

Protalix BioTherapeutics, Inc.  
Form 10-K/A  
July 13, 2007  
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2006

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

001-33357

(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Florida  
(State or other jurisdiction  
of incorporation or organization)

2 Snunit Street  
Science Park  
POB 455

Carmiel, Israel

(Address of principal executive office)

972-4-988-9488

65-0643773  
(I.R.S. Employer  
Identification No.)

20100  
(Zip Code)

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(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, par value \$0.001 per share	American Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:  
None

Indicate by check mark if the registration is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not registered to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. (See definition of "large accelerated filer" and "accelerated filer" in Rule 12b-2 of the Exchange Act). (check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting stock held by non-affiliates of the Registrant, as of June 30, 2006 was approximately \$12.6 million (based upon the closing price for shares of the Registrant's common stock as reported by the OTC Bulletin Board® as of June 30, 2006 of \$5.05), without giving effect to the one-for-ten reverse stock split we completed on December 29, 2006. Shares of common stock held by each officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 15, 2007, approximately 65,657,181 shares of the Registrant's common stock, \$0.001 par value, were outstanding.

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## PART I

Except where the context otherwise requires, the terms, “we”, “us”, “our” or “the Company,” refer to the business of Protalix BioTherapeutics, Inc. and its consolidated subsidiaries, and “Protalix” or “Protalix Ltd.” refers to the business of Protalix Ltd., our wholly-owned subsidiary and sole operating unit.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth under the captions “Business,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Risk Factors”, and other statements included elsewhere in this Annual Report on Form 10-K/A, 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 the expectations, beliefs, intentions or strategies for the future. When used in this report, the terms “anticipate,” “believe,” “estimate,” “expect” and “intend” and words or phrases of similar import, as they relate to 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 FDA, or other regulatory authorities;
- any lack of progress of our research and development (including the results of clinical trials being conducted by us);
- obtaining on a timely basis sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies;
- our ability to obtain additional 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 procedures in which our products are used;
- 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 in 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.

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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 “Risk Factors” in this Annual Report on Form 10-K/A. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

## Item 1. Business

We are a clinical stage biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx™ 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 development candidate is prGCD for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. We have received approval from the United States Food and Drug Administration, the FDA, in April 2007 to commence phase III clinical trials. We submitted to the FDA a request for a special protocol assessment (SPA) of the final design of our pivotal phase III clinical trial for prGCD. In July 2007, we reached an agreement with the FDA on the design that we submitted in the SPA request. We expect to initiate enrollment of patients in our phase III clinical trials in the third quarter of 2007. 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 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 billion in 2006, 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 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 as compared to the existing enzyme replacement therapy for Gaucher disease which may translate into lower dosages and/or less frequent treatments.

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 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 such 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.

Our ProCellEx protein expression system consists of a comprehensive set of technologies and capabilities for the development of recombinant proteins, including advanced genetic engineering

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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.

Our goal is to become a leading fully integrated biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins. To that end, we are leveraging our ProCellEx protein expression system to develop a pipeline of proprietary recombinant therapeutic proteins. 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 initial agreement in principle with the technology transfer arm of the Hebrew University of Jerusalem. In addition, we are 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.

## Industry Overview

Recombinant proteins have revolutionized the treatment of a variety of diseases and disorders. Recombinant proteins are forms of human proteins that are produced, or expressed, using a mammalian, plant, bacterial or yeast cell as a production engine. In the early 1970s, a number of key scientific breakthroughs, including, among others, the demonstration of genetic engineering and genetic sequencing techniques, as well as the synthesis of genes, led to the advancement of recombinant protein technology.

As a result, the market for pharmaceutical therapeutics has undergone a transformation as recombinant proteins and other biologic products have become an increasingly significant portion of

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the global drug market and the focus of research worldwide. Based upon data from the Biotechnology Industry Organization, an organization that provides information, advocacy and business support to the biotechnology industry, since the introduction in 1982 of recombinant human insulin, the world's first genetically engineered pharmaceutical product, over 254 biotechnology drugs have been approved for over 392 indications. According to Datamonitor, a provider of business information to the pharmaceutical and other industries, the overall global biologics market size is expected to grow to \$105.2 billion in 2010, from \$56.1 billion in 2004, representing a compounded annual growth rate (CAGR) of 11.1%.

Mammalian cell-based systems are the current industry standard for expression of recombinant therapeutic glycoproteins (complex proteins that contain sugar residues), including catalytic enzymes and monoclonal antibodies. Mammalian cell-based systems were first introduced in the late 1980s and are currently used to produce many of the biotechnology industry's largest and most successful therapeutic proteins, including Epogen<sup>®</sup>, Neupogen<sup>®</sup>, Cerezyme, Rituxan<sup>®</sup>, Enbrel<sup>®</sup>, Neulasta<sup>®</sup> and Herceptin<sup>®</sup>. Mammalian cell-based expression technology is based on the introduction of a human gene encoding for a specific therapeutic protein into the genome of a mammalian cell. The cells most often used in connection with mammalian cell-based protein expression are Chinese hamster ovary (CHO) cells.

Mammalian cell-based expression systems have become the dominant system for the expression of recombinant proteins due to their capacity for sophisticated, proper protein folding (which is necessary for proteins to carry out their intended biological activity), assembly and post-expression modification, such as glycosylation (the addition of sugar residues to a protein enabling specific biological activity). While bacterial and yeast cell-based expression systems were the first protein expression systems developed by the biotechnology industry and remain cost-effective compared to mammalian cell-based production methodologies, proteins expressed in bacterial and yeast cell-based systems lack the capacity for sophisticated protein folding, assembly and post-expression modifications, which are key factors of mammalian cell-based systems. Accordingly, such systems cannot be used to produce glycoproteins or other complex proteins and, therefore, bacterial and yeast cell-based systems are limited to the expression of the most basic, simple proteins, such as insulin and growth hormones. Due to their significant advantages, mammalian cell-based expression systems can produce proteins with superior quality and efficacy compared to proteins expressed in bacteria and yeast cell-based systems. As a result, the majority of currently approved therapeutic proteins, as well as those under development, are produced in mammalian cell-based systems.

Despite the utility and widespread use of mammalian cell-based systems, they have a number of disadvantages. CHO cells and other mammalian cells are highly sensitive and can only be grown under near perfect conditions, requiring highly complex, expensive, stainless steel bioreactors which tightly regulate the required temperature, pH and oxygen levels. As a result, such bioreactor systems are very costly and complicated to operate. CHO cells and other

mammalian cells are also susceptible to viral infections, including human viruses. The FDA and other regulatory authorities require viral inactivation and other rigorous and detailed procedures for mammalian cell-based manufacturing processes in order to address these potential hazards, thereby increasing the cost and time demands of such expression systems. Furthermore, the current FDA and other procedures only ensure screening for scientifically identified, known viruses. Accordingly, compliance with current FDA and other procedures does not fully guarantee that patients are protected against transmission of unknown or new potentially fatal viruses that may infect mammalian cells. In addition, mammalian cell-based expression systems require large quantities of sophisticated and expensive growth medium to accelerate the expression process.

Several companies and research institutions have explored alternatives to mammalian cell-based production technologies that overcome some of these disadvantages, focusing primarily on the expression of human proteins in genetically-modified organisms, or GMOs, such as transgenic field-grown, whole plants and transgenic animals. However, these alternate techniques may be restricted by regulatory and environmental risks and by the difficulty in applying cGMP standards of the pharmaceutical industry to these expression technologies.

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### ProCellEx: Our Proprietary Protein Expression System

ProCellEx is our proprietary production system that we have developed based on our plant cell culture technology for the development, expression and manufacture of recombinant proteins. Our expression system consists of a comprehensive set of capabilities and proprietary technologies, including advanced genetic engineering and plant cell culture technology, which enables us to produce complex, proprietary and biologically equivalent proteins for a variety of human diseases. Our protein expression system facilitates the creation and selection of high expressing, genetically stable cell lines capable of expressing recombinant proteins. The entire protein expression process, from initial nucleotide cloning to large-scale production of the protein product, occurs under cGMP-compliant, controlled processes. Our plant cell culture technology uses plant cells, such as carrot and tobacco cells, which undergo advanced genetic engineering and are grown on an industrial scale in a flexible bioreactor system. Cell growth, from scale up through large-scale production, takes place in flexible, sterile, polyethylene bioreactors which are confined to a clean-room environment. Our bioreactors are well-suited for plant cell growth using a simple, inexpensive, chemically-defined growth medium as a catalyst for growth. The reactors are custom-designed and optimized for plant cell cultures, easy to use, entail low initial capital investment, are rapidly scalable at a low cost and require less hands-on maintenance between cycles. Our protein expression system does not involve mammalian or animal components or transgenic field-grown, whole plants at any point in the production process.

Our ProCellEx system is capable of producing proteins with an amino acid structure practically equivalent to that of the desired human protein, and with a very similar, although not identical, glycan, or sugar, structure. Our internal research and external laboratory studies have demonstrated that ProCellEx is capable of producing recombinant proteins that exhibit a glycan and amino acid structure similar to their naturally-produced human counterparts. In addition, proteins produced by our ProCellEx system maintain the biological activity that characterize that of the naturally-produced proteins. In collaboration with Israel's Weizmann Institute of Science, we have demonstrated that the three-dimensional structure of a protein expressed in our proprietary plant cell-based expression system retains the same three-dimensional structure as exhibited by the mammalian cell-based expressed version of the same protein. Based on these results, we believe that proteins developed using our ProCellEx protein expression system have the intended composition and correct biological activity of their human equivalent 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.** We seek to develop recombinant proteins that we believe we can produce and commercialize without infringing upon the method-based patents or other intellectual property rights of third parties. In several cases, the marketed biotherapeutic protein is not itself subject to patent protection and is available for use in the public domain; however, the process of expressing the protein product in mammalian or bacterial cell systems is protected by method-based patents. Using our plant cell-based protein expression technology, we are able to express the equivalent protein without infringing upon these method-based patents. 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.

**Significantly Lower Capital and Production Costs.** Plant cells have a number of dynamic qualities that make them well-suited for the production of therapeutic proteins. Plant cells grow rapidly under a variety of conditions and are not as sensitive to temperature, pH and oxygen levels as mammalian cells. Our ProCellEx protein expression system, therefore, requires significantly less upfront capital expenditures as it does not use highly complex, expensive, stainless steel bioreactors typically used in mammalian cell-based production systems to maintain very specific temperature, pH and oxygen

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levels. Instead, we use simple polyethylene bioreactors that are able to be maintained at the room temperature of the clean-room in which they are placed. This system also reduces ongoing production and monitoring costs typically incurred by companies using mammalian cell-based expression technologies. Furthermore, while mammalian cell-based systems require very costly growth media at various stages of the production process to achieve target yields of their proteins, plant cells require only simple and much less expensive solutions based on sugar, water and microelements at infrequent intervals to achieve target yields. We believe that these factors will potentially result in lower capital and production costs for the commercial scale production of proteins by our ProCellEx system thereby providing us with a competitive advantage over competing protein expression technologies.

**More Effective and Potent End Product Relative to Mammalian Based Systems.** Our ProCellEx expression system produces enzymes which have uniform glycosilation patterns and therefore do not require the lengthy and expensive post-expression modifications that are required for certain proteins produced by mammalian cell-based systems, including the proteins for the treatment of Gaucher disease. Such post-expression modifications in mammalian cell-produced proteins are made in order to expose the terminal mannose sugar residues, which are structures on the protein that are key elements in allowing the produced protein to bind to a target cell and subsequently be taken into the target cell for therapeutic benefit. In the production of Cerezyme, exposing these terminal mannose sugar residues involves a multitude of highly technical steps which add time and cost to the production process. In addition, these steps do not guarantee the exposure of all of the required terminal mannose sugar residues, resulting in lower effective yields and inconsistency in potency from batch to batch. Our ProCellEx protein expression system, by contrast, produces prGCD in a “ready to use” form that does not require additional glycosilation or other modifications to make it

suitable for use in enzyme replacement therapy for Gaucher disease. We believe this quality increases the potency and consistency of the expressed proteins, thereby further increasing the cost advantages of our ProCellEx protein expression system over competing protein expression methodologies.

**Elimination of the Risk of Viral Transmission or Infection by Mammalian Components.** By nature, plant cells do not carry the risk of infection by human or other animal viruses. As a result, the risk of contamination of our products under development and the potential risk of viral transmission from our products under development to future patients, whether from known or unknown viruses, is eliminated. Because our product candidates do not bear the risk of viral transmission, we are not required by the FDA or other regulatory authorities to perform the constant monitoring procedures for mammalian viruses during the protein expression process that mammalian cell-based manufacturers are required to undertake. In addition, the production process of our ProCellEx protein expression system is void of any mammalian components which are susceptible to the transmission of prions, such as those related to bovine spongiform encephalopathy (commonly known as “mad-cow disease”). These factors further reduce the risks and operating costs of our ProCellEx system compared to mammalian cell-based expression systems.

**Broad Range of Expression Capabilities.** Unlike bacterial and yeast cell-based systems, which are unable to produce complex proteins, our ProCellEx protein expression system is able to produce a broad array of complex glycosylated proteins. We have successfully demonstrated the feasibility of our ProCellEx system by producing, on an exploratory, research scale, a variety of therapeutic proteins belonging to different classes of recombinant drugs, such as enzymes, hormones, monoclonal antibodies, cytokines and vaccines. We have demonstrated that the recombinant proteins we have expressed to date has the intended composition and correct biological activity of their human-equivalent protein, with several of such proteins demonstrating advantageous biological activity as compared to the currently available biotherapeutics.

#### 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.** We intend to commence a phase III clinical trial for prGCD in the third quarter of 2007 in selected leading medical centers worldwide and, if the phase III clinical trial produces favorable results, we expect to file a New

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Drug Application, an NDA, for prGCD with the FDA by the end of 2008 or early 2009. We believe that prGCD may have cost, efficacy and potency advantages over the currently available enzyme replacement therapy for Gaucher disease and we intend to pursue post-marketing studies to confirm these advantages. Although Gaucher disease is a relatively rare disease, it represents a substantial commercial market due to the severity of the symptoms and the chronic nature of the disease. We believe that prGCD, with its potentially longer acting profile and more cost-effective development process, may be able to increase the number of patients who will be able to have access and afford such treatment, thereby expanding the market for Gaucher disease treatments.

**Develop a Pipeline of Innovative Recombinant Therapeutic Proteins.** We are leveraging our ProCellEx protein expression system to develop a pipeline of innovative recombinant proteins, with an emphasis on therapeutic treatments with large market opportunities. We select additional therapeutic candidates for development through

in-house testing, licensing agreements with academic institutions and collaborations with pharmaceutical partners. We have currently identified several product candidates oriented towards the specialty disease and therapeutic market segments, including treatments for Fabry disease and female infertility disorders. We believe that the clinical and regulatory pathway for many of our pipeline product programs candidates is already established, and that this may reduce the risks and costs associated with our clinical development programs. Furthermore, established markets already exist for each of our current product candidates. We plan to apply the manufacturing, clinical and regulatory experience gained from our lead product candidate to advance a number of our preclinical product candidates into clinical trials over the next few years.

**Build a Targeted Sales and Marketing Infrastructure.** We plan to establish our own, internal sales and marketing capabilities in North America, the European Union and in other significant markets, including Israel. We believe that the focus of our current clinical pipeline on relatively rare genetic disorders with small patient populations and a highly concentrated group of physicians focused on treating patients with such disorders will enable us to create a targeted internal sales force.

**Establish Development and Commercialization Alliances with Corporate Partners.** We believe that our technology and know-how has broad applicability to many classes of proteins and can be used to develop and potentially enhance numerous existing marketed protein therapeutics. We intend to leverage our technology and know-how by pursuing development and commercialization alliances with corporate partners for specific products and territories in order to enable us to optimize our resources and effectively penetrate a wider range of target diseases and therapeutic markets. We entered into an agreement with Teva in September 2006 for the development of two proteins. We are in various stages of discussions with a number of multinational pharmaceutical companies regarding additional collaboration agreements.

**Acquire or In-License New Technologies, Products or Companies.** We continuously seek attractive product candidates and innovative technologies to in-license or acquire. We intend to focus on product candidates that would be synergistic with our ProCellEx protein expression system and expertise and that represent large potential market opportunities. We believe that by pursuing selective acquisitions of companies or technologies in businesses that complement our own, we will be able to enhance our competitiveness and strengthen our market position.

**Leverage Strength and Experience of Our Management Team and Board of Directors.** Our management team has extensive experience in the biotechnology and pharmaceutical industry. Our Board of Directors includes pharmaceutical industry veterans, such as our Chairman, Mr. Eli Hurvitz, current Chairman of the Board and former President and Chief Executive Officer of Teva, Dr. Phillip Frost, current Vice-Chairman of Teva and former President and Chief Executive Officer of Ivax Corporation and Dr. Jane Hsiao, former Vice Chairman of Ivax Corporation. We will continue to leverage their experience and established track record in building leading companies as well as their relationships across the biotechnology and pharmaceutical industries.

#### Our Pipeline Drug Candidates

#### Our Lead Product Candidate, prGCD

prGCD, our lead proprietary product candidate, is a plant cell expressed recombinant Glucocerebrosidase enzyme (GCD) for the treatment of Gaucher disease. In April 2007, we received

approval from the FDA to commence a phase III clinical trial of prGCD. We submitted to the FDA a request for a special protocol assessment (SPA) of the final design of our pivotal phase III clinical trial for prGCD. In July 2007, we reached an agreement with the FDA on the design that we submitted in the SPA request. We expect to initiate the clinical trial in the third quarter of 2007. In clinical trials in healthy subjects and in vivo primate studies, prGCD has demonstrated an increased half-life and prolonged presence of the enzyme in the blood serum of the subjects as compared to Cerezyme, the only enzyme replacement therapy currently marketed to treat Gaucher disease. We believe that prGCD, if approved, has the potential to offer patients and healthcare payors a more effective and cost efficient treatment of Gaucher disease because of the following features:

**Increased Glycan Efficacy and Consistency.** We believe that our ProCellEx protein expression system produces recombinant proteins that exhibit consistent enzymatic activity from batch to batch. This results in a highly active product that may achieve a desired therapeutic effect more effectively than the activity demonstrated in proteins produced through mammalian cell-based expression systems due to its greater glycan efficacy and consistency. This quality increases the effective consistency in potency and further increases the cost advantages from using our plant cell-based expression technology compared to competing protein expression methodologies.

**Longer Half-Life.** The data generated in preclinical and human clinical trials relating to the half-life of prGCD in the subjects' blood serum after infusion showed that the half-life of prGCD is significantly longer than that of Cerezyme when measured and compared to publicly available data on Cerezyme.

**Cost-Effective.** prGCD is potentially less expensive to produce as the manufacturing process does not require the large initial set-up investments involved in mammalian cell-based protein production, the extensive ongoing costs associated with growth media and monitoring throughout the production process nor any of the post-expression modification costs in order to modify the glycosilation of the proteins produced through the mammalian cell-based methodologies.

As such, we believe that prGCD's potential advantages may lead prGCD to become a highly efficacious and cost-effective treatment alternative for Gaucher disease patients.

#### Gaucher Disease Background

Gaucher disease, a hereditary, genetic disorder with severe and debilitating symptoms, is the most prevalent lysosomal storage disorder in humans. Lysosomes are small membrane-bound cellular structures within cells that contain enzymes necessary for intracellular digestion. Gaucher disease is caused by mutations or deficiencies in the gene encoding GCD, a lysosomal enzyme that catalyzes the degradation of the fatty substrate, glucosylceramide (GlcCer). The normal degradation products of GlcCer are glucose and ceramide, which are easily excreted by the cells through normal biological processes. Patients with Gaucher disease lack or otherwise have dysfunctional GCD and, accordingly, are not able to break down GlcCer. The absence of an active GCD enzyme leads to the accumulation of GlcCer in lysosomes of certain white blood cells called macrophages. Macrophages affected by the disease become highly enlarged due to the accumulation of GlcCer and are referred to as "Gaucher cells." Gaucher cells accumulate in the spleen, liver, lungs, bone marrow and brain. Signs and symptoms of Gaucher disease may include enlarged liver and spleen, abnormally low levels of red blood cells and platelets and skeletal complications.

#### Current Treatments for Gaucher Disease

The standard of care for Gaucher disease is enzyme replacement therapy using recombinant GCD to replace the mutated or deficient natural GCD enzyme. The latest studies estimate that there are approximately 10,000 patients suffering from Gaucher disease worldwide. Cerezyme, an enzyme replacement therapy commercialized by Genzyme Corporation, is the only recombinant GCD currently available on the market and approved worldwide for the treatment of Gaucher disease. According to public reports issued by Genzyme, Cerezyme was used to treat approximately 4,800 patients and had annual sales of approximately \$1 billion in 2006. Cerezyme is produced through

a mammalian cell-based protein expression process in CHO cells. There are no known severe side effects to the use of Cerezyme and its approved use over the past decade suggests that it is an effective treatment of Gaucher disease. However, Cerezyme is subject to the limitations of most

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mammalian cell-based therapeutic proteins, including lengthy and costly production processes. As enzyme replacement therapy does not cure the genetic disorder, but rather provides an external source for transfusion of the missing or mutated enzyme, Gaucher disease patients generally receive the treatment over their entire lifetime. The current average annual cost for enzyme replacement therapy for an adult Gaucher disease patient in the United States is in excess of \$200,000.

The only other approved drug for the treatment of Gaucher disease is Zavesca (miglustat), marketed by Actelion Ltd. Zavesca has been approved by the FDA for use in the United States as an oral treatment. However, it has many side effects and the FDA has approved it only for administration to those patients who cannot be treated through enzyme replacement therapy, and, accordingly, have no other treatment alternative. As a result, Zavesca's use has been extremely limited. Actelion has reported sales of Zavesca of approximately CHF 24.5 million (approximately \$20.0 million) for 2006.

### prGCD Development Program

We believe the clinical development path for prGCD will be similar to that followed by the existing enzyme replacement therapy currently on the market. Efficacy endpoints for these studies, including reduction in size of spleen and platelet count, are generally well-established and accepted by regulatory agencies.

### Laboratory Testing and Preclinical Studies of prGCD

We have conducted several in vitro tests and in vivo preclinical studies of prGCD. Our preclinical rodent and primate trials generated extensive toxicological and safety data that demonstrated no adverse effects, even with very high doses of prGCD being administered via intravenous infusions. In short term repeat dose studies in rodents and primates and nine month repeat dose studies in primates, no toxicity was observed at dosage levels of up to 10 times the current dose recommended for GCD in clinical use. Furthermore, no neutralizing antibodies were detected in any of the primates treated in the studies. The presence of neutralizing antibodies would have implied a likelihood of the host rejecting the therapeutic enzyme or reacting to it in a less efficient manner.

Our laboratory and preclinical data demonstrate that prGCD has the potential to be an efficacious enzyme replacement therapy for the treatment of Gaucher disease. Data produced from these preliminary development studies show that, relative to Cerezyme, prGCD has:

- an equivalent to superior level of enzymatic activity (see Figure 1);
- enhanced uptake based on observed GlcCer substrate degradation (see Figure 2); and
- a prolonged half-life (see Figure 3).

As shown in Figure 1, we compared the enzymatic activity of prGCD and Cerezyme using an in vitro assay where increasing amounts of GlcCer substrate (S), provided in millimolar, were degraded by a fixed amount of prGCD and Cerezyme, measured in milligrams. Enzymatic activity was measured by the rate of degradation of GlcCer into

glucose and ceramide (its normal degradation products), measured by millimoles of product produced per minute per fixed amount of enzyme. In the study assays performed, one demonstrated that prGCD had enzymatic activity that was equivalent to Cerezyme; the other studies demonstrated superior activity by prGCD. Figure 1 demonstrates that the enzymatic activity of prGCD was superior to Cerezyme.

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Figure 1: prGCD and Cerezyme Enzymatic Activity

As shown in Figure 2, we compared the uptake of increasing amounts of Cerezyme and prGCD into the target cell, using an ex vivo mouse macrophage cell model. Cellular uptake was measured in cell lysates, solutions containing the contents of burst cells, by comparing enzymatic activity at various enzyme concentrations of Cerezyme and prGCD based on the amount of GlcCer substrate degradation into glucose and ceramide, measured in a microplate absorbance reader, a flat plate with multiple “wells” used as small test tubes, at an optical density of 405 nanometers. The results in Figure 2 demonstrate that the uptake into the macrophage cells of prGCD was greater than the uptake of Cerezyme at higher enzyme concentrations, as measured by the resulting enzymatic activity in the cells. We believe that the ability of the plant cells to directly generate the required terminal mannose structures for efficient glycosilation of prGCD, results in the enhanced uptake of prGCD into the Gaucher cells. In contrast, Cerezyme requires post-expression and purification modifications to expose the terminal mannose structures, which modification process can yield enzymes with less consistent glycosilation patterns and could reduce cellular uptake of Cerezyme.

Figure 2: prGCD and Cerezyme Cellular Uptake

Furthermore, the data generated in preclinical trials relating to pharmacokinetic parameters, specifically the half-life of enzyme in the subjects’ blood serum after infusion, showed that the half-life of prGCD is significantly longer than that of Cerezyme as disclosed publicly by Genzyme. We believe the extended half-life of prGCD relative to Cerezyme is attributable to the different glycoside profile, thereby resulting in the enhanced uptake of prGCD into the Gaucher cells.

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Figure 3: prGCD and Cerezyme Half-Life Data

	prGCD	Cerezyme
Primates	~13.0-20.0 minutes	~6.8-8.0 minutes <sup>(1)</sup>
Humans	~10.5-14.5 minutes	~3.6-10.4 minutes <sup>(2)</sup>

(1) Source: Cerezyme NDA – PharmTox review

(2) Source: Cerezyme labeling approved by FDA for package insert  
Prior to submitting an NDA, if at all, we intend to conduct further, standard preclinical studies of prGCD.

#### Phase I Clinical Trial

We completed a phase I clinical trial of prGCD in June 2006 which was performed under an FDA Investigational New Drug (IND) approval. The phase I clinical trial was a single-center, non-randomized, open label, dose ranging study designed to evaluate the safety and pharmacokinetics of prGCD in healthy subjects. The trial was conducted on healthy subjects over a four-week period in which subjects received three single escalating doses of prGCD administered as intravenous infusions.

All doses administered to subjects in the phase I clinical trial, including the highest dose, which was the same dosage currently suggested with respect to the treatment by Cerezyme, demonstrated a strong safety profile. The data from our phase I clinical trial showed that prGCD was safe and well tolerated at all doses. See Figure 4.

Figure 4: Adverse Events presented by: Dose Group, Severity and Relation to Study Treatment  
(Incidents; Subjects (% of Subjects))

Relation between Event to Drug					Events	Total
	15 U/kg	30 U/kg	60 U/kg	Placebo	Severity	
Unrelated to drug <sup>(1)</sup>	0; 0 (0%)	0; 0 (0%)	2; 1 (17%)	0; 0 (0%)	Moderate	2
Remotely related to drug <sup>(2)</sup>	4; 2 (33%)	1; 1 (17%)	2; 1 (17%)	1; 1 (17%)	Mild	8
Possibly related to drug <sup>(3)</sup>	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)		0
Probably related to drug <sup>(4)</sup>	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)		0
Related to drug <sup>(5)</sup>	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)		0

- (1) The event is clearly related to other factors, such as a subject's clinical state, therapeutic interventions or concomitant medications.
- (2) The event was most likely produced by other factors, such as a subject's clinical state, therapeutic interventions or concomitant medications, and does not follow a known response pattern to the study drug.
- (3) The event has a reasonable temporal relationship to the study drug administration and follows a known response pattern to the study drug. However, a potential alternate etiology may be responsible for the event. The effect of drug withdrawal is unclear. Rechallenge information is unclear or lacking.
- (4) The event follows a reasonable temporal sequence from the time of drug administration, and follows a known response pattern to the study drug and cannot be reasonably explained by other factors. There is a reasonable response to withdrawal of the drug. Rechallenge information is not available or advisable.
- (5) The event follows a temporal sequence from the time of drug administration and follows a known response pattern to the study drug. The event either occurs immediately following the study drug administration, improves on stopping the drug or reappears on repeated exposure.

There were no serious adverse events and no subjects withdrew from the trial or discontinued treatment due to an adverse event.

In addition, as illustrated in Figure 3 above, the half-life of prGCD was found to be significantly longer than that of Cerezyme as disclosed publicly by Genzyme, which was consistent with our preclinical data.

Further, no neutralizing antibodies or adverse immunological responses were detected in any of the subjects treated in the phase I clinical trial. The presence of neutralizing antibodies would imply that the human body may reject the therapeutic enzyme.

We believe the results of our biochemical, biological and preclinical studies and pharmacokinetic data from our phase I clinical trial may support claims for less frequent treatment and lower dosages

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of prGCD for Gaucher disease patients, as compared to the current standard of care. This would represent a substantial improvement over currently marketed enzyme replacement therapies. However, further clinical evaluation will still be required to support these claims. We will explore the potential for lower dosages in our phase III clinical trial.

### Phase III Clinical Trial

After the conclusion of the phase I clinical trial and discussions with the FDA, we applied to commence a pivotal phase III clinical trial of prGCD, without the requirement to first complete a phase II clinical trial. In April 2007, we received approval from the FDA to initiate a pivotal phase III clinical trial. We submitted to the FDA a request for a special protocol assessment (SPA) of the final design of our pivotal phase III clinical trial for prGCD. In July 2007, we reached an agreement with the FDA on the design that we submitted in the SPA request. The phase III clinical trial is expected to include 30 patients in a randomized, double-blind, dose ranging study, with two parallel groups, one receiving a dosage equivalent to the prevalent standard of care for enzyme replacement therapy and one receiving a dosage equal to one half of that amount. We expect to initiate enrollment of patients in such trial in the third quarter of 2007.

### Other Drug Candidates in Our Pipeline

We are developing other recombinant therapeutic proteins to be expressed by our ProCellEx protein expression system, with an emphasis on treatments for which there are large, established pharmaceutical markets and where our proprietary protein expression system enables us to develop and commercialize recombinant proteins that are patent-protected and therapeutically equivalent or superior to the existing treatments. We select additional therapeutic candidates for development by testing candidates in-house and through collaborations with academic partners. We have identified several product candidates oriented towards specialty disease and therapeutic market segments, including treatments for Fabry disease and female infertility. In addition, we are conducting initial research to evaluate potential programs in the fields of monoclonal antibodies, cytokines and vaccines. We plan to file an investigational new drug application (IND) with the FDA with respect to at least one additional product during 2008. In addition, we are developing a new method for delivering active recombinant proteins systemically through oral administration of transgenic plant cells expressing such biotherapeutic proteins.

### PRX-102

We are developing a proprietary alpha Galactosidase enzyme, currently titled PRX-102, which is a therapeutic enzyme for the treatment of Fabry disease, a rare genetic lysosomal storage disorder in humans, the symptoms of which involve the accumulation of lipids in the cells of the kidneys, heart and other organs. Fabry disease affects more than 8,000 people globally. We believe that the treatment of Fabry disease is a specialty clinical niche with the potential for high growth. Currently there are two drugs available on the market to treat Fabry disease. Fabrazyme,

made by Genzyme, was approved for the treatment of Fabry disease in the European Union in 2001 and the United States in 2003. Genzyme reported \$359 million in worldwide sales of Fabrazyme in 2006. The other approved drug for the treatment of Fabry disease in the European Union is Replagal, which is sold by Shire plc. Shire reported \$118 million in sales of Replagal in 2006.

We are currently in the research phase of the development of PRX-102 and expect to initiate animal evaluation testing in the second half of 2007. As was the case in our development of prGCD, our development of PRX-102 involves the expression by our proprietary protein expression system of a naturally occurring enzyme to be used in enzyme replacement therapy for the treatment of Fabry disease. Based on our experience with prGCD and the experience of other companies developing enzyme replacement therapies for Fabry disease, we have reason to believe that, if favorable data is accumulated in preclinical and phase I clinical trials, the FDA may allow us to proceed directly with a pivotal phase III clinical trial without the need to complete a phase II clinical trial. However, there can be no assurance that we will initiate preclinical or phase I clinical trials and if we do, that such trials will result in favorable data. In addition, there can be no assurance that the FDA will allow us to proceed directly with a phase III clinical trial after completion of a phase I clinical trial.

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### PRX-111

We are developing two variants of Follicle Stimulating Hormone (FSH), a human fertility hormone targeted at the female infertility market, one of which is in collaboration with a third party. The three most active companies in the market for FSH biotherapeutic proteins are Merck Serono S.A., Organon, a subsidiary of Akzo Nobel N.V., and Ferring Pharmaceuticals, a private company. Merck Serono reported aggregate worldwide sales equal to approximately \$523 million for 2006 of its FSH protein, Gonal-f<sup>®</sup>, and based upon information disclosed by Akzo Nobel, Organon had worldwide sales of its FSH protein, Purgenon, of approximately \$591 million in 2006. To date, we believe that our in vitro experiments with these hormones have demonstrated equivalent to superior biochemical and cellular results when compared to the currently marketed biotherapeutic hormones used in approved female infertility treatments. We are currently performing additional in vivo animal research to evaluate the advantages of our FSH variants under development compared to the therapeutic proteins currently marketed to treat female infertility.

### Acetylcholinesterase

In January 2007, we entered into an agreement in principle with the Yissum Research and Development Company, the technology transfer arm of the Hebrew University of Jerusalem, Israel, and with the Boyce Thompson Institute, Inc., which is affiliated with Cornell University, pursuant to which we are developing a proprietary plant cell-based acetylcholinesterase (AChE) and its molecular variants for the use in several therapeutic and prophylactic indications, as well as in a biodefense program. Pursuant to the terms of the agreement in principle, which is subject to final agreement, we expect to license the technology underlying the developed acetylcholinesterase from Yissum Research/Hebrew University and Boyce Thompson. We are currently performing research in order to evaluate the potential for the developed acetylcholinesterase and its variants, for various therapeutic fields. To date, our in vitro experiments have shown that the acetylcholinesterase expressed in our ProCellEx expression system demonstrates promising biological activity on biochemical and cellular levels.

### Strategic Collaborations

#### Teva Pharmaceutical Industries

In September 2006, we entered into a Collaboration and Licensing Agreement with Teva for the development and manufacture of two proteins, to be identified by Teva and us using our ProCellEx protein expression system. These proteins are not part of our current product development pipeline. We have launched preliminary feasibility studies with respect to one protein under the agreement and we expect to launch feasibility studies with respect to the second protein before the end of 2007. Pursuant to the agreement, we have agreed to collaborate on the research and development of the two proteins utilizing our ProCellEx protein expression system. If the research and preclinical development efforts for either protein are successful and if Teva elects to pursue clinical trials for the development of either protein through our ProCellEx protein expression system, we have agreed to grant to Teva an exclusive license to commercialize the products developed based on the protein in return for royalty and milestone payments payable upon the achievement of certain pre-defined goals. We will retain certain exclusive manufacturing rights with respect to the active pharmaceutical ingredient of the proteins following the first commercial sale of a licensed product under the agreement and other rights.

#### Weizmann Institute of Science

In March 2006, we entered into a Research and License Agreement with the Yeda Research and Development Company Limited, the technology transfer arm of the Weizmann Institute of Science, pursuant to which Yeda is using its technology to design a next generation of GCD for the treatment of Gaucher disease that can be expressed using our ProCellEx protein expression system and that may have certain benefits over first generation treatments, including improved dosing. The technology licensed from Yeda provides a methodology for the rational design of an improved drug for the

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treatment of Gaucher disease by enzyme replacement therapy, based on the three-dimensional crystal structure of GCD that was solved by scientists from the Weizmann Institute of Science. In consideration for Yeda's research, we agreed to pay a fixed research budget amount. Yeda's activities under the agreement are also funded by a grant by the Magnetron program of the Ministry of Industry and Trade of Israel, a program created to support the transfer of emerging technologies from academic research to industrial commercialization. Yeda has granted us a license 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. We are responsible for commercializing the products developed under the license. Under the agreement, we are obligated to pay certain minimum royalty amounts and varying fixed royalty amounts on net sales of products developed using the licensed technology for the treatment of Gaucher disease and other indications as well as for sublicensing revenues. Accordingly, we will have certain payment obligations to Yeda even if we were to fail to generate any revenue from the licensed technology.

#### Intellectual Property

We maintain a proactive intellectual property strategy which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold eight granted patents and 44 patent applications currently pending with respect to various compositions, methods of production and methods of use relating to our ProCellEx protein expression system and our proprietary product pipeline. Of such patent applications, 12 have been filed since December 31, 2006, most of which were the result of existing patent applications reaching the national phase. We also have four joint patent applications and hold licensed rights to 2 patents and 21 patent

applications.

Our competitive position and future success depend in part on our ability, and that of our licensees, to obtain and leverage the intellectual property covering our product candidates, know-how, methods, processes and other technologies, to protect our trade secrets, to prevent others from using our intellectual property and to operate without infringing the intellectual property of third parties. We seek to protect our competitive position by filing United States, European Union, Israeli and other foreign patent applications covering our technology, including both new technology and improvements to existing technology. Our patent strategy includes obtaining patents, where possible, on methods of production, compositions of matter and methods of use. We also rely on know-how, continuing technological innovation, licensing and partnership opportunities to develop and maintain our competitive position. Lastly, we monitor third parties for activities that may infringe our intellectual property, as well as the progression of third party patent applications that may cover our product candidates or expression methods and thus, potentially, interfere with the development of our business. We are aware, for example, of United States patents, and corresponding international counterparts of such patents, owned by third parties that contain claims covering methods of producing GCD. We do not believe that, if any claim of infringement were to be asserted against us based upon such patents, prGCD would be found to infringe any valid claim under such patents. However, there can be no assurance that a court would find in our favor or that, if we choose or are required to seek a license to any one or more of such patents, a license would be available to us on acceptable terms or at all.

Our patent portfolio consists of several patent families (consisting of patents and/or patent applications) covering our technology, protein expression methodologies and system and product candidates. We have been issued, and hold licensed rights to, patents in the United States, the European Union, Israel, Canada, the Czech Republic, Hungary, Japan, Poland, Mexico, Hong Kong and India that cover our ProCellEx protein expression system, including the methods that we use for culturing and harvesting plant cells and/or tissues in consecutive cycles. Another patent family in our patent portfolio contains patent applications relating to our method for producing glycosylated proteins in a plant culture, particularly proteins having a high mannose glycosylation, including prGCD. An additional patent family contains patent applications relating to a system and method for production of antibodies in a plant cell culture, and antibodies produced in such a system. In addition, our patent portfolio includes a PCT for a new method for delivering active recombinant proteins systemically through oral administration of transgenic plant cells. Lastly, our patent portfolio includes a patent family containing patent applications that we co-own and that covers human glycoprotein

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hormone and chain splice variants, including isolated nucleic acids encoding these variants. More specifically, this patent portfolio covers a new splice variant of human FSH.

In April 2004, we entered into a Collaborative Research Agreement with Icon Genetics AG (which was subsequently acquired by Bayer Corporation) regarding an option to license Icon's amplification technology for utilization in the expression of our products under development in order to improve our yield. In connection with such option, we entered into a license agreement with Icon in April 2005, pursuant to which we received an exclusive worldwide license to develop, test, use and commercialize Icon's technology to express certain proteins in our ProCellEx protein expression system. In addition, we are entitled to a non-exclusive worldwide license to make and have made other proteins expressed by using Icon's technology in our technology. In consideration for the licenses, we are obligated to pay to Icon development milestone payments and royalties. See 'Risk Factors – 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.’’

## Manufacturing

Our drug product candidates, including prGCD, must be manufactured in a sterile environment and in compliance with cGMPs set by the FDA and other relevant foreign regulatory authorities. We use our current facility, which has approximately 5,000 sq/ft of clean rooms built according to industry standards, to develop, process and manufacture prGCD and other recombinant proteins. The entire protein production process takes place in a controlled environment. 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. We anticipate entering into further internal and collaborative programs in the future that will require us to scale-up our manufacturing capacity from time to time. Consequently, we are planning to establish larger scale manufacturing facilities that will satisfy our production needs for the foreseeable future. Although this will result in a significant increase in our capital expenditures, we expect these expenditures to be substantially lower than those associated with the construction of mammalian cell-based systems. We have begun to prepare conceptual designs of a new manufacturing facility and are currently evaluating potential locations for such facility.

Our current facility in Israel has been granted ‘‘Approved Enterprise’’ status, and we have elected to participate in the alternative benefits program. Our facility is located in a Zone A location, and, therefore, our income from the Approved Enterprise will be tax exempt in Israel for a period of 10 years, commencing with the year in which we first generate taxable income from the relevant Approved Enterprise. To remain eligible for these tax benefits, we must continue to meet certain conditions, and 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. In addition, our technology is subject to certain restrictions with respect to the transfer of technology and manufacturing rights.

## Raw Materials and Suppliers

We believe that the raw materials that we require throughout the manufacturing process of our current and potential drug product candidates are widely available from numerous suppliers and are generally considered to be generic industrial biological supplies. We do not rely on a single or unique supplier for any materials relating to the current production of any biotherapeutic proteins in our pipeline.

Development and regulatory approval of our pharmaceutical products are dependent upon our ability to procure active ingredients and certain packaging materials from sources approved by the FDA and other regulatory authorities. Since the FDA and other regulatory approval processes require manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier in connection with any drug candidate or approved product, if any, would be required if active ingredients or such packaging materials were no longer available from the specified supplier, which could result in manufacturing delays. From time to time, we intend to identify alternative FDA-approved suppliers to ensure the continued supply of necessary raw materials.

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### Competition

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technology and significant competition. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. Most of these companies have substantially greater research and development, manufacturing, marketing, financial, technological personnel and managerial resources than we do. In addition, many specialized biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with our current and future product candidates and technologies. Acquisitions of competing companies by large pharmaceutical or biotechnology companies could enhance such competitors' financial, marketing and other resources. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize competitive products or technologies on their own or through collaborations with pharmaceutical and biotechnology companies.

We specifically face competition from companies with approved treatments of Gaucher disease, including Genzyme 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 GCD enzyme expressed in human cancer cells to treat Gaucher disease. We also face competition from companies with approved enzyme 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.

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 protein 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 & Co. Inc.). 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.

Key differentiating elements affecting the success of our product candidates are likely to be their potency and efficacy profiles, as well as their cost-effectiveness as compared to other existing therapies.

#### Government Regulation

The testing, manufacture, distribution, advertising and marketing of drug products are subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by similar authorities in other countries. Any product that we develop must receive all relevant regulatory approvals or clearances, as the case may be, before it may be marketed in a particular country.

The regulatory process, which includes overseeing preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and efficacy and confirmation by the FDA that good laboratory, clinical and manufacturing practices were maintained during testing and manufacturing, can take many years, requires the expenditure of substantial resources and gives larger companies with greater financial resources a competitive advantage over us. Delays or terminations of clinical trials that we undertake would likely impair our development of product candidates. Delays or terminations could result from a number of factors, including stringent enrollment criteria, slow rate of enrollment, size of patient population, having to compete with other clinical trials for eligible patients, geographical considerations and others.

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The FDA review process can be lengthy and unpredictable, and we may encounter delays or rejections of our applications when submitted. Generally, in order to gain FDA approval, we must first conduct preclinical studies in a laboratory and in animal models to obtain preliminary information on a compound and to identify any potential safety problems. The results of these studies are submitted as part of an IND application that the FDA must review before human clinical trials of an investigational drug can commence. Clinical trials may be terminated by the clinical trial site, sponsor or the FDA if toxicities appear that are either worse than expected or unexpected.

Clinical trials are normally performed in three sequential phases and generally take two to five years, or longer, to complete. Phase I consists of testing the drug product in a small number of humans, normally healthy volunteers, to determine preliminary safety and tolerable dose range. Phase II usually involves studies in a limited patient population to evaluate the effectiveness of the drug product in humans having the disease or medical condition for which the product is indicated, determine dosage tolerance and optimal dosage and identify possible common adverse effects and safety risks. Phase III consists of additional controlled testing at multiple clinical sites to establish clinical safety and effectiveness in an expanded patient population of geographically dispersed test sites to evaluate the overall benefit-risk relationship for administering the product and to provide an adequate basis for product labeling. Phase IV clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication.

After completion of clinical trials of a new drug product, FDA and foreign regulatory authority marketing approval must be obtained. Assuming that the clinical data support the product's safety and effectiveness for its intended use, a New Drug Application (NDA) is submitted to the FDA for its review. Generally, it takes one to three years to obtain approval. If questions arise during the FDA review process, approval may take a significantly longer period of time. The testing and approval processes require substantial time and effort and we may not receive approval on a timely basis, if at all, or the approval that we receive may be for a narrower indication than we had originally sought, potentially undermining the commercial viability of the product. Even if regulatory approvals are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. For marketing outside the United States, we will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product licensing, pricing and medical reimbursement vary widely from country to country.

None of our products under development has been approved for marketing in the United States or elsewhere. We may not be able to obtain regulatory approval for any of our products under development in a timely manner, if at all. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude us, or our licensees or marketing partners, from marketing our products, or limit the commercial use of our products, and thereby would have a material adverse effect on our business, financial condition and results of operations. See "Risk Factors – 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."

The United States federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the Federal Food, Drug, and Cosmetic Act (FDCA), as well as other relevant laws; (ii) the Center for Medicare & Medicaid Services (CMS), which administers the Medicare and

Medicaid programs; (iii) the Office of Inspector General (OIG) which enforces various laws aimed at curtailing fraudulent or abusive practices, including by way of example, the Anti-Kickback Law, the Anti-Physician Referral Law, commonly referred to as Stark, the Anti-Inducement Law, the Civil Money Penalty Law and the laws that authorize the OIG to exclude healthcare providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights, which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All of the aforementioned are agencies within the Department of Health and Human Services (HHS). Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Department of Veterans Affairs, especially through the Veterans Health Care Act of 1992, the Public

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Health Service within HHS under Public Health Service Act § 340B (42 U.S.C. § 256b), the Department of Justice through the Federal False Claims Act and various criminal statutes, and state governments under the Medicaid and other state sponsored or funded programs and their internal laws regulating all healthcare activities. Many states also have anti-kickback and anti-physician referral laws that are similar to the federal laws, but may be applicable in situations where federal laws do not apply.

Medicare is the federal healthcare program for those who are (i) over 65 years of age, (ii) disabled, (iii) suffering from end-stage renal disease or (iv) suffering from Lou Gehrig's disease. Medicare consists of part A, which covers inpatient costs, part B, which covers services by physicians and laboratories, durable medical equipment and certain drugs, primarily those administered by physicians, and part D, which provides drug coverage for most prescription drugs other than those covered under part B. Medicare also offers a managed care option under part C. Medicare is administered by CMS. In contrast, Medicaid is a state-federal healthcare program for the poor and is administered by the states pursuant to an agreement with the Secretary of Health and Human Services. Most state Medicaid programs cover most outpatient prescription drugs.

## International Regulation

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of product standards, packaging requirements, labeling requirements, import and export restrictions and tariff regulations, duties and tax requirements. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

Pharmaceutical products may not be imported into, or manufactured or marketed in, the State of Israel absent drug registration. The three basic criteria for the registration of pharmaceuticals in Israel is quality, safety and efficacy of the pharmaceutical product and the Israeli Ministry of Health requires pharmaceutical companies to conform to international developments and standards. Regulatory requirements are constantly changing in accordance with scientific advances as well as social and ethical values.

The relevant legislation of the European Union requires that medicinal products, including generic versions of previously approved products, and new strengths, dosage forms and formulations, of previously approved products, shall have a marketing authorization before they are placed on the market in the European Union. Authorizations are granted after the assessment of quality, safety and efficacy by the respective health authorities. In order to obtain an authorization, an application must be made to the competent authority of the member state concerned. Besides various

formal requirements, the application must contain the results of pharmaceutical (physico-chemical, biological or microbiological) tests, of preclinical (toxicological and pharmacological) tests as well as of clinical trials. All of these tests must have been conducted in accordance with relevant European Union regulations and must allow the reviewer to evaluate the quality, safety and efficacy of the medicinal product.

#### Israeli Government Programs

The following is a summary of the current principal Israeli tax laws applicable to us and Protalix Ltd., and of the Israeli Government programs from which Protalix Ltd. benefits. Some parts of this discussion are based on new tax legislation that has not been subject to judicial or administrative interpretation. Therefore, the views expressed in the discussion may not be accepted by the tax authorities in question. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

#### General Corporate Tax Structure in Israel

Generally, Israeli companies are subject to corporate tax at the rate of 31% on taxable income and are subject to real capital gains tax at a rate of 25% on capital gains (other than gains derived from the sale of listed securities that are taxed at the prevailing corporate tax rates) derived after

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January 1, 2003. The corporate tax rate was reduced in June 2004, from 36% to 35% for the 2004 tax year, 34% for the 2005 tax year, 31% for the 2006 tax year, 29% for the 2007 tax year, 27% for the 2008 tax year, 26% for the 2009 tax year and 25% for the 2010 tax year and thereafter. As discussed below, the corporate tax rate may be less for income derived from an Approved Enterprise.

#### Law for the Encouragement of Capital Investments, 1959

The Law for the Encouragement of Capital Investments, 1959, known as the Investment Law, provides certain incentives for capital investments in a production facility (or other eligible assets). Generally, an investment program that is implemented in accordance with the provisions of the Investment Law, referred to as an "Approved Enterprise," is entitled to benefits. These benefits may include cash grants from the Israeli government and tax benefits, based upon, among other things, the location of the facility in which the investment is made and specific elections made by the grantee.

The Investment Law was significantly amended effective April 2005. Protalix Ltd. will continue to enjoy the tax benefits under the pre-revision provisions of the Investment Law. If any new benefits are granted to Protalix Ltd. in the future, Protalix Ltd. will be subject to the provisions of the amended Investment Law with respect to these new benefits. Therefore, the following discussion is a summary of the Investment Law prior to its amendment as well as the relevant changes contained in the new legislation.

Under the Investment Law prior to its amendment, a company that wished to receive benefits had to receive approval from the Investment Center of the Israeli Ministry of Industry, Trade and Labor, the "Investment Center". Each certificate of approval for an Approved Enterprise relates to a specific investment program in the Approved Enterprise, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset, e.g., the equipment to be purchased and utilized pursuant to the program.

An Approved Enterprise may elect to forego any entitlement to the grants otherwise available under the Investment Law and, instead, participate in an alternative benefits program under which the undistributed income from the Approved Enterprise is fully exempt from corporate tax for a defined period of time. Under the alternative package of benefits, a company's undistributed income derived from an Approved Enterprise will be exempt from corporate tax for a period of between two and 10 years from the first year of taxable income, depending upon the geographic location within Israel of the Approved Enterprise. Upon expiration of the exemption period, the Approved Enterprise is eligible for the reduced tax rates otherwise applicable under the Investment Law for any remainder of the otherwise applicable benefits period (up to an aggregate benefits period of either seven or 10 years, depending on the location of the company or its definition as a foreign investors' company). If a company has more than one Approved Enterprise program or if only a portion of its capital investments are approved, its effective tax rate is the result of a weighted combination of the applicable rates. The tax benefits from any certificate of approval relate only to taxable profits attributable to the specific Approved Enterprise. Income from activity that is derived from different Approved Enterprises does not enjoy these tax benefits.

A company that has an Approved Enterprise program is eligible for further tax benefits if it qualifies as a foreign investors' company. A foreign investors' company eligible for benefits is essentially a company in which more than 25% of the share capital (in terms of shares, rights to profit, voting and appointment of directors) is owned (measured by both share capital and combined share and loan capital) by non-Israeli residents. A company that qualifies as a foreign investors' company and has an Approved Enterprise program is eligible for tax benefits for a 10-year benefit period and may enjoy a reduced corporate tax rate of 10% to 25%, depending on the amount of the company's shares held by non-Israeli shareholders.

If a company that has an Approved Enterprise program is a wholly owned subsidiary of another company, then the percentage of foreign investments is determined based on the percentage of foreign investment in the parent company. The tax rates and related levels of foreign investments are set forth in the following table:

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Percent of Foreign Ownership	Rate of Reduced Tax
0 – 49%	25%
49 – 74%	20%
74 – 90%	15%
90 – 100%	10%

Our facility in Israel has been granted "Approved Enterprise" status, and it has elected to participate in the alternative benefits program. Under the terms of its Approved Enterprise program, the facility is located in a top priority location, or "Zone A", and, therefore, the income from that Approved Enterprise will be tax exempt in Israel for a period of 10 years, commencing with the year in which taxable income is first generated from the relevant Approved Enterprise. The current benefits program may not continue to be available and Protalix Ltd. may not continue to qualify for its benefits.

A company that has elected to participate in the alternative benefits program and that subsequently pays a dividend out of the income derived from the Approved Enterprise during the tax exemption period will be subject to corporate tax in respect of the amount distributed at the rate that would have been applicable had the company not elected the alternative benefits program (generally 10% to 25%, depending on the extent to which non-Israeli shareholders hold such company's shares). If the dividend is distributed within 12 years after the commencement of the benefits period (or, in the case of a foreign investor's company, without time limitation), the dividend recipient is taxed at the reduced

withholding tax rate of 15% applicable to dividends from approved enterprises, or at the lower rate under an applicable tax treaty. After this period, the withholding tax rate is 25%, or at the lower rate under an applicable tax treaty. In the case of a company with a foreign investment level (as defined by the Investment Law) of 25% or more, the 12-year limitation on reduced withholding tax on dividends does not apply. The company must withhold this tax at its source, regardless of whether the dividend is converted into foreign currency.

The Investment Law also provides that an Approved Enterprise is entitled to accelerated depreciation on its property and equipment that are included in an approved investment program. This benefit is an incentive granted by the Israeli government regardless of whether the alternative benefits program is elected.

The benefits available to an Approved Enterprise are conditioned upon terms stipulated in the Investment Law and regulations and the criteria set forth in the applicable certificate of approval. If Protalix Ltd. does not fulfill these conditions in whole or in part, the benefits can be canceled and Protalix Ltd. may be required to refund the received benefits, linked to the Israeli consumer price index with the addition of interest or alternatively with an additional penalty payment. We believe that Protalix Ltd. currently operates in compliance with all applicable conditions and criteria, but there can be no assurance that Protalix Ltd. will continue to do so. Furthermore, there can be no assurance that any Approved Enterprise status granted to Protalix Ltd.'s facilities will entitle Protalix Ltd. to the same benefits to which it is currently entitled.

Pursuant to the March 2005 amendment to the Investment Law, the approval of the Investment Center is required only for Approved Enterprises that receive cash grants. Approved Enterprises that do not receive benefits in the form of governmental cash grants, but only tax benefits, are no longer required to obtain this approval. Instead, these Approved Enterprises are required to make certain investments as specified in the Investment Law.

The amended Investment Law specifies certain conditions for an Approved Enterprise to be entitled to benefits. These conditions include:

- the Approved Enterprise's revenues from any single country or a separate customs territory may not exceed 75% of the Approved Enterprise's total revenues; or
- at least 25% of the Approved Enterprise's revenues during the benefits period must be derived from sales into a single country or a separate customs territory with a population of at least 12 million.

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There can be no assurance that Protalix Ltd. will comply with the above conditions in the future or that Protalix Ltd. will be entitled to any additional benefits under the Investment Law. In addition, it is possible that Protalix Ltd. may not be able to operate in a way that maximizes utilization of the benefits under the Investment Law.

From time to time, the Israeli Government has discussed reducing the benefits available to companies under the Investment Law. The termination or substantial reduction of any of the benefits available under the Investment Law could materially impact the cost of our future investments.

Encouragement of Industrial Research and Development Law, 1984

In the past, Protalix Ltd. received grants from the Office of the Chief Scientist of the Israeli Ministry of Industry,

Trade and Labor, the OCS, for the financing of a portion of its research and development expenditures in Israel. As of December 31, 2006, the OCS approved grants in respect of Protalix Ltd.'s continuing operations totaling approximately \$4.9 million, measured from inception. Protalix Ltd. is required to repay up to 100% of grants actually received (plus interest at the LIBOR rate applied to the grants received on or after January 1, 1999) to the OCS through payments of royalties at a rate of 3% to 6% of the revenues generated from an OCS-funded project, depending on the period in which revenues were generated. As of December 31, 2006, Protalix Ltd. had not paid or accrued royalties and Protalix Ltd.'s contingent liability to the OCS with respect to grants received was approximately \$4.2 million.

Under the Israeli Law for the Encouragement of Industrial Research and Development, 1984 and related regulations, the Research Law, recipients of grants from the OCS are prohibited from manufacturing products developed using these grants outside of the State of Israel without special approvals, although the Research Law does enable companies to seek prior approval for conducting manufacturing activities outside of Israel without being subject to increased royalties. If Protalix Ltd. receives approval to manufacture the products developed with government grants outside of Israel, it will be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest), depending on the manufacturing volume that is performed outside of Israel, as well as at a possibly increased royalty rate.

Additionally, under the Research Law, Protalix Ltd. is prohibited from transferring the OCS financed technologies and related intellectual property rights outside of the State of Israel except under limited circumstances and only with the approval of the Research Committee of the OCS. Protalix Ltd. may not receive the required approvals for any proposed transfer and, if received, Protalix Ltd. may be required to pay the OCS a portion of the consideration that it receives upon any sale of such technology by a non-Israeli entity. The scope of the support received, the royalties that Protalix Ltd. has already paid to the OCS, the amount of time that has elapsed between the date on which the know-how was transferred and the date on which the OCS grants were received and the sale price and the form of transaction will be taken into account in order to calculate the amount of the payment to the OCS. Approval of the transfer of technology to residents of the State of Israel is required, and may be granted in specific circumstances only if the recipient abides by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurances can be made that approval to any such transfer, if requested, will be granted.

In March 2005, an amendment to the Research Law was enacted. One of the main modifications included in the amendment was an authorization of the Research Committee to allow the transfer outside of Israel of know-how derived from an approved program and the related manufacturing rights. In general, the Research Committee may approve transfer of know-how in limited circumstances as follows:

- in the event of a sale of the know-how itself to a non affiliated third party, provided that upon such sale the owner of the know-how pays to the OCS an amount, in cash, as set forth in the Research Law. In addition, the amendment provides that if the purchaser of the know-how gives the selling Israeli company the right to exploit the know-how by way of an exclusive, irrevocable and unlimited license, the research committee may approve such transfer in special cases without requiring a cash payment.
- in the event of a sale of the company which is the owner of know-how, pursuant to which the company ceases to be an Israeli company, provided that upon such sale, the owner of the know-how makes a cash payment to the OCS as set forth in the Research Law.

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- in the event of an exchange of know-how such that in exchange for the transfer of know-how outside of Israel, the recipient of the know-how transfers other know-how to the company in Israel in a manner in which the OCS is convinced that the Israeli economy realizes a greater, overall benefit from the exchange of know-how.

Another provision in the amendment concerns the transfer of manufacturing rights. The research committee may, in special cases, approve the transfer of manufacture or of manufacturing rights of a product developed within the framework of the approved program or which results therefrom, outside of Israel.

The State of Israel does not own intellectual property rights in technology developed with OCS funding and there is no restriction on the export of products manufactured using technology developed with OCS funding. The technology is, however, subject to transfer of technology and manufacturing rights restrictions as described above. For a description of such restrictions, please see “Risk Factors – Risks Relating to Our Operations in Israel”. OCS approval is not required for the export of any products resulting from the research or development or for the licensing of any technology in the ordinary course of business.

## Special Provisions Relating to Taxation under Inflationary Conditions

We are taxed in Israel under the Income Tax Law (Inflationary Adjustments), 1985, generally referred to as the Inflationary Adjustments Law. The Inflationary Adjustments Law is highly complex, and represents an attempt to overcome the problems presented to a traditional tax system by an economy undergoing rapid inflation. The provisions that are material to us are summarized below:

- Where a company’s equity, as calculated under the Inflationary Adjustments Law, exceeds the depreciated cost of its fixed assets (as defined in the Inflationary Adjustments Law), a deduction from taxable income is permitted equal to this excess multiplied by the applicable annual rate of inflation. The maximum deduction permitted under this provision in any single tax year is 70% of taxable income. The unused portion linked to the Israeli consumer price index, may be carried forward.
- Where a company’s depreciated cost of fixed assets exceeds its equity, the excess multiplied by the applicable annual rate of inflation is added to taxable income.
- Subject to specified limitations, depreciation deductions carryforwards on fixed assets and losses are adjusted for inflation based on the change in the consumer price index.

Under the Inflationary Adjustments Law, results for tax purposes are measured in real terms, in accordance with changes in the Israeli consumer price index. The difference between the change in the Israeli consumer price index and the exchange rate of Israeli currency in relation to the U.S. dollar may in future periods cause significant differences between taxable income and the income measured in dollars as reflected in our consolidated financial statements.

## Law for the Encouragement of Industry (Taxes), 1969

We believe that Protalix Ltd. currently qualifies as an “Industrial Company” within the meaning of the Law for the Encouragement of Industry (Taxes), 1969, or the Industry Encouragement Law. The Industry Encouragement Law defines “Industrial Company” as a company resident in Israel that derives 90% or more of its income in any tax year (other than specified kinds of passive income such as capital gains, interest and dividends) from an “Industrial Enterprise” that it owns. An “Industrial Enterprise” is defined as an enterprise whose major activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization of the cost of purchased know-how and patents over an eight-year period for tax purposes;
- accelerated depreciation rates on equipment and buildings;
- under specified conditions, an election to file consolidated tax returns with other related Israeli Industrial Companies; and

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- expenses related to a public offering are deductible in equal amounts over three years.

Eligibility for the benefits under the Industry Encouragement Law is not subject to receipt of prior approval from any governmental authority. It is possible that Protalix Ltd. may fail to qualify or may not continue to qualify as an “Industrial Company” or that the benefits described above will not be available in the future.

## Tax Benefits for Research and Development

Under specified conditions, Israeli tax laws allow a tax deduction by a company for research and development expenditures, including capital expenditures, for the year in which such expenditures are incurred. These expenditures must relate to scientific research and development projects and must be approved by the OCS. Furthermore, the research and development projects must be for the promotion of the company and carried out by or on behalf of the company seeking such tax deduction. However, the amount of such deductible expenditures is reduced by the sum of any funds received through government grants for the finance of such scientific research and development projects. Expenditures not so approved are deductible over a three-year period.

## Tax Ruling and Lock-up Agreements Related to the Merger

In connection with the merger of Protalix Ltd. with our wholly-owned subsidiary, Protalix Acquisition Co. Ltd., which substantially all of the former shareholders of Protalix Ltd. entered into lock-up agreements 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 as a result of 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 the tax ruling described below, sell an aggregate of 10% of each such shareholder’s original number of locked-up shares. All permitted sales of locked-up shares that may be made during such time period are cumulative.

Furthermore, under applicable 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 holding 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. See “Risk Factors – Trading of our common stock is limited.”

We and Protalix Ltd. are entitled to issue up to 25% of our respective share capital to third parties or a higher number of shares in a public offering, provided that we and Protalix Ltd. each remain compliant with the limitations described above.

Notwithstanding the limitations described above, the following transactions shall not be subject to any limitation on the sale of shares under the ruling: (i) dispositions by any shareholder of our company that holds less than 5% of our voting rights or issued and outstanding share capital upon the merger; or (ii) a shareholder who is not subject to, or is exempt from, the payment of taxes in Israel. These transactions are restricted pursuant to the contractual lock-ups

described above.

According to the tax ruling, until the second anniversary of the closing of the merger, the operation of our company and/or that of Protalix Ltd. shall be further limited as follows:

- Most of Protalix Ltd.'s operations and activities shall be directed to research and development activities. The Encouragement of Industrial Research and Development Law, 1984, of the State of Israel defines research and development activity to include certain expenses incurred by a company in connection with the transition to the manufacturing and marketing of the products or technology that result from the research and development efforts.
- The consideration received and to be received in connection with the issuance of our shares or rights, or those of Protalix Ltd., shall be used and reinvested in research and development activity as defined above. Such consideration includes any investment made in Protalix Ltd. prior to the merger. We are allowed to use the cash held by us as of the closing of the merger, for the operation of our company in the United States.

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- At least 75% of the research and development expenditures of Protalix Ltd. shall be made in Israel. However, the Israeli tax authorities may establish a lower percentage if Protalix Ltd. makes expenditures in connection with clinical and toxicology trials that cannot be conducted in Israel.

#### Employees

As of February 28, 2007, we had 69 employees, of whom 14 have a Ph.D. or M.D. in their respective scientific fields. We believe that our relations with these employees are good. We intend to continue to hire additional employees in research and development, manufacturing and administration in order to meet our operating plans. We believe that our success will greatly depend on our ability to identify, attract and retain capable employees. The Israeli Ministry of Labor and Welfare is authorized to make certain industry-wide collective bargaining agreements that apply to types of industries or employees including ours ("Expansion Orders"). These agreements affect matters such as cost of living adjustments to salaries, length of working hours and week, recuperation, travel expenses, and pension rights. Otherwise, our employees are not represented by a labor union or represented under a collective bargaining agreement. See "Risk Factors – 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."

#### 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. 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. acquiring in excess of 99% of our outstanding shares of common stock. 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. Unless otherwise indicated, all share numbers in this annual report on Form 10-K give effect to such reverse stock split. 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(tm) is our trademark. Each of the other trademarks, trade names or service marks appearing in this prospectus belongs to its respective holder.

#### Available Information

Our corporate website is [www.protalix.com](http://www.protalix.com). We make available on our website, free of charge, our Securities and Exchange Commission filings, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these reports, as soon as reasonably practicable after we electronically file these documents with, or furnish them to, the Commission. Information on our website is not part of this document.

Our website also includes printable versions of our Code of Business Conduct and Ethics and the charters for each of the Audit, Compensation and Nominating Committees of our Board of Directors. Each of these documents is also available in print to any shareholder who requests a copy by addressing a request to:

Protalix BioTherapeutics, Inc.  
2 Snunit Street  
Science Park  
POB 455  
Carmiel 20100, Israel  
Attn: Mr. Yossi Maimon, Chief Financial Officer

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##### Item 1A. Risk Factors

You should carefully consider the risks described below together with the other information included in this Annual Report on Form 10-K/A. 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 December 31, 2006 was \$20.5 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 \$6 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 at least the next 18 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 expect to 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;
- implement additional internal systems and infrastructure;
- seek to license-in additional technologies to develop; and
- hire additional personnel.

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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, only one drug candidate, prGCD, has completed phase I clinical trials and the other drug candidates have not commenced the preclinical trial phase of development. 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 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;

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- 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;

- 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.

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.

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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.

Each of the diseases or disorders that our product candidates are intended to treat is 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 mandates 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 a product's approved labeling;
- 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;

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- 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; 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 harm 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, 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

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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 will not 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 our prGCD candidate, 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 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
- 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.

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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

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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 and to a certain extent, Actelion. 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 and Genzyme. Shire 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.

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 protein in anticipation of the expiration of certain patent claims covering marketed proteins. Competitors developing alternative expression technologies include Crucell, Shire and GlycoFi/Merck. Other companies are developing alternate plant-based technologies, include Biorex, Chlorogen, Greenovation Biotech 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 operation would suffer.

As of June 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,

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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 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

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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 Yeda 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. 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

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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, Dr. David Aviezer, as well as our directors, including Eli Hurvitz and Phillip Frost, M.D., 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.

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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. 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 scientist acting as a key 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 would 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. 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

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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 Congress and in some state legislatures, 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 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

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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 recent events in the Gaza region and the current dispute and armed struggle between the Hamas movement and the Palestinian Authority has resulted in a further escalation in violence among Israel, the Palestinian Authority and other groups. In mid-2006, there was a war between Israel and the Hezbollah in Lebanon, resulting in 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 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.

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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

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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;

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- 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.

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. Some or all of the “restricted” shares of our common stock issued to former shareholders of Protalix Ltd. in connection with the merger or held by other shareholders may be offered from time to time in the open market pursuant to an effective registration statement or Rule 144, and these sales may have a depressive effect on the market for our common stock. 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 are 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 of 1933, as amended.

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, substantially all of the former shareholders of Protalix Ltd. entered into lock-up agreements with respect to their shares of our common stock 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 the tax ruling described below, sell an aggregate of 10% of each such shareholder’s original number of locked-up shares. All permitted

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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 holding 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.

In the absence of an active public trading market, an investor may be unable to liquidate its investment in our common stock. 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.

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 70% 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 amended Annual Report, 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.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

Our manufacturing facility and executive offices, which are leased for a period ending in April 2009, are located in Carmiel, Israel. The facilities contain approximately 5,000 sq/ft of laboratory and office space and are leased at a rate of approximately \$10,000 per month. Our facilities are equipped with the requisite laboratory services required to conduct our business, and we believe that the existing facilities are adequate to meet our needs for the foreseeable future. In addition, we sublease an office in Ramat Gan, Israel, for approximately \$1,400 per month.

#### Item 3. Legal Proceedings

We are not involved in any material legal proceedings.

#### Item 4. Submission of Matters to a Vote of Security Holders

On December 13, 2006, the holders of a majority of our issued and outstanding voting securities approved actions by written consent in lieu of a special meeting in accordance with the relevant sections of the Florida Business Corporation Act to amend our Articles of Incorporation to change our name from Orthodontix, Inc. to Protalix BioTherapeutics, Inc. and to terminate our 1998 Stock Option Plan and adopt our 2006 Stock Incentive Plan.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock began trading on the American Stock Exchange under the symbol PLX on March 12, 2007. Prior to March 12, 2007, our common stock was quoted on the OTC Bulletin Board® under the symbols PXBT.OB, ORTX.OB, and OTIX.OB. High and low closing bid quotations, for the last two fiscal years, do not give effect to the one-for-ten reverse stock split effected on December 29, 2006, and were:

Quarter Ended	2006		2005	
	High	Low	High	Low
March 31	\$ 4.25	\$ 3.58	\$ 0.20	\$ 0.16
June 30	\$ 5.39	\$ 3.50	\$ 0.23	\$ 0.16
September 31	\$ 5.30	\$ 3.20	\$ 0.35	\$ 0.13
December 31	\$ 3.95	\$ 1.52	\$ 5.11	\$ 0.20

These quotations reflect prices between dealers and do not include retain mark-ups, mark-downs, and commissions and may not necessarily represent actual transactions.

There were approximately 514 stockholders of record at March 15, 2007. To date, we have not declared or paid any cash dividends on our common stock. We do not anticipate paying any dividends on our common stock in the foreseeable future.

Equity Compensation Plan Information

The following table provides information as of December 31, 2006 with respect to the shares of our common stock that may be issued under our existing equity compensation plan.

Plan Category	A	B	C
	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities

			Reflected in Column A)
Equity Compensation Plans Approved by Shareholders	5,375,174	\$ 0.30	4,366,481
Equity Compensation Plans Not Approved by Shareholders	6,341,618	\$ 7.14	—
Total	11,716,792	\$ 4.00	4,366,481

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### Item 6. Selected Financial Data

The selected consolidated financial data below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. The selected consolidated statements of operations data for the years ended December 31, 2006, 2005 and 2004 and for the period from December 27, 1993 through December 31, 2006 and the selected consolidated balance sheet data as of December 31, 2006 and 2005, are derived from, and are qualified by reference to, the audited consolidated financial statements included elsewhere in this Annual Report. The statement of operations data for the years ended December 31, 2002 and 2003 and the balance sheet data as of December 31, 2002, 2003 and 2004 are derived from audited financial statements not included in this Annual Report. The historical results presented below are not necessarily indicative of future results.

	Year Ended December 31,					Period from
	2002	2003	2004	2005	2006	Dec. 27, 1993 through Dec. 31, 2006
	(in thousands, except share and per share amounts)					
Consolidated Statement of Operations Data:						
Revenues	— \$	250 \$	430 \$	150	—	\$ 830
Cost of revenues	—	51	120	35	—	206
Gross profit	—	199	310	115	—	624
Research and development expenses, net	375	239	1,920	3,773	\$ 5,246	12,545
General and administrative expenses	502	603	807	2,131	4,525	8,996
Finance expense (income)	(11)	3	4	(43)	(344)	(368)
Net loss before change in accounting principle	\$ 866	\$ 646	\$ 2,421	\$ 5,746	\$ 9,427	\$ 20,549
Cumulative effect of change in accounting principle		3	—	—	(37)	(37)
Net loss	\$ 866	\$ 646	\$ 2,421	\$ 5,746	\$ 9,390	\$ 20,512
Net loss per share of common stock,						

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basic and diluted:

Prior to cumulative effect of change in accounting principle	\$	0.05	\$	0.03	\$	0.13	\$	0.31	\$	0.32
Cumulative effect of change in accounting principle		—		—		—		—		*
Net loss per share of common stock, basic and diluted <sup>(1)</sup>	\$	0.05	\$	0.03	\$	0.13	\$	0.31	\$	0.32
Weighted average number of shares of common stock used in computing net loss per share of common stock <sup>(2)</sup>		18,801,527		18,801,527		18,801,527		18,801,527		29,300,987
Consolidated Balance Sheet Data:										
Cash and cash equivalents	\$	215	\$	1,261	\$	1,477	\$	4,741	\$	15,378
Other assets		281		464		2,478		2,484		