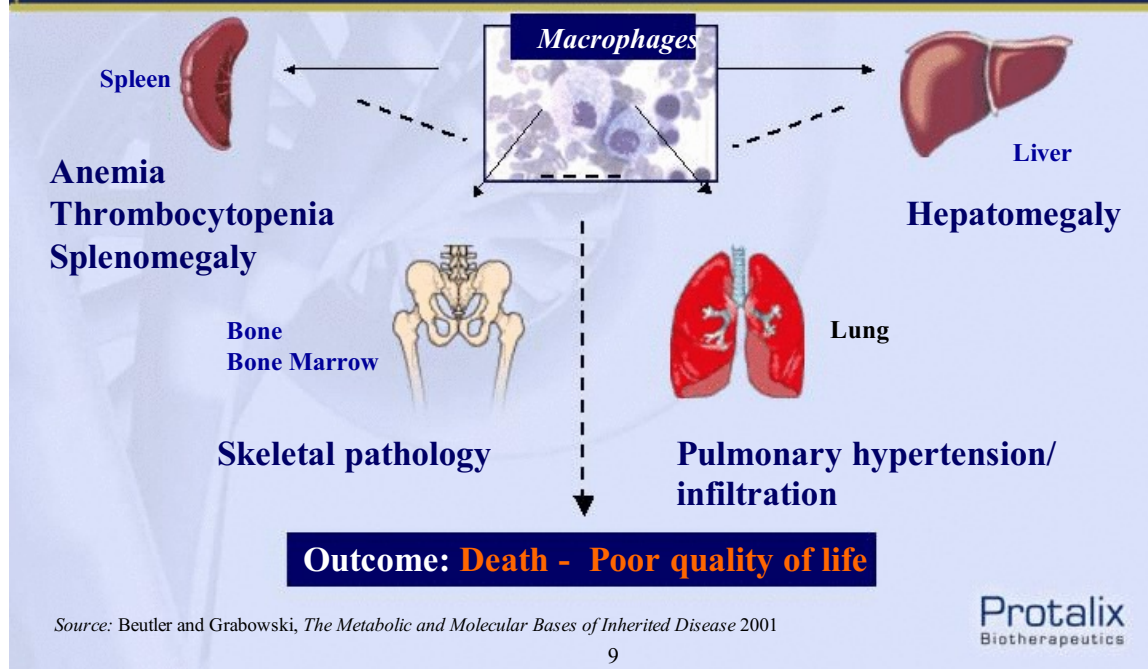
- Flexible polyethylene bioreactors entail low initial capital investment.
- Rapidly scalable at low cost in compliance with cGMP.
- Requires less costly hands-on maintenance.

## Significant Advantages Over Mammalian Cell-based Systems

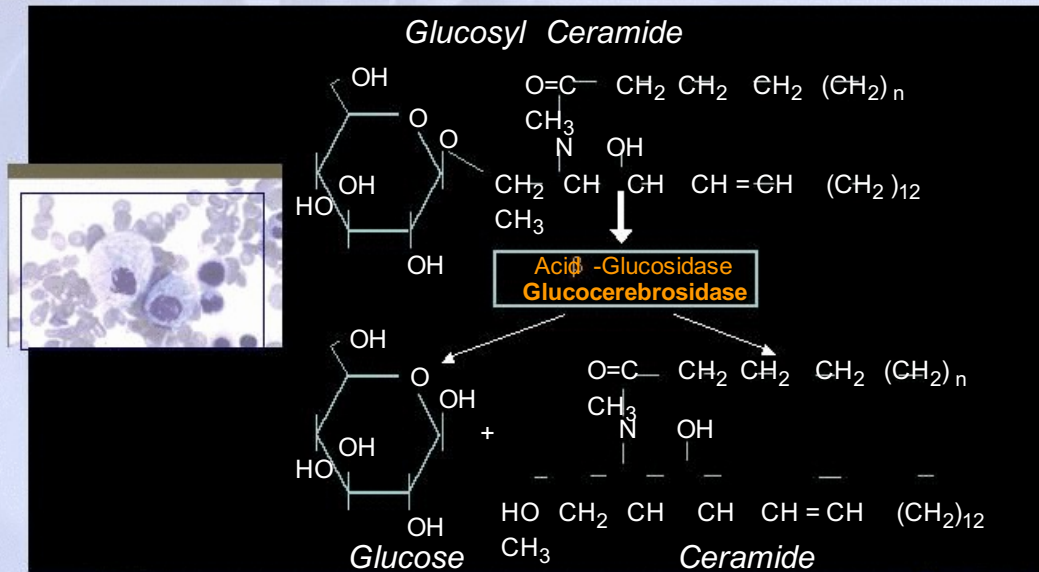
- Excellent safety profile – No risk of mammalian viral transmission or infection.
- Substantial cost benefits.
- Uniform glycosilation patterns result in greater effectiveness and potency.
- Longer half life and superior cell uptake (in prGCD).

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# Gaucher Disease: A genetically inherited disorder



# The Enzymatic Defect in Gaucher Disease



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# Gaucher Disease: Attractive Market Characteristics

## Characteristic

## Comment

## Cerezyme ® Growth (\$m)

Large  
Market  
Size

- Only player in the market has annual revenues of > \$1bn
- Approx. 10,000 patients (treated and untreated) globally
- Enzyme replacement therapy is gold standard treatment

Attractive  
Patient  
Profile

- No cure for Gaucher, ongoing chronic therapeutic treatment
- Treatment cost of ~\$200,000 p.a.,
- Less than 5,000 treated patients
- Relatively concentrated group of prescribing physicians

Steady  
Growth  
Prospects

- Historic annual market growth of approx 10-15%
- Estimated global market penetration of ~50%
- Future penetration to be driven by patient education and screening

Competition

- *Cerezyme ® (Genzyme)* : The only recombinant GCD on the market with ~100% share
- *Zavesca ® - (Actelion)*: Small molecule drug - Usage extremely limited due to significant side effects

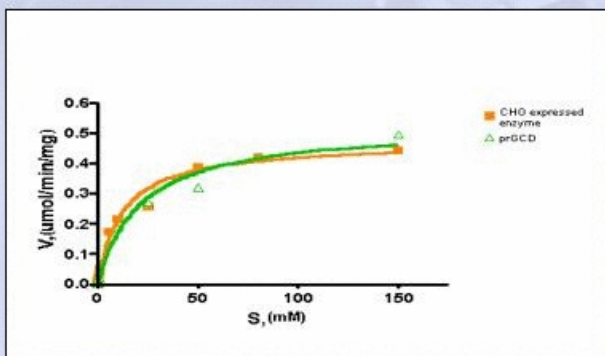


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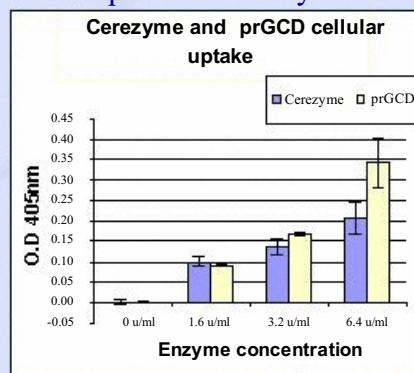
# prGCD: Equal to Superior Biological Activity

- prGCD has equal to superior enzymatic activity degrading the natural substrate when compared to Cerezyme® :



- Gaucher patients macrophages model: prGCD demonstrates superior uptake vs. Cerezyme® following 24 and 48 hours of incubation

- Enhanced uptake of prGCD by mouse macrophages compared to Cerezyme® :



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# Similar three Dimensional structure

- 3-D crystal structure of prGCD solved by a team of world renowned scientists from the Weizmann Institute of Science and compared to Cerezyme® structure.

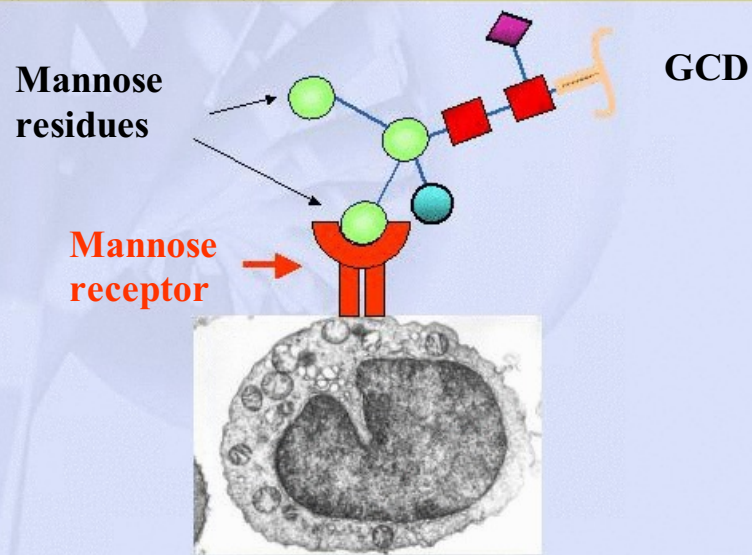


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# Technology Animation



# Glucocerebrosidase Binds to its Target Cells via the Mannose Receptor

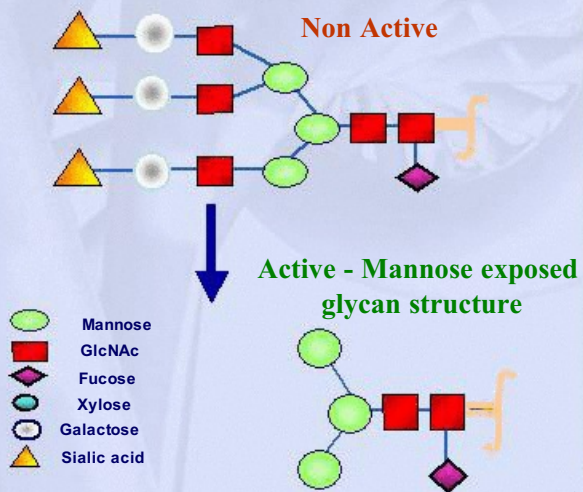


**Macrophage**

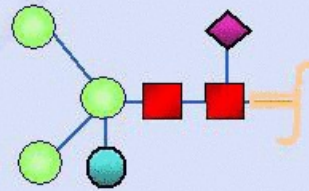
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# Protalix technology does not require additional glycan processing

- ❑ Mammalian technology requires multiple post-expression modifications:

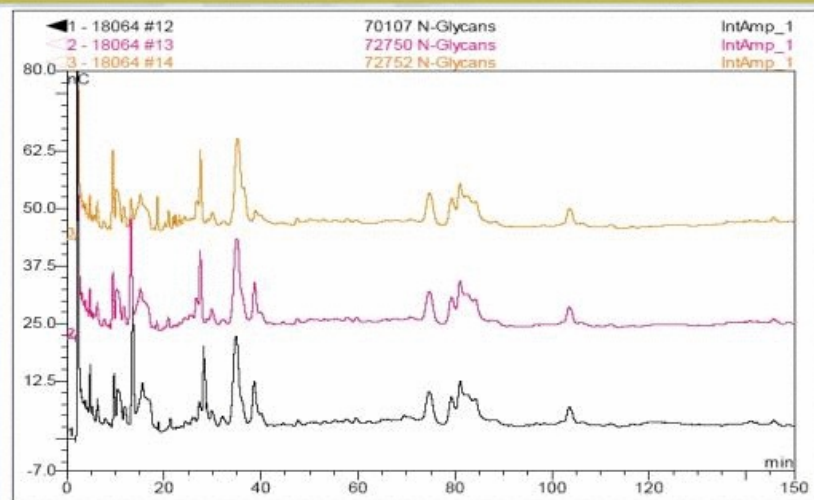


✓ Protalix plant cell technology produces a “ready to use” bioactive enzyme:



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# Batch to Batch Consistency of Glycoforms produced by the ProCellEx™ system



Overlaid HPAEC-PAD chromatograms of the data obtained from the analysis of the PNGase A released N-glycans isolated from three batches of Glucocerebrosidase produced in carrot suspension cells.

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# Successful Phase I Clinical Study

## Design

- Single-center, non-randomized, open label performed at Hadassah Medical Center, Jerusalem
- Study performed under FDA IND approval.

## Objectives


- Primary: To evaluate the safety of three escalating doses of human prGCD in healthy volunteers
- Secondary: To determine the pharmacokinetics of prGCD in human subjects

## Results

- **prGCD was well tolerated.**
- **Highly satisfactory safety laboratory results.**
  - No anti prGCD antibodies
  - No immune reaction against prGCD.
- **Pharmacology – prolonged half life of drug in serum**

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## Pharmacokinetic data: prGCD vs. Cerezyme (IV administration)

	Preclinical –Primate data	Human data
prGCD data:	■ T1/2 <u>13-20</u> minutes	■ T1/2 <u>10.5-14.5</u> minutes
Cerezyme (published data)	■ T1/2 <u>6.8-8</u> minutes	■ T1/2 ~ <u>3.6-10.4</u> minutes



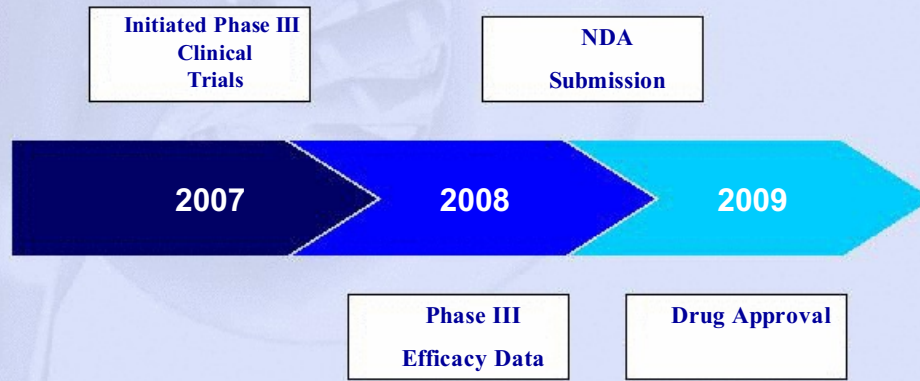
## prGCD Phase III Trial – Launched Aug 07

- Multi-center world wide study
  - Efficacy and safety in 30 untreated patients with significant symptoms of Gaucher disease treated with prGCD for 9 months
- Special Protocol Assessment approved by FDA in July 2007
  - Randomized, double blind, parallel groups, dose-ranging study
- Primary End Point
  - Mean decrease of 20% in spleen volume would represent a clinically relevant improvement
- Three Major Secondary Endpoints
  - decrease in liver volume , increase in Hemoglobin concentration, increase in platelet count

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# prGCD Clinical Development Timeline



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# prGCD for Gaucher Disease

## prGCD

- Plant cell expressed recombinant GCD for enzyme replacement therapy
  - Enzyme replacement therapy is gold standard of care
- Substantially similar amino acid, glycan and three dimensional structure compared to Cerezyme
- Major proof of concept for ProCellEx™ Protein Expression System



## Clear Clinical Path

- Following clinical protocol similar to Cerezyme
- Clinical data demonstrated increased half-life and increased in vitro and uptake efficacy
- Implies potential for more potent and effective drug
- Demonstrated safety and no immunological responses in intensive animal studies or Phase I human study
- Initiated 30 patient Phase III clinical trial in August 2007 under SPA

## An Effective and Cost Efficient Treatment

- Low production costs result from:
  - Lower initial set-up investment and ongoing growth media, labor and monitoring costs
  - Absence of post-expression glycosylation modification which are needed for Cerezyme

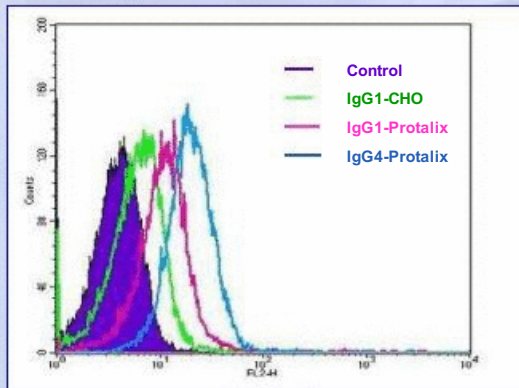
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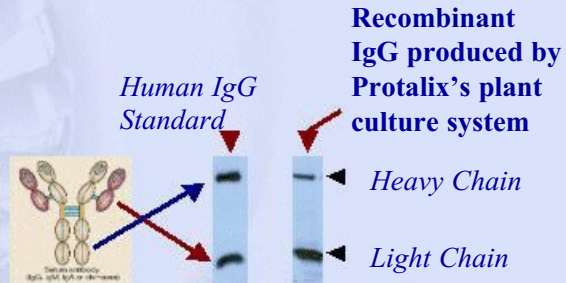
# Leveraging our Platform into Attractive Market Opportunities

Pipeline Candidate	Indication	Phase of Development	Market Opportunity	Market Dynamic
<b>prGCD</b>	Enzyme replacement therapy for Gaucher Disease	Phase III in progress	>\$1 B	<ul style="list-style-type: none"> <li>Currently only one meaningful market player - Genzyme</li> <li>Incurable disease, ongoing chronic treatment</li> </ul>
<b>Acetyl-Cholinesterase</b>	Biodefense and organophosphate poisoning	R & D, Animal Studies	~ \$500 mm	<ul style="list-style-type: none"> <li>Unmet medical need in rapidly growing biodefense market</li> <li>Vast potential of civilian applications</li> </ul>
<b>PRX-102 Fabry Disease</b>	Enzyme replacement therapy for Fabry Disease	R & D, Animal Studies	>\$500 mm	<ul style="list-style-type: none"> <li>One product in US and another in EU and Rest of World</li> <li>Rapidly growing market</li> <li>Enzyme replacement therapy is standard of care</li> </ul>
<b>PRX-111 FSH</b>	Follicle Stimulating Hormone for Female Infertility	R & D, Animal Studies	>\$1,200 mm	<ul style="list-style-type: none"> <li>Currently three meaningful products and only two recombinant hormone market players</li> </ul>

# Monoclonal Antibodies Expression



*Binding to Jurkat Leukemia cells*



✓ Protalix system represents an alternative platform for hard-to-express proteins in mammalian systems, including monoclonal antibodies

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# Strategic Collaborations

- In addition to internal, proprietary development, Protalix also seeks to share risk and enter into partnerships for the early-stage co-development for biotherapeutic proteins



- Framework agreement for R&D collaboration on two proteins using ProCellEx system
- TEVA to be granted license to commercialize the developed products
- Protalix will receive milestone and royalties and retain exclusive manufacturing rights



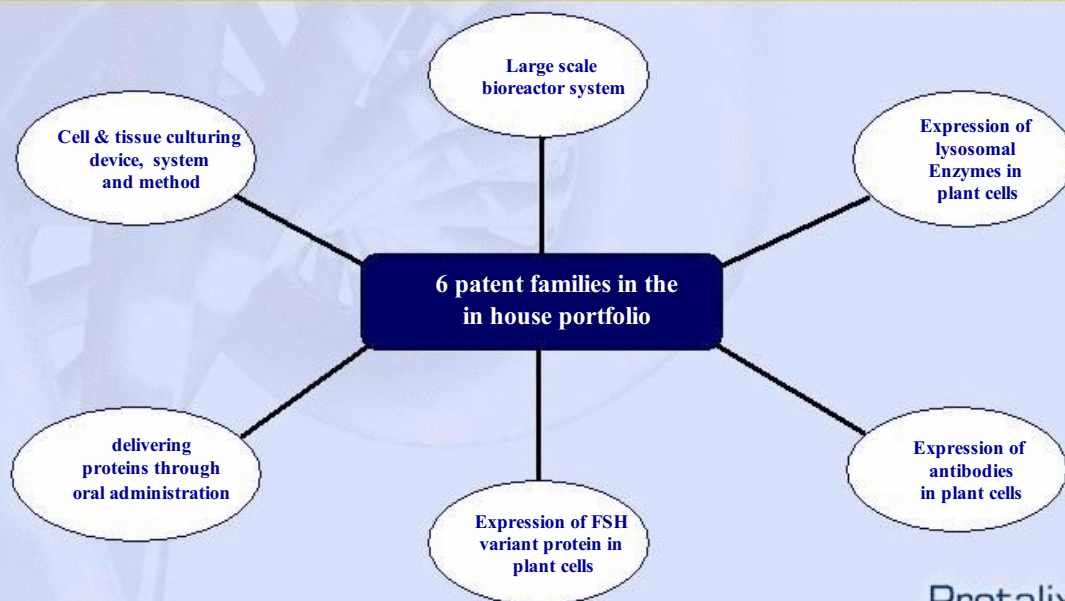
- Licensed technology from Weizmann to design next generation of GCD for Gaucher
- Based on a 3-D crystal structure of prGCD technology provides methodology for rational design for an improved drug
- Protalix pays fixed research budget and some royalties for any commercialized products



- Agreement with Hebrew University and Boyce Thompson of Cornell University to license the technology underlying the developed acetylcholinesterase and its molecular variants for the use in several therapeutic and prophylactic indications, as well as in a biodefense program
- Protalix pays some royalties for any commercialized products

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# Strong Intellectual Property Protection: 50+ Patents & Applications



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# Company Highlights

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Gaucher Disease**

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  - Similar to Cerezyme, the only approved enzyme replacement therapy
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**Proprietary Protein  
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- **Proprietary ProCellEx™ plant cell-based expression system offers significant advantages over existing expression systems**
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**World Class  
Management & Board**

- **Experienced board and management team**
  - Mr. Eli Hurvitz, Chairman of the Board, Chairman of the Teva
  - Dr. Phillip Frost, former Chairman and CEO of IVAX
  - Dr. David Aviezer, Director, President and CEO

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***Contact:***

***Dr. David Aviezer***

***President & CEO***

***david@protalix.com***

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