

As filed with the Securities and Exchange Commission on January 31, 2008

Registration No. 333-

---

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

---

**FORM S-8  
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

---

**Protalix BioTherapeutics, Inc.**

(Exact name of registrant as specified in its Charter)

---

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

**65-0643773**  
(I.R.S. Employer  
Identification Number)

**2 Snunit Street  
Science Park  
POB 455  
Carmiel, Israel 20100  
972-4-988-9488**

(Address of principal executive offices)

---

**Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan**

**(Full title of plan)**

**David Aviezer, Ph.D.  
President and Chief Executive Officer  
2 Snunit Street  
Science Park  
POB 455  
Carmiel, Israel 20100  
972-4-988-9488**

---

**CT Corporation System  
111 Eighth Avenue  
New York, NY 10011  
Tel: (212) 894-8400**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

---

***With a Copy to:***

**James R. Tanenbaum, Esq.  
Morrison & Foerster LLP  
1290 Avenue of the Americas  
New York, New York 10104  
(212) 468-8000**

---

**CALCULATION OF REGISTRATION FEE**

---

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price	Proposed maximum aggregate offering price	Amount of registration fee
Common stock, par value \$0.001 per share	9,741,655	\$3.02(2)	\$29,419,798(2)	1,156.20

---

- (1) This Registration Statement also registers additional securities to be offered or issued upon adjustments or changes made to registered securities by reason of any stock splits, stock dividends or similar transactions as permitted by Rule 416(a) and Rule 416(b) under the Securities Act of 1933, as amended (the "Securities Act").

- (2) Estimated pursuant to Rule 457(h) solely for purposes of calculating the aggregate offering price and the amount of the registration fee based upon the average of the high and low prices reported for the shares on The American Stock Exchange on January 29, 2008.
- 
-

## EXPLANATORY NOTE

This Registration Statement contains two parts:

The first part contains a Reoffer Prospectus prepared in accordance with the requirements of Part I of Form S-3. The Prospectus covers reoffers and resales of shares of our common stock, par value \$.001 per share, by certain of our executive officers (as such term is defined under Rule 405 of the Securities Act of 1933, as amended (the “Securities Act”)) with respect to options granted prior to the date hereof (3,093,178 shares) pursuant to certain of the Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan. All such individuals are listed on the selling securityholder table set forth herein.

The second part contains “Information Required in the Registration Statement” prepared in accordance with the requirements of Part II of Form S-8 with respect to the authorized issuance, as of the date hereof and subsequent to the date hereof, equity awards granted under the Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan that relate to, in the aggregate, 9,741,655 shares of our common stock, including the 3,093,178 shares of our common stock being offered under the Reoffer Prospectus. The Reoffer Prospectus does not contain all of the information included in the Registration Statement, certain items of which are contained in exhibits to the Registration Statement as permitted by the rules and regulations of the Securities and Exchange Commission (the “Commission”). Statements contained in the Reoffer Prospectus as to the contents of any agreement, instrument or other document referred to are not necessarily complete. With respect to each such agreement, instrument or other document filed as an exhibit to the Registration Statement, we refer you to the exhibit for a more complete description of the matter involved, and each such statement shall be deemed qualified in its entirety by this reference.

## PART I

### INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

#### **Item 1. Plan Information.**

The documents containing the information specified in Part I (plan and registrant information) will be delivered in accordance with Rule 428(b)(1) under the Securities Act. Such documents are not required to be, and are not, filed with the Commission, either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 under the Securities Act. These documents, and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Form S-8, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

#### **Item 2. Registrant Information and Employee Plan Annual Information.**

Upon written or oral request, any of the documents incorporated by reference in Item 3 of Part II of this Registration Statement, which are also incorporated by reference in the Section 10(a) prospectus, other documents required to be delivered to eligible participants pursuant to Rule 428(b), or additional information about the Protalix Biotherapeutics, Inc. 2006 Stock Incentive Plan (the “Plan”), will be available without charge by contacting the Corporate Secretary, Protalix BioTherapeutics, Inc., 2 Snunit Street, Science Park, POB 455, Camiel, Israel 20100, Telephone: 972-4-988-9488.

REOFFER PROSPECTUS

3,093,178 Shares



**PROTALIX BIOTHERAPEUTICS, INC.**

**Common Stock**

**Issued or issuable under certain awards granted under the  
Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan**

This Reoffer Prospectus relates to the public resale, from time to time, of an aggregate of 3,093,178 shares of our common stock by certain securityholders identified herein in the section entitled "Selling Securityholders". Such shares have been or may be acquired in connection with awards granted under the Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan. You should read this prospectus and the applicable prospectus supplement carefully before you invest in our common stock.

We will not receive any proceeds from the sale by the selling securityholders of the shares covered by this Reoffer Prospectus.

We have not entered into any underwriting arrangements in connection with the sale of the shares covered by this Reoffer Prospectus. The selling securityholders identified in this Reoffer Prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares covered by this Reoffer Prospectus from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

Our common stock is traded on the American Stock Exchange, or the AMEX, under the symbol "PLX." On January 30, 2008, the last reported sales price for our common stock on the AMEX was \$3.07 per share.

---

**Investing in our common stock involves a high degree of risk. You should read and consider carefully the risk factors beginning on page 4 of this prospectus.**

---

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this Prospectus is January 31, 2008.

---

## TABLE OF CONTENTS

	<u>Page</u>
<a href="#"><u>Disclosure Regarding Forward-Looking Statements</u></a>	<a href="#"><u>1</u></a>
<a href="#"><u>Our Business</u></a>	<a href="#"><u>2</u></a>
<a href="#"><u>Risk Factors</u></a>	<a href="#"><u>5</u></a>
<a href="#"><u>Use of Proceeds</u></a>	<a href="#"><u>26</u></a>
<a href="#"><u>Selling Securityholders</u></a>	<a href="#"><u>26</u></a>
<a href="#"><u>Plan of Distribution</u></a>	<a href="#"><u>28</u></a>
<a href="#"><u>Where You Can Find More Information</u></a>	<a href="#"><u>29</u></a>
<a href="#"><u>Incorporation of Certain Information by Reference</u></a>	<a href="#"><u>29</u></a>
<a href="#"><u>Legal Matters</u></a>	<a href="#"><u>30</u></a>
<a href="#"><u>Experts</u></a>	<a href="#"><u>30</u></a>
<a href="#"><u>Disclosure of Commission Position on Indemnification for Securities Act Liabilities</u></a>	<a href="#"><u>30</u></a>

---

## DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth and incorporated by reference in this prospectus, which are not historical, constitute “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, including statements regarding our expectations, beliefs, intentions or strategies for the future. When used in this prospectus, the terms “anticipate,” “believe,” “estimate,” “expect” and “intend” and words or phrases of similar import, as they relate to us, our subsidiary or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to, the following:

- 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 United States Food and Drug Administration, or the FDA, or other regulatory authorities;
- any lack of progress of our research and development (including the results of clinical trials we are conducting);
- 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 financing required to fund our research programs;
- the risk that we will not be able to develop a successful sales and marketing organization in a timely manner, if at all;
- 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 availability of reimbursement to patients from health care payors for our drug products, if approved;
- the possibility of infringing a third party’s patents or other intellectual property rights;
- the uncertainty of obtaining patents covering our products and processes and successfully enforcing them against third parties; and
- the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiary, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

In addition, companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. These and other risks and uncertainties are detailed under the heading “Risk Factors” herein and in our filings with the Securities and Exchange Commission incorporated by reference in this prospectus. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

## OUR BUSINESS

*The Commission allows us to “incorporate by reference” certain information that we file with the Commission, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the Commission will update automatically, supplement and/or supersede the information disclosed in this prospectus. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other document that also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should read the following summary together with the more detailed information regarding our company, our common stock securities and our financial statements and notes to those statements appearing elsewhere in this prospectus or incorporated herein by reference.*

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx<sup>tm</sup> protein expression system. Using our ProCellEx system we are developing a pipeline of proprietary recombinant therapeutic proteins based on our plant cell-based expression technology that target large, established pharmaceutical markets and that rely upon known biological mechanisms of action. Our initial commercial focus has been on complex therapeutic proteins, including proteins for the treatment of genetic disorders, such as Gaucher disease and Fabry disease, and female infertility disorders. We believe our ProCellEx protein expression system will enable us to develop proprietary recombinant proteins that are therapeutically equivalent or superior to existing recombinant proteins currently marketed for the same indications. Because we are targeting biologically equivalent versions of highly active, well-tolerated and commercially successful therapeutic proteins, we believe our development process is associated with relatively less risk compared to other biopharmaceutical development processes for novel therapeutic proteins.

### **Our Lead Product Candidate, prGCD**

Our lead product development candidate is prGCD for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. In July 2007, we reached an agreement with the United States Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of prGCD, through the FDA’s special protocol assessment (SPA) process. In the third quarter of 2007, we initiated enrollment and treatment of patients in our phase III clinical trial of prGCD. prGCD is our proprietary recombinant form of Glucocerebrosidase (GCD), an enzyme naturally found in human cells that is mutated or deficient in patients with Gaucher disease. The current standard of care for Gaucher disease is enzyme replacement therapy, a medical treatment in which GCD is replaced for patients in whom the enzyme is lacking or dysfunctional. Although Gaucher disease is a relatively rare disease, it represents a large commercial market due to the severity of the symptoms and the chronic nature of the disease. The annual worldwide sales of Cerezyme®, an enzyme replacement therapy produced by Genzyme Corporation and currently the only approved enzyme replacement therapy for Gaucher disease, were approximately \$1.1 billion in 2007, according to public reports by Genzyme. prGCD is a plant cell expressed version of the GCD enzyme, developed through our ProCellEx protein expression system. prGCD has an amino acid, glycan and three-dimensional structure that is very similar to its naturally-produced counterpart as well as to Cerezyme, the mammalian cell expressed version of the same protein. We believe prGCD may prove more cost-effective than the currently marketed alternative due to the cost benefits of expression through our ProCellEx protein expression system. In addition, based on our laboratory testing, preclinical and clinical results, we believe that prGCD may have the potential for increased potency and efficacy compared to the existing enzyme replacement therapy for Gaucher disease which may translate into lower dosages and/or less frequent treatments.

## **Other Drug Candidates in Our Pipeline**

In addition to prGCD, we are developing an innovative product pipeline using our ProCellEx protein expression system, including therapeutic protein candidates for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans and female infertility disorders. We plan to file an investigational new drug application (IND) with the FDA with respect to at least one additional product during 2008. Because these product candidates are based on well-understood proteins with known biological mechanisms of action, we believe we may be able to reduce the development risks and time to market for our product candidates. We hold the worldwide commercialization rights to our proprietary development candidates and we intend to establish an internal, commercial infrastructure and targeted sales force to market prGCD and our other products, if approved, in North America, the European Union and in other significant markets, including Israel.

## **ProCellEx: Our Proprietary Protein Expression System**

Our ProCellEx protein expression system consists of a comprehensive set of technologies and capabilities for the development of recombinant proteins, including advanced genetic engineering technology and plant cell-based protein expression methods. Through our ProCellEx protein expression system, we can develop highly complex recombinant therapeutic proteins all the way to the scale-up of a purified product produced in compliance with current good manufacturing practices, or cGMP. We believe that our plant cell-based expression technology will enable us, in certain cases, to develop and commercialize recombinant proteins without infringing upon the method-based patents or other intellectual property rights of third parties. Moreover, we expect to enjoy method-based patent protection for the proteins we develop using our proprietary ProCellEx protein expression technology, although there can be no assurance that any such patents will be granted. In some cases, we may be able to obtain patent protection for the compositions of the proteins themselves. We have filed for United States and international composition of matter patents for prGCD.

Our ProCellEx protein expression system is built on flexible custom-designed bioreactors made of polyethylene and optimized for the development of complex proteins in plant cell cultures. These bioreactors entail low initial capital investment, are rapidly scalable at a low cost and require less hands-on maintenance between cycles, compared to the highly complex, expensive, stainless steel bioreactors typically used in mammalian cell-based production systems. As a result, through our ProCellEx protein expression system, we believe that we can develop recombinant therapeutic proteins yielding substantial cost advantages, accelerated development and other competitive benefits as compared to mammalian cell-based protein expression systems.

We have successfully demonstrated the feasibility of our ProCellEx system by expressing, on an exploratory, research scale, many complex therapeutic proteins belonging to different drug classes, such as enzymes, hormones, monoclonal antibodies, cytokines and vaccines. The therapeutic proteins we have expressed to date in research models have produced the intended composition and similar biological activity compared to their respective human-equivalent proteins. Moreover, several of such proteins demonstrated advantageous biological activity when compared to the biotherapeutics currently available in the market to treat the applicable disease or disorder. We believe that clinical success of prGCD would be a strong proof-of-concept for our ProCellEx protein expression system and plant cell-based protein expression technology. We also believe that the significant benefits of our ProCellEx protein expression system, if further substantiated in clinical trials and commercialization of our product candidates, have the potential to transform the industry standard for the development of complex therapeutic proteins.

## **Competitive Advantages of Our ProCellEx Protein Expression System**

We believe that our ProCellEx protein expression system, including our advanced genetic engineering technology and plant cell-based protein expression methods, affords us a number of significant advantages over mammalian, bacterial, yeast and transgenic cell-based expression technologies, including the following:

- Ability to penetrate certain patent-protected markets.
- Significantly lower capital and production costs.



## [Table of Contents](#)

- More effective and potent end product relative to mammalian based systems.
- Elimination of the risk of viral transmission or infection by mammalian components.
- Broad range of expression capabilities.

## **Strategic Collaborations**

In addition to the product candidates that we are developing internally, we have entered into agreements for additional compounds with academic institutions, including a licensing agreement with the technology transfer arm of Israel's Weizmann Institute of Science and an agreement with the technology transfer arm of the Hebrew University of Jerusalem. We are also collaborating with other pharmaceutical companies to develop therapeutic proteins that can benefit from the significant cost, intellectual property and other competitive advantages of our ProCellEx protein expression system. We entered into an agreement with Teva Pharmaceutical Industries Ltd. in September 2006 under which we have agreed to collaborate on the research and development of two proteins to be developed using our ProCellEx protein expression system. We also continuously review and consider additional development and commercialization alliances with other pharmaceutical companies and academic institutions.

## **Our Strategy**

Our goal is to become a leading fully integrated biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins. To achieve our goal, we intend to:

- Obtain regulatory approval for prGCD for the treatment of Gaucher disease.
- Develop a pipeline of innovative recombinant therapeutic proteins.
- Build a targeted sales and marketing infrastructure.
- Establish development and commercialization alliances with corporate partners.
- Acquire or in-license new technologies, products or companies.
- Leverage strength and experience of our management team and board of directors.

## **Recent Developments**

On October 25, 2007, we issued and sold 10,000,000 shares of common stock in an underwritten public offering at a price of \$5.00 per share. The net proceeds to the Company were approximately \$46.0 million after deducting underwriting discounts and commissions and offering expenses.

## **Company Background**

Our principal business address is 2 Snunit Street, Science Park, POB 455, Carmiel, Israel 20100, where our executive offices are located and we operate our research and manufacturing facility. Our telephone number is +972-4-988-9488. From May 2001 through December 31, 2006, our company had no operations. On December 31, 2006, we acquired, through a merger with our wholly-owned subsidiary, Protalix Acquisition Co. Ltd., all of the outstanding shares of Protalix Ltd., in exchange for shares of our common stock. As a result, Protalix Ltd. is now our wholly-owned subsidiary, with the former shareholders of Protalix Ltd. having acquired in excess of 99% of our outstanding shares of common stock as of the closing of the merger. In connection with the merger, we effected a one-for-ten reverse stock split and on February 26, 2007, we changed our name to Protalix BioTherapeutics, Inc. On March 12, 2007, our shares of common stock were listed on the American Stock Exchange under the symbol PLX.

Our wholly-owned subsidiary and sole operating unit, Protalix Ltd., is an Israeli corporation and was originally incorporated in Israel as Metabogal Ltd. on December 27, 1993. During 1999, Protalix Ltd. changed its focus from plant secondary metabolites to the expression of recombinant therapeutic proteins in plant cells, and in April 2004 changed its name to Protalix Ltd.

ProCellEx™ is our trademark. Each of the other trademarks, trade names or service marks appearing in this prospectus supplement belongs to its respective holder.

## RISK FACTORS

*Investment in our securities involves a high degree of risk. Our business, financial condition or results of operations could be adversely affected by any of these risks. If any of these risks occur, the value of our common stock and our other securities may decline. You should carefully consider the risk factors discussed in this section with the other information included in this prospectus, as well as the discussion set forth under the caption "Risk Factors" in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2006, before making your investment decision, as well as those contained in any filing with the Commission subsequent to the date of the Annual Report. Our business, financial condition or results of operations could be adversely affected by any of these risks. If any of these risks occur, the value of our common stock could decline.*

### Risks related to our business

***We currently have no product revenues and will need to raise additional capital to operate our business, which may not be available on favorable terms, or at all, and which will have a dilutive effect on our shareholders.***

To date, we have generated no revenues from product sales and only minimal revenues from research and development services and other fees. Our accumulated deficit as of September 30, 2007 was \$37.9 million. For the years ended December 31, 2006, 2005 and 2004, we had net losses of \$9.4 million, \$5.7 million and \$2.4 million, respectively, primarily as a result of expenses incurred through a combination of research and development activities and expenses supporting those activities. Drug development and commercialization is very capital intensive. Until we receive approval from the FDA and other regulatory authorities for our drug candidates, we cannot sell our drugs and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of any equity or debt offerings, cash on hand, licensing fees and grants. Over the next 12 months, we expect to spend a minimum of approximately \$11 million on preclinical and clinical development for our products under development. Based on our current plans and capital resources, we believe that our cash and cash equivalents will be sufficient to enable us to meet our minimum planned operating needs for the next 24 months. However, changes may occur that could consume our existing capital at a faster rate than projected, including, among others, changes in the progress of our research and development efforts, the cost and timing of regulatory approvals and the costs of protecting our intellectual property rights. We may seek additional financing to implement and fund product development, preclinical studies and clinical trials for the drugs in our pipeline, as well as additional drug candidates and other research and development projects. If we are unable to secure additional financing in the future on acceptable terms, or at all, we may be unable to commence or complete planned preclinical and clinical trials or obtain approval of our drug candidates from the FDA and other regulatory authorities. In addition, we may be forced to reduce or discontinue product development or product licensing, reduce or forego sales and marketing efforts and other commercialization activities or forego attractive business opportunities in order to improve our liquidity and to enable us to continue operations which would have a material adverse effect on our business and results of operations. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our shareholders.

***We are not currently profitable and may never become profitable which would have a material adverse effect on our business and results of operations and could negatively impact the value of our common stock.***

We expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures, and we anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical development and clinical trials for our current and new drug candidates;
- seek regulatory approvals for our drug candidates;

[Table of Contents](#)

- implement additional internal systems and infrastructure;
- seek to license-in additional technologies to develop; and
- hire additional personnel.

We also expect to continue to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Any failure to achieve or maintain profitability would have a material adverse effect on our business and results of operations and could negatively impact the value of our common stock.

***We have a limited operating history which may limit the ability of investors to make an informed investment decision.***

We are a clinical stage biopharmaceutical company. To date, we have not commercialized any of our drug candidates or received any FDA or other approval to market any drug. The successful commercialization of our drug candidates will require us to perform a variety of functions, including:

- continuing to undertake preclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary technology and undertaking, through third parties, preclinical trials and clinical trials of our principal drug candidates. To date, we have commenced a phase III clinical trial in connection with only one drug candidate, prGCD, and we have not commenced the preclinical trial phase of development under Good Laboratory Practice (GLP) standards for any of our other drug candidates. These operations provide a limited basis for investors to assess our ability to commercialize our drug candidates and whether to invest in us.

***Our ProCellEx protein expression system is based on our proprietary plant cell-based expression technology which has a limited history and any material problems with the system, which may be unforeseen, may have a material adverse effect on our business and results of operations.***

Our ProCellEx protein expression system is based on our proprietary plant cell-based expression technology. Our business is dependent upon the successful development and approval of our product candidates produced through our protein expression system. Our ProCellEx protein expression system is novel and is still in the early stages of development and optimization, and, accordingly, is subject to certain risks. Mammalian cell-based protein expression systems have been used in connection with recombinant therapeutic protein expression for more than 20 years and are the subject of a wealth of data; in contrast, there is not a significant amount of data generated regarding plant cell-based protein expression and, accordingly, plant cell-based protein expression systems may be subject to unknown risks. In addition, the protein glycosylation pattern created by our protein expression system is not identical to the natural human glycosylation pattern and its long term effect on human patients is still unknown. Lastly, as our protein expression system is a new technology, we cannot always rely on existing equipment; rather, there is a need to design custom-made equipment and to generate specific growth media for the plant cells, which may not be available at favorable prices, if at all. Any material problems with the technology underlying our plant cell-based protein expression system may have a material adverse effect on our business and results of operations.

***We currently depend heavily on the success of prGCD, our lead product candidate which is in clinical development. Any failure to commercialize prGCD, or the experience of significant delays in doing so, will have a material adverse effect on our business, results of operations and financial condition.***

We have invested a significant portion of our efforts and financial resources in the development of prGCD. Our ability to generate product revenue, which we do not expect to occur in the near term, if

[Table of Contents](#)

at all, will depend heavily on the successful development and commercialization of prGCD. The successful commercialization of prGCD will depend on several factors, including the following:

- successful completion of our clinical trials for prGCD;
- obtaining marketing approvals from the FDA and other foreign regulatory authorities;
- maintaining the cGMP compliance of our manufacturing facility or establishing manufacturing arrangements with third parties;
- the successful audit of our facilities by the FDA and other foreign regulatory authorities;
- the development of a successful sales and marketing organization;
- the availability of reimbursement to patients from health care payors for our drug products, if approved;
- a continued acceptable safety and efficacy profile of our product candidates following approval; and
- other risks described in these Risk Factors.

Any failure to commercialize prGCD or the experience of significant delays in doing so will have a material adverse effect on our business, results of operations and financial condition.

***All of our product candidates other than prGCD are in research stages. If we are unable to develop and commercialize our other product candidates, our business will be adversely affected.***

A key element of our strategy is to develop and commercialize a portfolio of new products in addition to prGCD. We are seeking to do so through our internal research programs and strategic collaborations for the development of new products. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory approval;
- a product candidate is not capable of being produced in commercial quantities at an acceptable cost, or at all; or
- a product candidate may not be accepted by patients, the medical community or third-party payors.

***We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our drug candidates in a timely manner, if at all, which would have a material adverse effect on our business and results of operations.***

We will need FDA approval to commercialize our drug candidates in the United States and approvals from foreign regulators to commercialize our drug candidates elsewhere. In order to obtain FDA approval of any of our drug candidates, we must submit to the FDA a New Drug Application, an NDA, demonstrating that the drug candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, and depends upon the type, complexity and novelty of the drug candidate and requires substantial resources for research, development and testing. Our research and clinical efforts may not result in drugs that the FDA considers safe for

humans and effective for indicated uses which would have a material adverse effect on our business and results of operations. After clinical trials are completed for any drug candidate, if at all, the FDA has substantial discretion in the drug approval process of the drug candidate and may require us to conduct additional clinical testing or to perform post-marketing studies which would cause us to incur additional costs. Incurring such costs could have a material adverse effect on our business and results of operations.

The approval process for any drug candidate may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review of such drug candidate. Delays in obtaining regulatory approvals with respect to any drug candidate may:

- delay commercialization of, and our ability to derive product revenues from, such drug candidate;
- require us to perform costly procedures with respect to such drug candidate; or
- otherwise diminish any competitive advantages that we may have with respect to such drug candidate.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of the NDAs we file in the future, if any, or we might not obtain regulatory clearance in a timely manner. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Failure to obtain FDA approval of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any drug. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We might not be able to obtain the approvals necessary to commercialize our drug candidates for sale outside of the United States in a timely manner, if at all, which could adversely affect our business, operating results and financial condition.

***Clinical trials are very expensive, time-consuming and difficult to design and implement and may result in unforeseen costs which may have a material adverse effect on our business and results of operations.***

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. Our drug candidates are in early stages of preclinical studies or clinical trials. We estimate that clinical trials of prGCD or any of our other potential drug candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we may encounter problems that cause us to abandon or repeat preclinical studies or clinical trials. Failure or delay in the commencement or completion of our clinical trials 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.

[Table of Contents](#)

Any failure or delay in commencement or completion of any clinical trials may have a material adverse effect on our business and results of operations. In addition, we or the FDA or other regulatory authorities may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable safety or health risks or if the FDA or such other regulatory authorities, as applicable, find deficiencies in our IND submissions or the conduct of these trials. Any suspensions of our clinical trials may have a material adverse effect on our business and results of operations.

***If the results of our clinical trials do not support our claims relating to any drug candidate or if serious side effects are identified, the completion of development of such drug candidate may be significantly delayed or we may be forced to abandon development altogether, which will significantly impair our ability to generate product revenues.***

The results of our clinical trials with respect to any drug candidate might not support our claims of safety or efficacy, the effects of our drug candidates may not be the desired effects or may include undesirable side effects or the drug candidates may have other unexpected characteristics. Further, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our drug candidates are safe for humans and effective for indicated uses. In addition, our clinical trials may involve a specific and small patient population. Because of the small sample size, the results of these early clinical trials may not be indicative of future results. Adverse or inconclusive results may cause us to abandon a drug candidate and may delay development of other drug candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, significantly impair our ability to commercialize our drug candidates and generate product revenues which would have a material adverse effect on our business and results of operations.

***We may find it difficult to enroll patients in our clinical trials, which could cause significant delays in the completion of such trials or may cause us to abandon one or more clinical trials.***

Most of the diseases or disorders that our product candidates are intended to treat are relatively rare and we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Given that each of our product candidates is in the early stages of preclinical or clinical development, we may not be able to initiate or continue clinical trials for each or all of our product candidates if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA and/or other foreign regulatory authorities. The requirements of our clinical testing mandate that a patient cannot be involved in another clinical trial for the same indication. We are aware that our competitors have ongoing clinical trials for products that are competitive with our product candidates and subjects who would otherwise be eligible for our clinical trials may be involved in such testing, rendering them unavailable for testing of our product candidates. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether, which would have a material adverse effect on our business.

***If physicians, patients, third party payors and others in the medical community do not accept and use our drugs, our ability to generate revenue from sales of our products under development will be materially impaired.***

Even if the FDA or other foreign regulatory authorities approve any of our drug candidates for commercialization, physicians and patients, and other healthcare providers, may not accept and use such candidates. Future acceptance and use of our products will depend upon a number of factors including:

- perceptions by physicians, patients, third party payors and others in the medical community, about the safety and effectiveness of our drug candidates;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the prevalence and severity of any side effects, including any limitations or warnings contained in our products' approved labeling;

## [Table of Contents](#)

- pharmacological benefit of our products relative to competing products and products under development;
- the efficacy and potential advantages relative to competing products and products under development;
- relative convenience and ease of administration;
- effectiveness of education, marketing and distribution efforts by us and our licensees and distributors, if any;
- publicity concerning our products or competing products and treatments;
- reimbursement of our products by third party payors; and
- the price for our products and competing products.

Because we expect sales of our current drug candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would have a material adverse effect on our business and revenues from sales of our products would be materially impaired.

***Because our clinical trials depend upon third-party researchers, the results of our clinical trials and such research activities are subject to delays and other risks which are, to a certain extent, beyond our control, which could impair our clinical development programs and our competitive position.***

We depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials. These collaborators are not our employees, and we cannot control the amount or timing of resources that they devote to our clinical development programs. The investigators may not assign as great a priority to our clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly. If outside collaborators fail to devote sufficient time and resources to our clinical development programs, or if their performance is substandard, the approval of our FDA and other applications, if any, and our introduction of new drugs, if any, may be delayed which could impair our clinical development programs and would have a material adverse effect on our business and results of operations. The collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators also assist our competitors, our competitive position could be harmed.

***Our strategy, in many cases, is to enter into collaboration agreements with third parties to leverage our ProCellEx system to develop product candidates. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements or terminate or elect to discontinue the collaboration, it could have a material adverse affect on our revenues.***

Our strategy, in many cases, is to enter into collaboration arrangements with pharmaceutical companies to leverage our ProCellEx system to develop additional product candidates. Under these arrangements, we may grant to our collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Our collaboration partners may control key decisions relating to the development of the products and we may depend on our collaborators' expertise and dedication of sufficient resources to develop and commercialize the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of the developed products. To date, we have entered into an agreement with Teva Pharmaceutical Industries Ltd., which relates to the development of two proteins, and licensing by Teva of such proteins in consideration for royalties and milestone payments. If we or any of our partners breach or terminate the agreements that make up such collaboration arrangements or such partners otherwise fail to conduct their collaboration-related activities in a timely manner or if there is a dispute about their obligations or if either party terminates the agreement or elects not to continue the collaboration, we may not enjoy the benefits of the collaboration agreements or receive any royalties or milestone payments from them.



***The manufacture of our products is an exacting and complex process, and if we or one of our materials suppliers encounter problems manufacturing our products, it will have a material adverse effect on our business and results of operations.***

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug candidates. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products. Our current facility has not been audited by the FDA or other foreign regulatory authorities and is unlikely to be audited until we submit an NDA for a product candidate. There can be no assurance that we will be able to comply with FDA or foreign regulatory manufacturing requirements for our current facility or any future facility that we may establish, which would have a material adverse effect on our business.

***We rely on third parties for final processing of prGCD, which exposes us to a number of risks that may delay development, regulatory approval and commercialization of our product candidates or result in higher product costs.***

We have no experience in the final filling and freeze drying steps of the drug manufacturing process. We have entered into a contract with Teva pursuant to which Teva has agreed to perform the final filling and freeze drying steps for prGCD in connection with our clinical trials. If any of our product candidates receive FDA or other regulatory authority approval, we will rely on Teva or other third-party contractors to perform the final manufacturing steps for our products on a commercial scale. We may be unable to identify manufacturers and replacement manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA and other regulatory authorities, as applicable, must approve any replacement manufacturer, including us, and we or any such third party manufacturer might be unable to formulate and manufacture our drug products in the volume and of the quality required to meet our clinical and commercial needs. If we engage any contract manufacturers, such manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical or commercial needs. Each of these risks could delay our clinical trials, the approval, if any, of prGCD and our other potential drug candidates by the FDA or other regulatory authorities, or the commercialization of prGCD and our other drug candidates or could result in higher product costs or otherwise deprive us of potential product revenues.

***We have no experience selling, marketing or distributing products and no internal capability to do so.***

We currently have no sales, marketing or distribution capabilities and no experience in building a sales force and distribution capabilities. To commercialize our product candidates, we must either develop internal sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services. If we decide to market any of our products directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Building an in-house marketing and sales force with technical expertise and distribution capabilities will require significant expenditures, management resources and time. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and



[Table of Contents](#)

- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

We may not be successful in recruiting the sales and marketing personnel necessary to sell our products and even if we do build a sales force, they may not be successful in marketing our products, which would have a material adverse effect on our business and results of operations.

***If the market opportunities for our current product candidates are smaller than we believe they are, then our revenues may be adversely affected and our business may suffer.***

The focus of our current clinical pipeline is on relatively rare disorders with small patient populations, in particular Gaucher disease and Fabry disease. Currently, most reported estimates of the prevalence of these diseases are based on studies of small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the diseases in the broader world population. As new studies are performed, the estimated prevalence of these diseases may change. There can be no assurance that the prevalence of Gaucher disease or Fabry disease in the study populations, particularly in these newer studies, accurately reflect the prevalence of these diseases in the broader world population. If the market opportunities for our current product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

***We may enter into distribution arrangements and marketing alliances for certain products and any failure to successfully identify and implement these arrangements on favorable terms, if at all, may impair our ability to commercialize our product candidates.***

While we intend to build a sales force to market prGCD and other product candidates, we do not anticipate having the resources in the foreseeable future to develop global sales and marketing capabilities for all of the products we develop, if any. We may pursue arrangements regarding the sales and marketing and distribution of one or more of our product candidates and our future revenues may depend, in part, on our ability to enter into and maintain arrangements with other companies having sales, marketing and distribution capabilities and the ability of such companies to successfully market and sell any such products. Any failure to enter into such arrangements and marketing alliances on favorable terms, if at all, could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Our use of distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including the following:

- we may be required to relinquish important rights to our products or product candidates;
- we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;
- our distributors or collaborators may experience financial difficulties;
- our distributors or collaborators may not devote sufficient time to the marketing and sales of our products; and
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

We may need to enter into additional co-promotion arrangements with third parties where our own sales force is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements we enter into may not be favorable to us.

***Developments by competitors may render our products or technologies obsolete or non-competitive which would have a material adverse effect on our business and results of operations.***

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and

other public and private research organizations. Our drug candidates will have to compete with existing therapies and therapies under development by our competitors. In addition, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug products. Other companies have drug candidates in various stages of preclinical or clinical development to treat diseases for which we are also seeking to develop drug products. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products may not compete successfully with products produced by our competitors.

We specifically face competition from companies with approved treatments of Gaucher disease, including Genzyme Corporation and to a certain extent, Actelion Ltd. In addition, we are aware of other early stage, experimental, small molecule, oral drugs which are being developed for the treatment of Gaucher disease by Amicus Therapeutics, Inc. and Genzyme. Shire plc is currently developing a gene-activated enzyme expressed in human cancer cells to treat Gaucher disease. We also face competition from companies with approved treatments of Fabry disease, including Genzyme and Shire, and we are aware of other early stage drugs which are being developed for the treatment of Fabry disease, including a drug being developed by Amicus Therapeutics.

We also face competition from companies that are developing other platforms for the expression of recombinant therapeutic pharmaceuticals. We are aware of companies that are developing alternative technologies to develop and produce therapeutic proteins in anticipation of the expiration of certain patent claims covering marketed proteins. Competitors developing alternative expression technologies include Crucell N.V., Shire and GlycoFi Inc. (which was acquired by Merck). Other companies are developing alternate plant-based technologies, include Biolex, Inc., Chlorogen, Inc., Greenovation Biotech GmbH and Dow Agrosience.

Several biogeneric companies are pursuing the opportunity to develop and commercialize follow-on versions of other currently marketed biologic products, including growth factors, hormones, enzymes, cytokines and monoclonal antibodies, which are areas that interest us. These companies include, among others, Novartis AG/Sandoz Pharmaceuticals, BioGeneriX AG, Barr Pharmaceuticals, Stada Arzneimittel AG, BioPartners GmbH and Teva.

Most of our competitors, either alone or together with their collaborative partners, operate larger research and development programs, staff and facilities and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

These organizations also compete with us to attract qualified personnel, acquisitions and joint ventures candidates and for other collaborations. Activities of our competitors may impose unanticipated costs on our business which would have a material adverse effect on our business and results of operations.

***If we fail to adequately protect or enforce our intellectual property rights or secure rights to third party patents, the value of our intellectual property rights would diminish and our business, competitive position and results of operations would suffer.***

As of September 30, 2007, we had 44 pending patent applications and four joint pending patent applications, and held licensed rights to 21 pending patent applications. However, the filing of a patent application does not mean that we will be issued a patent, or that any patent eventually issued will be as broad as requested in the patent application or sufficient to protect our technology. Any modification required to a current patent application may delay the approval of such patent

application which would have a material adverse effect on our business and results of operations. In addition, there are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications to not be granted, including known or unknown prior art, deficiencies in the patent application or the lack of originality of the technology.

Our competitive position and future revenues will depend in part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We have filed United States and international patent applications for process patents, as well as composition of matter patents, for prGCD. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors and those who infringe upon our patents, including whether third parties will find ways to invalidate or otherwise circumvent our licensed patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our licensed patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings, which may be costly, and whether we win or lose.

We hold, or have license rights to, eight patents. If patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against our competitors and those who infringe upon our patents.

Furthermore, the life of our patents is limited. The patents we hold relating to our ProCellEx protein expression system will expire in 2016. If patents issue from other currently pending patent applications, those patents will expire between 2023 and 2027.

***We rely on confidentiality agreements that could be breached and may be difficult to enforce which could have a material adverse effect on our business and competitive position.***

Our policy is to enter agreements relating to the non-disclosure of confidential information with third parties, including our contractors, consultants, advisors and research collaborators, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. However, these agreements can be difficult and costly to enforce. Moreover, to the extent that our contractors, consultants, advisors and research collaborators apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach; or
- our trade secrets or proprietary know-how will otherwise become known.

Any breach of our confidentiality agreements or our failure to effectively enforce such agreements would have a material adverse effect on our business and competitive position.

***If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages and required to defend against litigation which could result in substantial costs and may have a material adverse effect on our business and results of operations.***

We have not received to date any claims of infringement by any third parties. However, as our drug candidates progress into clinical trials and commercialization, if at all, our public profile and that of our drug candidates may be raised and generate such claims. Defending against such claims, and occurrence of a judgment adverse to us, could result in unanticipated costs and may have a material adverse effect on our business and competitive position. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our drug candidates;
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or
- pay damages.

Any costs incurred in connection with such events or the inability to sell our products may have a material adverse effect on our business and results of operations.

***If we cannot meet requirements under our license agreements, we could lose the rights to our products, which could have a material adverse effect on our business.***

We depend on licensing agreements with third parties to maintain the intellectual property rights to certain of our products under development. Presently, we have licensed rights from the Yeda Research and Development Company Limited, the technology transfer arm of the Weizman Institute of Science, which allow us to use their technology and discoveries for the development, production and sale of enzymatically active mutations of GCD and derivatives thereof for the treatment of Gaucher disease. In addition, pursuant to our agreement with the Yissum Research and Development Company, the technology transfer arm of the Hebrew University of Jerusalem, Israel, and the Boyce Thompson Institute for Plant Research, at Cornell University, we have received an exclusive worldwide right and license to certain technology, including patents and additional patent applications relating to acetylcholinesterase (AChE), for all therapeutic and prophylactic indications as well as an exclusive license not limited to such indications with respect to certain of these patents and patent applications. Under the agreement with Yissum, we intend to develop a proprietary plant cell-based acetylcholinesterase (AChE) and its molecular variants for the use in several therapeutic and prophylactic indications, including a biodefense program. Our license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. All of these agreements last either throughout the life of the patents that are the subject of the agreements, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology which could have a material adverse effect on our business.

***If we in-license drug candidates, we may delay or otherwise adversely affect the development of our existing drug candidates, which may negatively impact our business, results of operations and financial condition.***

In addition to our own internally developed drug candidates, we proactively seek opportunities to in-license and advance other drug candidates that are strategic and have value-creating potential to take advantage of our development know-how and technology. If we in-license any additional drug

candidates, our capital requirements may increase significantly. In addition, in-licensing additional drug candidates may place a strain on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing drug candidates or cause us to re-prioritize our drug pipeline if we do not have the necessary capital resources to develop all of our drug candidates, which may delay the development of our drug candidates and negatively impact our business, results of operations and financial condition.

***If we are unable to successfully manage our growth, there could be a material adverse impact on our business, results of operations and financial condition.***

We have grown rapidly and expect to continue to grow. We expect to hire more employees, particularly in the areas of drug development, regulatory affairs and sales and marketing, and increase our facilities and corporate infrastructure, further increasing the size of our organization and related expenses. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We have begun to prepare conceptual designs of a new manufacturing facility and are currently evaluating potential locations for such facility. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability on the part of our management to manage growth could delay the execution of our business plans or disrupt our operations. If we are unable to manage our growth effectively, we may not use our resources in an efficient manner, which may delay the development of our drug candidates and negatively impact our business, results of operations and financial condition.

***If we acquire companies, products or technologies, we may face integration risks and costs associated with those acquisitions that could negatively impact our business, results from operations and financial condition.***

If we are presented with appropriate opportunities, we may acquire or make investments in complementary companies, products or technologies. We may not realize the anticipated benefit of any acquisition or investment. If we acquire companies or technologies, we will face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations of an acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired business and impairment charges if future acquisitions are not as successful as we originally anticipate. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets. Any failure to successfully integrate other companies, products or technologies that we may acquire may have a material adverse effect on our business and results of operations. Furthermore, we may have to incur debt or issue equity securities to pay for any additional future acquisitions or investments, the issuance of which could be dilutive to our existing shareholders.

***We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.***

We are highly dependent upon the principal members of our management team, especially our President and Chief Executive Officer, David Aviezer, Ph.D., as well as our directors, including Eli Hurvitz, the Chairman of our Board of Directors, our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved with us for many years and have played integral roles in our progress, and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have employment agreements with Dr. Aviezer and four other officers that may be terminated by us or the applicable officer at any time with varying notice periods of 60 to 90 days. Although these employment agreements generally include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the applicable noncompetition provisions

can be difficult and costly to monitor and enforce. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key-man life insurance.

We also depend in part on the continued service of our key scientific personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

***Our collaborations with outside scientists and consultants may be subject to restriction and change.***

We work with chemists, biologists and other scientists at academic and other institutions, and consultants who assist us in our research, development, regulatory and commercial efforts, including the members of our scientific advisory board. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice on our programs. These scientists and consultants are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product or compound that is more scientifically interesting to his or her professional interests, his or her availability to remain involved in such clinical trials could be restricted or eliminated.

***Under current U.S. and Israeli law, we may not be able to enforce employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.***

We have entered into non-competition agreements with all of our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under current U.S. and Israeli law, we may be unable to enforce these agreements against most of our employees and it may be difficult for us to restrict our competitors from gaining the expertise our former employees gained while working for us. If we cannot enforce our employees' non-compete agreements, we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

***If product liability claims are brought against us, it may result in reduced demands for our products or damages that exceed our insurance coverage.***

The clinical testing, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. We presently carry clinical trial liability insurance with coverages of up to \$5 million per occurrence and \$5 million in the aggregate, an amount we consider reasonable and customary. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional clinical trial liability coverage prior to initiating additional clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, such insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development, which could have a material adverse effect on our business and results

of operations. Product liability claims may result in reduced demand for our products, if approved, which would have a material adverse effect on our business and results of operations. In addition, the existence of a product liability claim could affect the market price of our common stock.

***Reimbursement may not be available for our product candidates, which could diminish our sales or affect our ability to sell our products profitably.***

Market acceptance and sales of our product candidates will depend on worldwide reimbursement policies. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for any of our product candidates, if approved for marketing and sale. Obtaining reimbursement approval for an approved product from every government or other third party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products, if and when approved, to every payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement or we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any approved products, if any, to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Even if a payor determines that an approved product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other regulatory authorities. In addition, there is a risk that full reimbursement may not be available for high priced products. Moreover, eligibility for coverage does not imply that any approved product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidates. We have not commenced efforts to have our product candidates reimbursed by government or third-party payors. If reimbursement is not available or is available only to limited levels, the sales of our products, if approved may be diminished or we may not be able to sell such products profitably.

***Reforms in the healthcare industry and the uncertainty associated with pharmaceutical pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products, if approved.***

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the United States healthcare system have been introduced or proposed in the United States Congress and in some state legislatures within the United States, including reductions in the pricing of prescription products and changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products. For example, the Medicare Prescription Drug Improvement, and Modernization Act of 2003 and the proposed rules thereunder impose new requirements for the distribution and pricing of prescription drugs that began in 2006, which could reduce reimbursement of prescription drugs for healthcare providers and insurers. Although we cannot predict the full effect on our business of the implementation of this legislation, it is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will result in additional government reimbursement for prescription drugs, which may make some prescription drugs more affordable but may further exacerbate industry-wide pressure to reduce prescription drug prices. We believe that legislation that reduces reimbursement for our product candidates could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our products. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products, if approved. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales, upon approval, if at all.



***Governments outside the United States tend to impose strict price controls and reimbursement approval policies, which may adversely affect our prospects for generating revenue.***

In some countries, particularly European Union countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time (six to 12 months or longer) after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries with respect to any product candidate that achieves regulatory approval, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products upon approval, if at all, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected which would have a material adverse effect on our business and results of operations. Further, if we achieve regulatory approval of any product, we must successfully negotiate product pricing for such product in individual countries. As a result, the pricing of our products, if approved, in different countries may vary widely, thus creating the potential for third-party trade in our products in an attempt to exploit price differences between countries. This third-party trade of our products could undermine our sales in markets with higher prices.

**Risks Relating to Our Operations in Israel**

***Potential political, economic and military instability in the State of Israel, where the majority of our senior management and our research and development facilities are located, may adversely affect our results of operations.***

Our executive office and operations are located in the State of Israel. Accordingly, political, economic and military conditions in Israel directly affect our business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could affect adversely our operations. Since October 2000 there have been increasing occurrences of terrorist violence. Ongoing and revived hostilities or other Israeli political or economic factors could harm our operations and product development and cause our revenues to decrease. Furthermore, several countries, principally those in the Middle East, still restrict business with Israel and Israeli companies. These restrictive laws and policies may limit seriously our ability to sell our products in these countries.

Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, there have been times since October 2000 when Israel has experienced an increase in unrest and terrorist activity. The establishment in 2006 of a government in the Palestinian Authority by representatives of the Hamas militant group has created additional unrest and uncertainty in the region. In mid-2006, there was a war between Israel and the Hezbollah in Lebanon, resulting in thousands of rockets being fired from Lebanon up to 50 miles into Israel. Our current facilities are located in northern Israel, are in range of rockets that were fired from Lebanon into Israel during the war and suffered minimal damages during one of the rocket attacks. In the event that our facilities are damaged as a result of hostile action, our operations may be materially adversely affected.

***Our operations may be disrupted by the obligations of our personnel to perform military service which could have a material adverse effect on our business.***

Many of our male employees in Israel, including members of senior management, are obligated to perform up to one month (in some cases more) of annual military reserve duty until they reach age 45 and, in the event of a military conflict, could be called to active duty. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of military service of one or more of our key employees. A disruption could have a material adverse effect on our business.



***Because a certain portion of our expenses is incurred in New Israeli Shekels, or NIS, our results of operations may be seriously harmed by currency fluctuations and inflation.***

We report our financial statements in U.S. dollars, our functional currency, but we pay a meaningful portion of our expenses in NIS. As a result, we are exposed to risk to the extent that the inflation rate in Israel exceeds the rate of devaluation of the NIS in relation to the U.S. dollar or if the timing of these devaluations lags behind inflation in Israel. In that event, the U.S. dollar cost of our operations in Israel will increase and our U.S. dollar-measured results of operations will be adversely affected. To the extent that the value of the NIS increases against the dollar, our expenses on a dollar cost basis increase. Our operations also could be adversely affected if we are unable to guard against currency fluctuations in the future. To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS. These measures, however, may not adequately protect us from material adverse effects.

***The tax benefits available to us require that we meet several conditions and may be terminated or reduced in the future, which would increase our taxes and would have a material adverse effect on our business and results of operations.***

We are able to take advantage of tax exemptions and reductions resulting from the “Approved Enterprise” status of our facilities in Israel. To remain eligible for these tax benefits, we must continue to meet certain conditions, including making specified investments in property and equipment, and financing at least 30% of such investments with share capital. If we fail to meet these conditions in the future, the tax benefits would be canceled and we may be required to refund any tax benefits we already have enjoyed. These tax benefits are subject to investment policy by the Israeli Government Investment Center and may not be continued in the future at their current levels or at any level. In recent years the Israeli government has reduced the benefits available and has indicated that it may further reduce or eliminate some of these benefits in the future. The termination or reduction of these tax benefits or our inability to qualify for additional “Approved Enterprise” approvals may increase our tax expenses in the future, which would reduce our expected profits and adversely affect our business and results of operations. Additionally, if we increase our activities outside of Israel, for example, by future acquisitions, such increased activities generally may not be eligible for inclusion in Israeli tax benefit programs.

***The Israeli government grants we have received for certain research and development expenditures restrict our ability to manufacture products and transfer technologies outside of Israel and require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received together with interest and penalties which could have a material adverse effect on our business and results of operations.***

Our research and development efforts have been financed, in part, through grants that we have received from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or OCS. We, therefore, must comply with the requirements of the Israeli Law for the Encouragement of Industrial Research and Development, 1984, and related regulations, or the Research Law.

Under the Research Law, the discretionary approval of an OCS committee is required for any transfer of technology developed with OCS funding. OCS approval is not required for the export of any products resulting from the research or development, or for the licensing of the technology in the ordinary course of business. We may not receive the required approvals for any proposed transfer. Such approvals, if granted, may be subject to the following additional restrictions:

- we may be required to pay the OCS a portion of the consideration we receive upon any sale of such technology to an entity that is not Israeli. The scope of the support received, the royalties that were paid by us, the amount of time that elapses between the date on which the know-how is transferred and the date on which the grants were received, as well as the sale price, will be taken into account in order to calculate the amount of the payment; and
- the transfer of manufacturing rights could be conditioned upon an increase in the royalty rate and payment of increased aggregate royalties (up to 300% of the amount of the grant plus interest, depending on the percentage of the manufacturing that is foreign).

These restrictions may impair our ability to sell our technology assets or to outsource manufacturing outside of Israel. We have no current intention to manufacture or transfer technologies out of Israel. The restrictions will continue to apply even after we have repaid the full amount of royalties payable for the grants. If we fail to satisfy these conditions, we may be required to refund grants previously received together with interest and penalties which could have a material adverse effect on our business and results of operations.

***Investors may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws against us, our executive officers and most of our directors or asserting U.S. securities laws claims in Israel.***

Most of our directors and officers are not residents of the United States and most of their assets and our assets are located outside the United States. Service of process upon our non-U.S. resident directors and officers and enforcement of judgments obtained in the United States against us, some of our directors and executive officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that investors may find it difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws against us, our officers and our directors. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our officers and directors because Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above.

Israeli courts might not enforce judgments rendered outside Israel which may make it difficult to collect on judgments rendered against us. Subject to certain time limitations, an Israeli court may declare a foreign civil judgment enforceable only if it finds that:

- the judgment was rendered by a court which was, according to the laws of the state of the court, competent to render the judgment;
- the judgment may no longer be appealed;
- the obligation imposed by the judgment is enforceable according to the rules relating to the enforceability of judgments in Israel and the substance of the judgment is not contrary to public policy; and
- the judgment is executory in the state in which it was given.

Even if these conditions are satisfied, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel. An Israeli court also will not declare a foreign judgment enforceable if:

- the judgment was obtained by fraud;
- there is a finding of lack of due process;
- the judgment was rendered by a court not competent to render it according to the laws of private international law in Israel;
- the judgment is at variance with another judgment that was given in the same matter between the same parties and that is still valid; or
- at the time the action was brought in the foreign court, a suit in the same matter and between the same parties was pending before a court or tribunal in Israel.

## **Risks Related to Investing in Our Common Stock**

### ***The market price of our common stock may fluctuate significantly.***

The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- developments in the biotechnology industry; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for biotechnology companies in particular, has recently experienced price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Price volatility of our common stock may be worse if the trading volume of our common stock is low. We have not paid, and do not expect to pay, any cash dividends on our common stock as any earnings generated from future operations will be used to finance our operations. As a result, investors will not realize any income from an investment in our common stock until and unless their shares are sold at a profit.

### ***All liabilities of our company have survived the merger and there may be undisclosed liabilities that could harm our revenues, business, prospects, financial condition and results of operations.***

Protalix Ltd. and its counsel conducted due diligence on us that was customary and appropriate for the reverse merger transaction consummated on December 31, 2006. However, the due diligence process may not have revealed all our material liabilities then existing or that could be asserted in the future against us relating to our activities before the consummation of the merger. Any such potential liabilities survive the merger and could harm our revenues, business, prospects, financial condition and results of operations.

### ***Trading of our common stock is limited.***

Our common stock began trading on the American Stock Exchange in March 2007. To date, the liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and changes in security analyst and media coverage, if at all. These factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our common stock.

In connection with the merger with Protalix Ltd., substantially all of the former shareholders of Protalix Ltd. (holding, in the aggregate, 65,094,232 shares of our common stock and options and warrants to purchase 3,628,826 shares of our common stock) entered into lock-up agreements with respect to the securities of our company to satisfy Israeli tax laws and contractual obligations. The lock-up agreements prohibit such former shareholders of Protalix Ltd. from, directly or indirectly, selling or otherwise transferring the shares of our common stock issued to them in connection with the merger, including those underlying warrants, during a period commencing upon the closing of the merger and ending on January 1, 2009. However, during such period, each such former Protalix Ltd. shareholder may, under the terms of the lock-up agreements and a tax ruling received by Protalix Ltd. from the Israeli tax authorities in connection with the merger, sell an aggregate of 10% of each such shareholder's original number of locked-up shares. Accordingly, up to 6,872,306 shares of our common

stock, or approximately 9.1% of our outstanding shares of common stock, are available for sale by such shareholders. All permitted sales of locked-up shares that may be made during such time period are cumulative. Furthermore, under applicable Israeli tax law incorporated by reference into the tax ruling obtained by Protalix Ltd. from the Israeli tax authorities, during the lock-up period, we must maintain our holdings of at least 51% of Protalix Ltd. and our shareholders at the time of the consummation of the merger must maintain, in the aggregate, holdings of at least 51% of our outstanding share capital. These restrictions limit, to an extent, the volume of our shares available for public trading.

Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. Further, the limited liquidity could be an indication that the trading price is not reflective of the actual fair market value of our common stock.

***Future sales of our common stock could reduce our stock price.***

Sales by shareholders of substantial amounts of our shares, the issuance of new shares by us or the perception that these sales may occur in the future, could affect materially and adversely the market price of our common stock. As described herein, substantially all of the former shareholders of Protalix Ltd. (holding, in the aggregate, 65,094,232 shares of our common stock and options and warrants to purchase 3,628,826 shares of our common stock) entered into lock-up agreements with respect to their securities of our company to satisfy Israeli tax laws and contractual obligations. The lock-up agreements prohibit such former shareholders of Protalix Ltd. from, directly or indirectly, selling or otherwise transferring the shares of our common stock issued to them in connection with the merger during a period commencing upon the closing of the merger and ending on January 1, 2009. However, during such period, each such former Protalix Ltd. shareholder may, under the terms of the lock-up agreements and a tax ruling received by Protalix Ltd. from the Israeli tax authorities in connection with the merger, sell an aggregate of 10% of each such shareholder's original number of locked-up shares. Accordingly, up to 6,872,306 additional shares of our common stock, or approximately 9.1% of our outstanding shares of common stock, are eligible for sale in the public market by such shareholders. In connection with our public offering in October 2007, we, our executive officers and directors and substantially all of the former Protalix Ltd. shareholders agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 120 days after the date of the prospectus supplement we issued in connection with such offering, or February 22, 2008, without first obtaining the written consent of UBS Securities. After the lock-up agreements entered into in connection with the underwritten offering expire, an aggregate of approximately 6,872,306 additional shares of common stock, or approximately 9.1% of our outstanding shares of common stock, will be eligible for sale in the public market, subject in most cases to the limitations of either Rule 144 or Rule 701 under the Securities Act.

We have agreed to use our best efforts to file a shelf registration statement with the Securities and Exchange Commission covering the resale of all shares of common stock received by Protalix Ltd.'s former shareholders after our common stock has been listed for trading on the American Stock Exchange, and to use our best efforts to cause such registration statement to be declared effective as promptly as possible after filing. We will be obligated to maintain the effectiveness of this shelf registration statement until the shares registered under it are eligible for resale under Rule 144(k) of the Securities Act.

***Directors, executive officers, principal shareholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that an investor may not consider to be in the best interests of our shareholders.***

Our directors, executive officers, principal shareholders and affiliated entities beneficially own, in the aggregate, approximately 60% of our outstanding common stock. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our shareholders. This

concentration of ownership may have the effect of delaying or preventing a change in control of our company that may be favored by other shareholders. This could prevent the consummation of transactions favorable to other shareholders, such as a transaction in which shareholders might otherwise receive a premium for their shares over current market prices.

***Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and operating results. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of our common stock.***

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our results of operation could be harmed.

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accounting firm addressing these assessments. As of the date of the filing of this prospectus supplement, we will be required to comply with the Section 404 of the Sarbanes-Oxley Act of 2002 in connection with our annual report for the year ended December 31, 2007. We are in the process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404, and we may identify deficiencies that we may not be able to remediate in time to meet the deadlines imposed by the Sarbanes-Oxley Act. This process may divert internal resources and will take a significant amount of time and effort to complete.

If it is determined that we are not in compliance with Section 404, we may be required to implement new internal control procedures and reevaluate our financial reporting. We may experience higher than anticipated operating expenses as well as increased independent auditor fees during the implementation of these changes and thereafter. Further, we may need to hire additional qualified personnel. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, which could result in our being unable to obtain an unqualified report on internal controls from our independent auditors, which is required under current regulation for the fiscal year ended December 31, 2007. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

***Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses, divert management's attention from operating our business which could have a material adverse effect on our business.***

There have been other changing laws, regulations and standards relating to corporate governance and public disclosure in addition to the Sarbanes-Oxley Act, as well as new regulations promulgated by the Commission and rules promulgated by the national securities exchanges, including the American Stock Exchange, and the NASDAQ. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our board members, Chief Executive Officer and Chief Financial Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could have a material adverse effect on our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, we may incur additional expenses to comply with

standards set by regulatory authorities or governing bodies which would have a material adverse effect on our business and results of operations.

***We are a holding company with no operations of our own.***

We are a holding company with no operations of our own. Accordingly, our ability to conduct our operations, service any debt that we may incur in the future and pay dividends, if any, is dependent upon the earnings from the business conducted by Protalix Ltd., our only subsidiary. The distribution of those earnings or advances or other distributions of funds by our subsidiary to us, as well as our receipt of such funds, are contingent upon the earnings of our subsidiary and are subject to various business considerations and United States and Israeli law. If Protalix Ltd. is unable to make sufficient distributions or advances to us, or if there are limitations to our ability to receive such distributions or advances, we may not have the cash resources necessary to conduct our corporate operations which would have a material adverse effect on our business and results of operations.

## USE OF PROCEEDS

We will not receive any proceeds from the sale of shares covered by this Prospectus. While we may receive sums upon the exercise of certain awards by the selling securityholders, we currently have no plans for their application, other than for general corporate purposes. We cannot assure you that any of such options will be exercised.

## SELLING SECURITYHOLDERS

We are registering for resale the shares covered by this prospectus to permit the selling securityholders identified below and their pledgees, donees, transferees and other successors-in-interest that receive their shares from a securityholder as a gift, partnership distribution or other non-sale related transfer after the date of this prospectus to resell the shares when and as they deem appropriate. The selling securityholders acquired, or may acquire, these shares from us pursuant to the Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan. The shares may not be sold or otherwise transferred by the selling securityholders unless and until the applicable awards vest and are exercised, as applicable, in accordance with the terms and conditions of such plan.

The following table sets forth:

- the name of each selling securityholder;
- the position(s), office or other material relationship with our company and its predecessors or affiliates, over the last three years of each selling securityholder;
- the number and percentage of shares of our common stock that each selling securityholder beneficially owned as of December 15, 2007 prior to the offering for resale of the shares under this prospectus;
- the number of shares of our common stock that may be offered for resale for the account of each selling securityholder under this prospectus; and
- the number and percentage of shares of our common stock to be beneficially owned by each selling securityholder after the offering of the resale shares (assuming all of the offered resale shares are sold by such selling securityholder).

The number of shares in the column “Number of Shares Being Offered” represents all of the shares of our common stock that each selling securityholder may offer under this prospectus. We do not know how long the selling securityholders will hold the shares before selling them or how many shares they will sell, and we currently have no agreements, arrangements or understandings with any of the securityholders regarding the sale of any of the resale shares. The shares of our common stock offered by this prospectus may be offered from time to time by the securityholders listed below. We cannot assure you that any of the selling securityholders will offer for sale or sell any or all of the shares of common stock offered by them by this prospectus.

Securityholders	Number of Shares Beneficially Owned Prior to Offering(1)		Number of Shares Being Offered	Number of Shares Beneficially Owned After Offering(2)	
	Number	Percent		Number	Percent
David Aviezer, Ph.D., MBA(3)	1,785,154	2.3%	1,785,154	—	—
Einat Brill Almon, Ph.D.(4)	483,701	*	483,701	—	—
Yossi Maimon(5)	619,972	*	619,972	—	—
Iftah Katz(6)	204,351	*	204,351	—	—

\* less than 1%

- (1) Applicable percentage ownership is based on 75,685,318 shares of common stock outstanding as of December 15, 2007, plus any common stock equivalents or convertible securities held and shares beneficially owned by each such holder as set forth herein.

[Table of Contents](#)

- (2) Assumes that all shares of common stock to be offered, as set forth above, are sold pursuant to this offering and that no other shares of common stock are acquired or disposed of by the selling securityholders prior to the termination of this offering. Because the selling securityholders may sell all, some or none of their shares of common stock or may acquire or dispose of other shares of common stock, no reliable estimate can be made of the aggregate number of shares of common stock that will be sold pursuant to this offering or the number or percentage of shares of common stock that each selling securityholder will own upon completion of this offering.
- (3) Dr. Aviezer is a director of our company and serves as our President and Chief Executive Officer. Consists of 1,785,154 shares of our common stock issuable upon the exercise of vested and unvested options.
- (4) Dr. Brill Almon serves as our Vice President, Product Development. Consists of 483,701 shares of our common stock issuable upon the exercise of vested and unvested options.
- (5) Mr. Maimon serves as our Chief Financial Officer. Consists of 619,972 shares of our common stock issuable upon the exercise of vested and unvested options.
- (6) Mr. Katz serves as our Vice President of Operations. Consists of 204,351 shares of our common stock issuable upon the exercise of vested and unvested options.



## PLAN OF DISTRIBUTION

The selling securityholders and any of their respective pledgees, donees, assignees and other successors-in-interest may, from time to time, sell any or all of their shares of our common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling securityholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales after this registration statement becomes effective;
- broker-dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;
- through the writing of options on the shares;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling securityholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus. The selling securityholders will have the sole and absolute discretion not to accept any purchase offer or make any sale of shares if they deem the purchase price to be unsatisfactory at any particular time.

The selling securityholders may also engage in short sales against the box after this registration statement becomes effective, puts and calls and other transactions in our securities or derivatives of our securities and may sell or deliver shares in connection with these trades.

The selling securityholders or their respective pledges, donees, transferees or other successors in interest, may also sell the shares directly to market makers acting as principals and/or broker-dealers acting as agents for themselves or their customers. Such broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling securityholders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principal or both, which compensation as to a particular broker-dealer might be in excess of customary commissions. Market makers and block purchasers purchasing the shares of common stock in block transactions to market makers or other purchasers at a price per share which may be below the then market price. The selling securityholders cannot assure that all or any of the shares offered in this prospectus will be issued to, or sold by, the selling securityholders. The selling securityholders and any brokers, dealers or agents, upon effecting the sale of any of the shares offered in this prospectus, may be deemed to be “underwriters” as that term is defined under the Securities Act or the Securities Exchange Act of 1934, as amended, or the rules and regulations under such acts. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the selling securityholders. The selling securityholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling securityholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their

[Table of Contents](#)

secured obligations, the pledge or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or any other applicable provision of the Securities Act amending the list of selling securityholders to include the pledge, transferee or other successors in interest as selling securityholders under this prospectus.

The selling securityholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledges or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling securityholders to include the pledge, transferee or other successors in interest as selling securityholders under this prospectus.

Each of the selling securityholders acquired the securities offered hereby in the ordinary course of business and have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling securityholder. If we are notified by any selling securityholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling securityholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of our common stock and activities of the selling securityholders.

#### **WHERE YOU CAN FIND MORE INFORMATION**

This prospectus is part of a registration statement on Form S-8 that we filed with the Commission under the Securities Act. You should rely only on the information contained in this prospectus or incorporated by reference in this prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of common stock.

We file annual, quarterly and special reports, proxy statements and other information with the Commission. You may read, without charge, and copy the documents we file at the Commission's public reference rooms at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the Commission and paying a fee for the copying cost. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Our Commission filings are also available to the public at no cost from the Commission's website at [www.sec.gov](http://www.sec.gov) and our website at [www.protalix.com](http://www.protalix.com). We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document.

#### **INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, other than information that is furnished in such documents but deemed by the rules of the Commission not to have been filed:

- our Annual Report on Form 10-K, for the year ended December 31, 2006, as amended by our Annual Report on Form 10-K/A for the year ended December 31, 2006;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2007, June 30, 2007, and September 30, 2007;

[Table of Contents](#)

- our Current Reports on Form 8-K filed with the Commission on February 5, 2007, February 7, 2007 (as amended by a Form 8-K/A filed on February 22, 2007), March 2, 2007, March 12, 2007, April 18, 2007, May 4, 2007, June 4, 2007, June 20, 2007, June 27, 2007, July 13, 2007, July 30, 2007, August 6, 2007, August 10, 2007, August 27, 2007, September 19, 2007, October 9, 2007, October 25, 2007, October 25, 2007, November 2, 2007, November 29, 2007, December 3, 2007, December 5, 2007, January 17, 2008, and January 22, 2008; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the Commission on March 9, 2007.

All documents filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date of this prospectus shall be deemed to be incorporated by reference in the registration statement and to be a part hereof from the date of filing of such documents (other than information that is furnished in such documents but deemed by the rules of the Commission not to have been filed). Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement. You may request and obtain a copy of these filings, at no cost, by writing or telephoning us at the following address or phone number:

2 Snunit Street  
Science Park  
POB 455  
Carmiel, Israel 20100  
972-4-988-9488  
Attn: Yossi Maimon, Chief Financial Officer

#### **LEGAL MATTERS**

The validity of the issuance of the shares of common stock offered by this prospectus will be passed upon for us by Morrison & Foerster LLP, New York, New York.

#### **EXPERTS**

The consolidated financial statements incorporated in this Prospectus by reference to the Annual report on Form 10-K for the year ended December 31, 2006 have been so incorporated in reliance on the reports of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

#### **DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant, the registrant has been informed that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## PART II

### INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

#### Item 3. Incorporation of Documents by Reference.

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus supplement and the accompanying prospectus, and any future filings we will make with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, other than information that is furnished in such documents but deemed by the rules of the Commission not to have been filed:

- our Annual Report on Form 10-K, for the year ended December 31, 2006, as amended by our Annual Report on Form 10-K/A for the year ended December 31, 2006;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2007, June 30, 2007, and September 30, 2007;
- our Current Reports on Form 8-K filed with the Commission on February 5, 2007, February 7, 2007 (as amended by a Form 8-K/A filed on February 22, 2007), March 2, 2007, March 12, 2007, April 18, 2007, May 4, 2007, June 4, 2007, June 20, 2007, June 27, 2007, July 13, 2007, July 30, 2007, August 6, 2007, August 10, 2007, August 27, 2007, September 19, 2007, October 9, 2007, October 25, 2007, November 2, 2007, November 29, 2007, December 3, 2007, December 5, 2007, January 17, 2008, and January 22, 2008; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the Commission on March 9, 2007.

All documents filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date of this prospectus shall be deemed to be incorporated by reference in the registration statement and to be a part hereof from the date of filing of such documents (other than information that is furnished in such documents but deemed by the rules of the Commission not to have been filed). Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You may request and obtain a copy of these filings, at no cost, by writing or telephoning us at the following address or phone number:

2 Snunit Street  
Science Park  
POB 455  
Carmiel, Israel 20100  
972-4-988-9488  
Attn: Yossi Maimon, Chief Financial Officer

**Item 4. Description of Securities.**

Not applicable.

**Item 5. Interests of Named Experts and Counsel.**

Not applicable.

**Item 6. Indemnification of Directors and Officers.**

We indemnify our directors and officers to the maximum extent permitted by Florida law for the costs and liabilities of acting or failing to act in an official capacity. We also have purchased insurance in the aggregate amount of \$1,000,000 for our directors and officers against all of the costs of such indemnification or against liabilities arising from acts or omissions of the insured person in cases where we may not have power to indemnify the person against such liabilities. Such policy will be in a run-off “tail” coverage phase as of the merger effective date and will cover those individuals who were our officers and directors prior to the merger for a period of six-years after such individual resigned his/her position with our company.

In addition, we have entered into indemnification agreements with each of our executive officers and directors, to provide them with the maximum indemnification allowed under our bylaws and applicable Florida law, including indemnification for all judgments and expenses incurred as the result of any lawsuit in which such person is named as a defendant by reason of being our director, officer or employee, to the extent indemnification is permitted by the laws of Florida. We believe that the indemnification agreements will enhance our ability to continue to attract and retain qualified individuals to serve as directors and officers.

The articles of association of Protalix Ltd., our wholly-owned subsidiary, allow it to exculpate, indemnify, and insure its office holders to the fullest extent permitted by Israeli law. Accordingly, Protalix Ltd. has entered into indemnification agreements with each of its officers and directors undertaking to indemnify them to the fullest extent permitted by law, including with respect to liabilities resulting from the merger. This indemnification is limited to events determined as foreseeable by the Board of Directors based on the activities of Protalix Ltd., and to an amount determined by the Board of Directors as reasonable under the circumstances.

Protalix Ltd. further purchased and maintains directors and officers liability insurance policy coverage in the aggregate amount of \$3,000,000. In addition, we maintain additional directors and officers liability insurance policy coverage in the aggregate amount of \$20,000,000.

As of the date of hereof, no claims for directors and officers’ liability insurance have been filed under this policy and Protalix Ltd. is not aware of any pending or threatened litigation or proceeding involving any of the directors or officers of Protalix Ltd. in which indemnification is sought.

We have undertaken to fulfill and honor in all respects the obligations of Protalix Ltd. pursuant to any indemnification agreements between Protalix Ltd. and its directors in effect prior to December 31, 2006. We further agreed that any provision of Protalix Ltd.’s charter documents in relation to exculpation and indemnification of officers and directors of Protalix Ltd. will not be amended, repealed, or otherwise modified in any manner that would adversely affect the rights thereunder of individuals who, immediately prior to the closing of the merger, were directors, officers, employees or agents of Company, unless such modification is required by any applicable law.

Under Israeli law, an Israeli company may not exculpate an office holder from liability for a breach of the duty of loyalty of the office holder. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for a breach of duty of care (other than in the event that such liability arises out of a prohibited dividend or distribution) but only if a provision authorizing such exculpation is inserted in its articles of association. Protalix Ltd.’s articles of association include such a provision.

An Israeli company may indemnify an office holder in respect of certain liabilities either in advance of an event or following an event provided a provision authorizing such indemnification is

[Table of Contents](#)

inserted in its articles of association. Protalix Ltd.'s articles of association contain such an authorization. An undertaking provided in advance by an Israeli company to indemnify an office holder with respect to a financial liability imposed on or incurred by him or her in favor of another person pursuant to a judgment, settlement or arbitrator's award approved by a court must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned events and amount or criteria. In addition, a company may indemnify an office holder against the following liabilities incurred for acts performed as an office holder:

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf or by a third party or in connection with criminal proceedings in which the office holder was acquitted or as a result of a conviction for a crime that does not require proof of criminal intent.

An Israeli company may insure an office holder against the following liabilities incurred for acts performed as an office holder:

- a breach of duty of loyalty to the company, to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not be detrimental to the interests of the company;
- a breach of duty of care to the company or to a third party; and
- a financial liability imposed on the office holder in favor of a third party in respect of an act performed in his or her capacity as an office holder.

An Israeli company may not indemnify or insure an office holder against any of the following:

- a breach of duty of loyalty, except to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not be detrimental to the interests of the company;
- a grossly negligent or intentional violation of an office holder's duty of care;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine levied against the office holder.

Under the Israeli law, exculpation, indemnification, and insurance of office holders must be approved by the board of directors of Protalix Ltd. and, in respect of directors of Protalix Ltd., by us as the sole securityholder of Protalix Ltd.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors and officers or persons controlling us pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the Commission, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

**Item 7. Exemption from Registration Claims.**

Not applicable.

**Item 8. Exhibits.**

Exhibit Number	Exhibit Description	Method of Filing
4.1	Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan	Incorporated by reference to the Company's Annual Report on Form 10-K/A filed on July 13, 2007
5.1	Opinion of Morrison & Foerster LLP, New York, New York as to the legality of the securities being registered	Filed herewith
23.1	Consent of Morrison & Foerster LLP, New York, New York (included in Exhibit 5.1)	Filed herewith
23.2	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant	Filed herewith
24.1	Power of Attorney (included on signature page)	Filed herewith

**Item 9. Undertakings.**

The undersigned registrant hereby undertakes:

(1) to file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement;

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the Registration statement (or most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the change in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement.

*provided, however*, that paragraphs (1)(i) and (1)(ii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the Registration Statement;

(2) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof; and

[Table of Contents](#)

(3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.



## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Tel Aviv, State of Israel, on the 31st day of January, 2008.

### PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ David Aviezer  
David Aviezer, Ph.D.

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Aviezer, Ph.D. and Yossi Maimon, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for the undersigned and in his or her name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to the Registration Statement and to file the same, with all exhibits thereto, and all documents in connection therewith, including any subsequent registration statement for the same offering that may be filed under Rule 462(b), with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, the following persons in the capacities and on the dates indicated have signed this Registration Statement below on behalf of the Registrant.

<u>/s/ David Aviezer</u> David Aviezer, Ph.D.	President, Chief Executive Officer (Principal Executive Officer) and Director	January 31, 2008
<u>/s/ Yossi Maimon</u> Yossi Maimon	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	January 31, 2008
<u>/s/ Yoseph Shaaltiel</u> Yoseph Shaaltiel, Ph.D.	Executive VP, Research and Development and Director	January 31, 2008
<u>/s/ Eli Hurvitz</u> Eli Hurvitz	Chairman of the Board	January 31, 2008
<u>/s/ Amos Bar-Shalev</u> Amos Bar-Shalev	Director	January 31, 2008
<u>/s/ Zeev Bronfeld</u> Zeev Bronfeld	Director	January 31, 2008

[Table of Contents](#)

<u>/s/ Yodfat Harel Gross</u> Yodfat Harel Gross	Director	January 31, 2008
<u>/s/ Eyal Sheratzky</u> Eyal Sheratzky	Director	January 31, 2008
<u>/s/ Sharon Toussia-Cohen</u> Sharon Toussia-Cohen	Director	January 31, 2008

## INDEX TO EXHIBITS

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Method of Filing</b>
4.1	Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan	Incorporated by reference to the Company's Annual Report on Form 10-K/A filed on July 13, 2007
5.1	Opinion of Morrison & Foerster LLP, New York, New York as to the legality of the securities being registered	Filed herewith
23.1	Consent of Morrison & Foerster LLP, New York, New York (included in Exhibit 5.1)	Filed herewith
23.2	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant	Filed herewith
24.1	Power of Attorney (included on signature page)	Filed herewith

---

[LETTERHEAD OF MORRISON & FOERSTER LLP]

January 31, 2008

Protalix BioTherapeutics, Inc.  
2 Snunit Street  
Science Park  
POB 455  
Carmiel, Israel 20100

Re: Protalix BioTherapeutics, Inc. – Registration Statement on Form S-8

Ladies and Gentlemen:

We have acted as counsel to Protalix BioTherapeutics, Inc., a Florida corporation (the “Company”), in connection with the preparation and filing with the Securities and Exchange Commission (the “Commission”) of a Registration Statement on Form S-8 (the “Registration Statement”), relating to the registration by the Company under the Securities Act of 1933, as amended (the “Securities Act”), of up to 9,741,655 shares of its common stock, \$.001 par value per share (the “Common Stock”), which will be issuable under the Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan (the “Plan”). This opinion is being rendered in connection with the filing of the Registration Statement.

As your counsel in connection with the Registration Statement, we have examined the proceedings taken by you in connection with the adoption of the Plan and the authorization of the issuance of the shares of common stock under the Plan (the “Plan Shares”), and such documents as we have deemed necessary to render this opinion. For the purpose of the opinion rendered below, we have assumed that in connection with the issuance of shares under the Plan, the Company will receive consideration in an amount not less than the aggregate par value of the Plan Shares covered by each such issuance. In our examination, we have assumed the genuineness of all signatures, the legal capacity of natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified or photostatic copies and the authenticity of the originals of such copies.

Based upon and subject to the foregoing, it is our opinion that the Plan Shares, when issued and sold in the manner referred to in the Plan and pursuant to any agreements that accompany the Plan, the shares will be validly issued, fully paid and nonassessable.

It is understood that this opinion is to be used only in connection with the offer and sale of the Plan Shares while the Registration Statement is in effect.

Please note that we are opining only as to the matters expressly set forth herein, that no opinion should be inferred as to any other matter. In rendering the foregoing opinion, we have relied, for matters involving Florida law, solely on the opinion of Shutts & Bowen LLP, Miami, Florida. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein.

We hereby consent to the use of our name under the heading “Legal Matters” in the Registration Statement to be filed by the Company with the Commission. We further consent to your filing a copy of this opinion as Exhibit 5.1 to the Registration Statement. In giving such permission, we do not admit hereby that we come within the category of persons whose consent is required under Section 7 of the Securities Act, or the rules and regulations of the Commission thereunder. We disclaim any undertaking to advise you of any subsequent changes of the facts stated or assumed herein or any subsequent changes in applicable law.

Very truly yours,

/s/ Morrison & Foerster LLP

---



**CONSENT OF  
INDEPENDENT  
REGISTERED  
PUBLIC  
ACCOUNTING FIRM**

Kesselman & Kesselman  
Certified Public Accountants (Ist.)  
Trade Tower, 25 Harmered Street  
Tel Aviv 68125 Israel  
P.O. Box 452 Tel Aviv 61003 Israel  
Telephone +972-3-7954555  
Facsimile +972-3-7954556

We hereby consent  
to the incorporation by  
reference in this

Registration Statement on Form S-8 of our report dated March 30, 2007 relating to the financial statements which appears in Protalix BioTherapeutics, Inc.'s Annual Report on Form 10-K/A for the year ended December 31, 2006. We also consent to the references to us under the heading "Experts" in such Registration Statement.

/s/ Kesselman & Kesselman

Tel Aviv, Israel  
January 29, 2008