

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): May 3, 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 21000

(Address of principal executive offices) (Zip Code)

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

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

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 May 3, 2007, Protalix BioTherapeutics, Inc. (the "Company") issued a press release to announce that the Company would present at the Biotechnology Industry Organization's (BIO), 2007 International Convention being held at the Boston Convention & Exhibition Center, Boston, Massachusetts, on May 7, 2007. The full text of the press release is set forth in Exhibit 99.1.

A copy of the Company's presentation materials for the convention, 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 May 3, 2007, titled "Protalix BioTherapeutics to Present at the BIO International Convention on May 7, 2007".
- 99.2 Slide Presentation to be used at the Biotechnology Industry Organization's (BIO), 2007 International Convention on May 7, 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: May 4, 2007

By: /s/ David Aviezer

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

**Protalix BioTherapeutics to Present at the BIO International Convention on May 7, 2007**

CARMIEL, Israel, May 3, 2007 — Protalix BioTherapeutics (AMEX: PLX) today announced that Dr. David Aviezer, President and Chief Executive Officer, will present at the Biotechnology Industry Organization's (BIO), 2007 International Convention on Monday, May 7, 2007 at 10:20 a.m. EDT, at the Boston Convention & Exhibition Center, Boston, Massachusetts.

Dr. Aviezer will present Protalix's proprietary and innovative underlying platform technology, as well as recent advances in the clinical development of prGCD, its lead product for treating Gaucher Disease.

The Convention will feature a program packed with more than 200 sessions and speakers focusing on the global aspects of biotechnology. More than 20,000 leaders from across the industry are expected to be in attendance. Additional information is available at [www.bio2007.org](http://www.bio2007.org).

**About Protalix BioTherapeutics, Inc.**

Protalix's proprietary technology is based on its plant cell culture and bioreactor system which provides an effective and scaleable cell system for industrial production of recombinant biopharmaceuticals. Protalix is pursuing advanced clinical studies for its enzyme therapy for Gaucher Disease and intends to advance additional recombinant biopharmaceutical drug development programs. Protalix's plant-based expression has significant advantages over more traditional mammalian and bacterial expression technology with respect to patient safety, cost and scalability.

**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, the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; 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; any lack of progress of our research and development (including the results of clinical trials being conducted by us); obtaining on a timely basis sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional financings required to fund our research programs; our ability to establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationships with collaborators, distributors and partners; potential product liability risks and risks of securing adequate levels of product liability and clinical trial insurance coverage; the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, couriers, collaborative partners, licensees, and clinical trial sites; 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 Investor Relations: [investors@protalix.com](mailto:investors@protalix.com)

**AMEX IR Alliance for Protalix:**

Lee Roth / David Burke  
212-896-1209 / 212-896-1258  
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## **Exhibit 99.2**

**Protalix**  
Biotherapeutics

**BIO** International  
Convention

May 7, 2007



## ***Novel and Biogeneric Protein Therapeutics***

**Dr. David Aviezer**  
**President & CEO**



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# About Protalix

Protalix has developed a proprietary plant cell culture technology and innovative bioreactor system for the efficient and safe, large-scale production of complex human therapeutic proteins in plant cells.

The company's platform technology is designed to produce a range of human protein therapeutics for the biopharmaceutical market.

The lead product, prGCD, Glucocerebrosidase enzyme, for treating Gaucher Disease, targets a \$1 billion market and is scheduled to initiate Phase III clinical trial in mid 2007.

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# Company Highlights

- **Product-driven strategy:** lead product, prGCD, Glucocerebrosidase for treating Gaucher Disease, targets a **\$1 billion market**.
- prGCD - scheduled to initiate **Phase III in 2007**.
- **Pipeline** includes novel and biogeneric therapeutic proteins.
- **Strong IP positioning** based on proprietary protein manufacturing platform in plant cell culture with advantages in terms of the glycosylation process, cost-effectiveness and safety.
- Experienced **Management Team** led by board members such as Mr. Eli Hurvitz, Chairman of Teva, and Dr. Phillip Frost, current Vice Chairman of Teva and former Chairman and CEO of IVAX.
- **Partnership strategy:** generating alliances with biopharmaceutical and large cap pharmaceutical companies.
- **Protalix BioTherapeutics, Inc. - Publicly traded** on the American Stock Exchange (AMEX: PLX).

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# Board of Directors

**Mr. Eli Hurvitz - Chairman of Protalix's BOD; Chairman, Teva Pharmaceutical Industries**

**Dr. Phillip Frost - Vice Chairman Teva; Former Chairman & CEO, IVAX Corp.**

**Mr. Zeev Bronfeld - CEO, Biocell**

**Mr. Amos Bar-Shalev - Director, Technorov VC fund**

**Dr. Jane Hsiao - Former Vice Chairman, IVAX Corp.**

**Mr. Eyal Sheratzki - Co-CEO, Ituran**

**Gen. (res.) Pinchas Buchris - Managing Director, Tamares, Venture Partner, APAX**

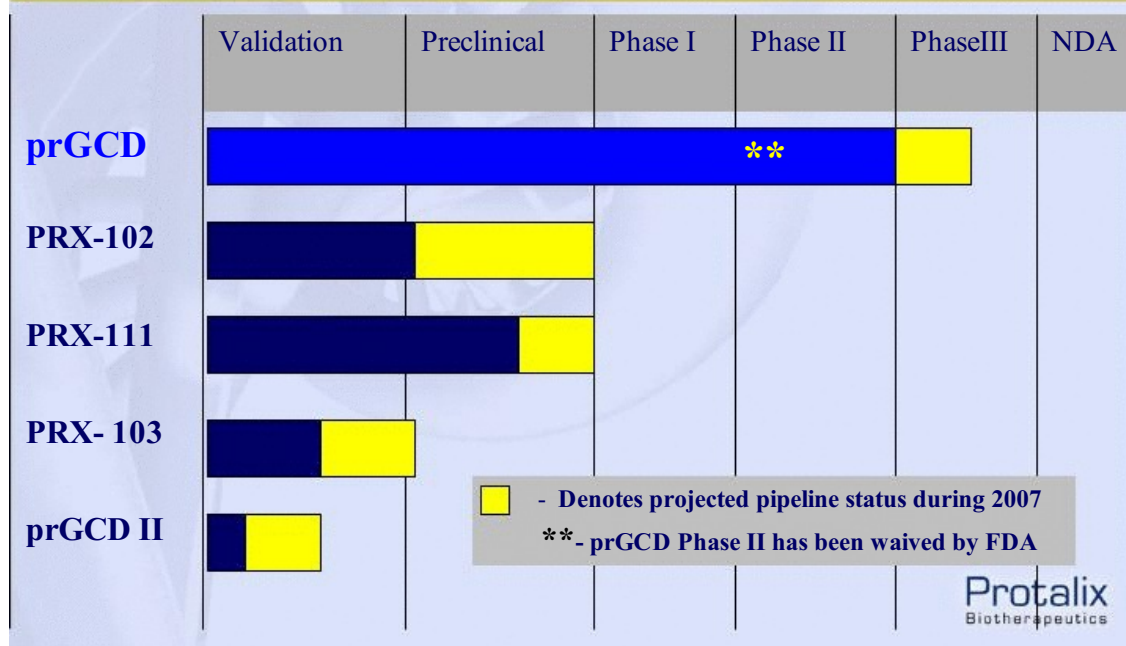
**Mr. Sharon Toussia-Cohen - CEO, Marathon VC fund**

**Dr. Yoseph Shaaltiel - Founder & E.VP of R&D, Protalix**

**Dr. David Aviezer - President & CEO, Protalix**

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# Protalix Pipeline





## Target selection-Global strategy

- First target: Gaucher Disease.
- Think “**Big**” and Globally, for a well established and lucrative market, but seek a “**Small**” niche market as to number of patients, treatment centers, marketing efforts, etc.
- Seek **Global** collaboration partners for large patient population targets.



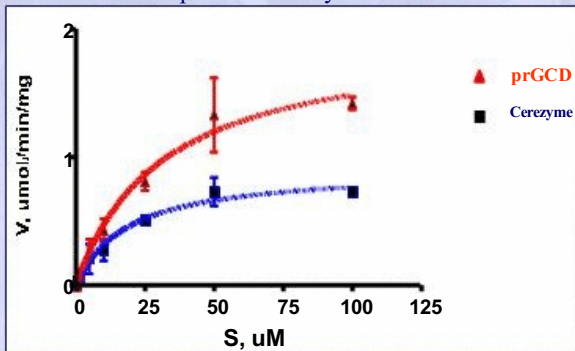
# prGCD for treating Gaucher Disease: Highlights

- **Well established, lucrative billion dollar niche market** with wide profit margins. Cerezyme® produced in mammalian cells, generated 2006 sales of \$ 1 Billion, **without competition on the market** (Source: Genzyme announcement 2007)
- FDA- approved **clinical regulatory path**:
  - ✓ Phase I: **completed**
  - ✓ Phase II: **waived** by FDA
  - ✓ Phase III: **initiation** -mid 2007
- Proven superior bioactivity in various models
- Strong IP positioning due to circumvention of patents
- prGCD clinical grade production serves as major proof of concept for Protalix's platform

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# prGCD: Equal to Superior Biological Activity

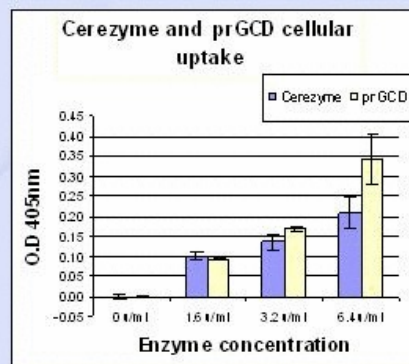
- prGCD has superior enzymatic activity degrading the natural substrate when compared to Cerezyme® :



- 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

- Three dimensional crystal structure of prGCD solved by a team of world renowned scientists from the Weizmann Institute of Science is comparable to Cerezyme® structure



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## Regulatory Development - Global Thinking

- First target: Gaucher Disease
- Meet with FDA very early in the process.
- Gain insight as to what the regulatory global “real world” will require, as early as possible in the development stage of your drug candidate.
- Perform clinical studies globally.





# prGCD Phase I Study: Summary

- Safety study of three single escalating doses administered as intravenous infusions in healthy volunteers.
- **Design:** Single-center, non-randomized, open label performed at Hadassah Medical Center, Jerusalem, Israel.
- Study performed under **FDA IND approval**.
- **Results:** Treatment successfully completed:
  - prGCD was well tolerated.
  - Highly satisfactory safety lab results.
  - Pharmacology – prolonged half life of drug in serum.
  - Final report submitted.





## Comparison of PK data: prGCD vs. Cerezyme®

- prGCD data:

- Preclinical-Primates
  - T1/2~13-20 minutes
- Phase I: Human data:  
T1/2~10.5-14.5 minutes

- Cerezyme (published data):

- Preclinical-Primates:
  - T1/2~ 6.8-8 minutes
- Human data
  - T1/2~3.6-10.4 minutes



## prGCD Phase III: Study Design

- Multi-center world wide study: efficacy and safety in untreated patients with significant symptoms of Gaucher Disease.
- Protocol outline reviewed by FDA: randomized, double blind, parallel groups, dose-ranging study.
- Measurable efficacy end point.

# Phase III Milestones

- ✓ Israel Ministry of Health approval to initiate Phase III study
- ✓ FDA approval to initiate Phase III study
- Initiate Phase III trial



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# Plant Cell Technology Demonstration



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# The Technology Platform



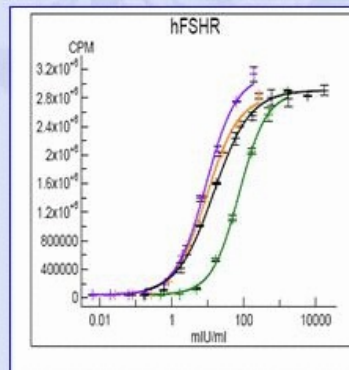
✓ Protalix Manufacturing Facility:  
~ 5000 Sq/ft. of clean rooms

- Expression of recombinant human proteins in a proprietary plant cell bioreactors:
  - safe
  - simple to handle
  - friendly to plant cell growth
  - cost efficient
  - easily up-scalable
- Built in line with FDA guidelines and GMP standards

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# Follicle Stimulating Hormone

- Follicle-Stimulating Hormone (FSH) regulates several major reproductive functions of the human female body (IVF).
- Growing \$1 billion market.
- Protein consisting of a common alpha subunit non-covalently bound to a beta subunit.
- Protalix is also co-developing a **proprietary variant** of FSH with Compugen.

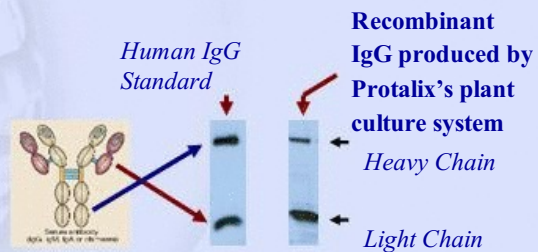
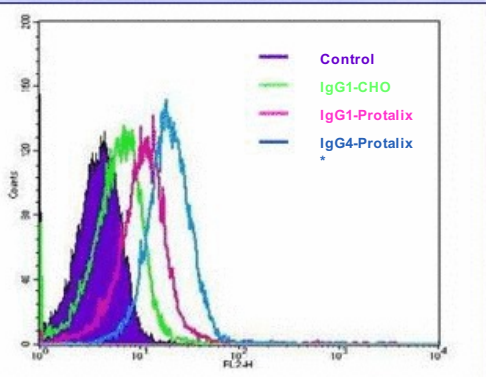


**Figure 1.** Dose-response curves of the Protalix compounds 1651 (in purple), 1652 (in orange), and 1653 (in dark green), and of rec-FSH (Gonal-F RFF) (in black) on the hFSHR. Each data point is in duplicate and each compound was tested in 4 independent experiments with a representative plot shown here.

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# Monoclonal Antibodies: Proof of concept

**FACS Analysis of Protalix IgG1 and IgG4 Ab's Binding to Jurkat Leukemia Cells- Compared to CHO IgG1:**



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

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# Two-Armed Business Model



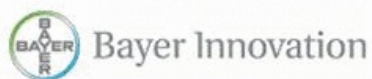
- Share risks and profits by forming **early-stage** co-development **partnering deals** for biotherapeutic proteins
- *Examples:* TEVA

- **Internal development** of Protalix's **proprietary specialty** market oriented therapeutic proteins **into advanced commercial stage**
- *Example:* prGCD, for treating Gaucher Disease



# Partnership Validation

- **2006- Teva Pharmaceutical Industries:**  
Agreement for co-development of two therapeutic proteins
- **2005- Bayer (Icon Genetics):**  
License agreement for complementary technology



✓ Protalix is constantly seeking new value-adding partnerships

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# Global Financial Strategy

- Use non-equity funding from sources such as Israeli chief scientist governmental grants at early stage.
- Bring in top-tier early stage US and global investors early in the financing process.
- Select late stage investors with global perception of capital markets and the pharmaceutical arena.
- Increase financial and strategic visibility by becoming public in the US (AMEX:PLX).



**Thank  
You!**

**Contact:**

**Dr. David Aviezer**

**President & CEO  
david@protalix.com**



***Innovative and Biogeneric  
Protein Therapeutics***

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