Protalix BioTherapeutics, Inc.
Form 10-K
March 06, 2009

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

FORM 10-K

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

(Mark One)

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

For the fiscal year ended December 31, 2008

OR

o **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	**65-0643773**
State or other jurisdiction of incorporation or organization	**(I.R.S. Employer Identification No.)**
2 Snunit Street Science Park POB 455 Carmiel, Israel	**20100**
(Address of principal executive offices)	**(Zip Code)**

972-4-988-9488
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	**NYSE Alternext US**

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

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

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

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 þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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. o

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

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o
		(Do not check if a smaller reporting company)	

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant, as of June 30, 2008 was approximately $93.6 million (based upon the closing price for shares of the Registrant s common stock as reported by the NYSE Alternext US (then known as the American Stock Exchange) as of June 30, 2008 of $2.71). 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 1, 2009, approximately 75,943,392 shares of the Registrant s common stock, par value $0.001 per share, 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, 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 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 or ou subsidiary or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

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

- the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;
- delays in our preparation and filing of applications for regulatory approval;
- delays in the approval or potential rejection of any applications we file with the United States Food and Drug Administration, or the FDA, or other regulatory authorities;
- any lack of progress of our research and development (including the results of clinical trials we are conducting);
- obtaining on a timely basis sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies;
- our ability to obtain additional financing required to fund our research programs;
- the risk that we will not be able to develop a successful sales and marketing organization in a timely manner, if at all;
- our ability to establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationships with collaborators, distributors and partners;
- potential product liability risks and risks of securing adequate levels of product liability and clinical trial insurance coverage;
- the availability of reimbursement to patients from health care payors for any of our drug products, if approved;
- the possibility of infringing a third party s patents or other intellectual property rights;

the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third parties;

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; and

other risks and uncertainties detailed in Section 1A of this Annual Report on Form 10-K.

In addition, companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. These and other risks and uncertainties are detailed under the heading Risk Factors in this Annual Report on Form 10-K and are described from time to time in the reports we file with the Securities and Exchange Commission. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

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Item 1. Business

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx[tm] 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. 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. In addition, we believe our ProCellEx protein expression system will enable us to express and produce bio similar or generic versions of other recombinant proteins not protected through patents in a cost effective manner. Because we are primarily 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 completely 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. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. 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. Lysosomal storage disorders are metabolic disorders in which the lysosomal enzyme, a protein that degrades cellular substrates in the lysosomes of cells, is mutated or deficient. In July 2007, we reached an agreement with the United States Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of prGCD, through the FDA s special protocol assessment (SPA) process. We completed enrollment of patients in the phase III clinical trial in December 2008 and expect to report results of the clinical trial in the second half of 2009. We anticipate submitting a New Drug Application (NDA) for prGCD to the FDA and other comparable regulatory agencies in other countries in the fourth quarter of 2009. In addition to our phase III clinical trial, we initiated, during the third quarter of 2008, a double-blind, follow-on extension study as part of our phase III clinical trial. In December 2009, we also initiated a clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with prGCD. The switchover-study is not a prerequisite for approval of prGCD. The current standard of care for Gaucher patients is enzyme replacement therapy with Cerezyme which is produced by Genzyme Corporation and currently the only approved enzyme replacement therapy for Gaucher disease. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are injected into patients in whom the enzyme is lacking or dysfunctional.

Although Gaucher disease is a relatively rare disease, it represents a large commercial market due to the severity of the symptoms and the chronic nature of the disease. The annual worldwide sales of Cerezyme were approximately $1.2 billion in 2008 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, which is a mammalian cell expressed version of the same protein. We believe prGCD may prove more cost-effective than the currently marketed alternative due to the cost benefits of expression through our ProCellEx protein expression system. In addition, based on our laboratory testing, preclinical and clinical results, we believe that prGCD may have the potential for increased potency and efficacy compared to the existing enzyme replacement therapy for Gaucher disease, which may translate into lower dosages and/or less frequent treatments.

In addition to prGCD, we are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates, therapeutic protein candidates for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, an acetylcholinesterase enzyme-based therapy for biodefense and intoxication treatments and an additional undisclosed therapeutic protein, all of which are currently being evaluated in animal studies. We plan to file an investigational new drug application (IND) with the FDA with respect to at least one additional product during 2009 and to initiate human clinical studies immediately thereafter. We believe that we may be able to reduce the development risks and time to market for our product

candidates as our product candidates are based on well-understood proteins with known biological mechanisms of actions. 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. In addition we are continuously evaluating potential strategic marketing partnerships.

Our ProCellEx protein expression system consists of a comprehensive set of technologies and capabilities for the development of recombinant proteins, including advanced genetic engineering technology and plant cell-based protein expression methods. Through our ProCellEx protein expression system, we can develop highly complex recombinant

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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. The major elements of our ProCellEx system are patent protected in most major countries. 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 and biosimilar or generic versions of recombinant therapeutic proteins. To that end, we are leveraging our ProCellEx protein expression system to develop a pipeline of proprietary and biosimilar versions of 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 agreement 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 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-

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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®, Neupogen®, Cerezyme, Rituxan®, Enbrel®, Neulasta® and Herceptin®. 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 glycosilation (the addition of sugar residues to a protein which is necessary to enable specific biological activity by the protein). 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 are subject to 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 regarding contamination of agricultural crops and by the difficulty in applying cGMP standards of the pharmaceutical industry to these expression technologies.

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

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exhibit a glycan and amino acid structure similar to their naturally-produced human counterparts. 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. In addition, proteins produced by our ProCellEx system maintain the biological activity that characterize that of the naturally-produced proteins. 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, a 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 an 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 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 protein 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 a 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 potentially 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 prGCD 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

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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 glycosilated 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 have the intended composition and correct biological activity of their human-equivalent protein, with several of such proteins demonstrating advantageous biological activity compared to the currently available biotherapeutics. In specific cases, we have been successful in expressing proteins that have not been successfully expressed in other production systems.

Our Strategy

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

Obtain Regulatory Approval for prGCD for the Treatment of Gaucher Disease. We completed enrollment of all the patients required for our phase III pivotal clinical trial of prGCD on December 2008 and expect to announce the initial study results in the second half of 2009. We anticipate submitting a New Drug Application (NDA) to the FDA and other comparable regulatory agencies in the fourth quarter of 2009. We are currently conducting the phase III clinical trial in selected leading medical centers worldwide in North America, South America, Israel, Europe and South Africa. In the third quarter of 2008, we initiated a double blind, follow-on extension study as part of the phase III clinical trial in which patients that successfully completed treatment in the trial were given the opportunity to continue to be treated with prGCD at the same dose that they received in the trial. We are compiling additional information relating to the long term safety and efficacy of prGCD through the follow-on study. In addition, in the fourth quarter of 2008 we announced the enrollment of the first patient in a worldwide, multi-center, open-label, switch-over trial to assess the safety and efficacy of prGCD. The switch-over trial, which is not a pre requisite for approval, is designed to include 15 patients with Gaucher disease that are currently undergoing enzyme replacement therapy with imiglucerase (Cerezyme). 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 the approval of prGCD as a treatment for Gaucher disease, if at all, with its potentially longer acting profile and more cost-effective development process, may lead 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 or Biosimilar Versions of Recombinant Therapeutic Proteins. We are leveraging our ProCellEx protein expression system to develop a pipeline of innovative or biosimilar versions of 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 that are mainly oriented towards the specialty disease and therapeutic market segments, including treatments for Fabry disease and an acetylcholinesterase enzyme based therapy for biodefense and intoxication treatments. 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 the development of most of our current product candidates. We plan to apply the manufacturing, clinical and regulatory experience we have gained from the development of 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 facilitate our creation of a targeted internal sales force. In addition we are continuously evaluating potential strategic marketing partnerships.

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

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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. In August 8, 2007, we entered into an agreement with the Yissum Research and Development Company, the technology transfer arm of the Hebrew University of Jerusalem, Israel, and the Boyce Thompson Institute for Plant Research, at Cornell University, Ithaca, New York, to develop a proprietary plant cell-based acetylcholinestrase (AChE) and its molecular variants for the use in several therapeutic indications, including a biodefense program and an organophosphate-based pesticide treatment program. The scope of this program was expanded in January 2008. See Acetylcholineterase. We believe that by pursuing selective acquisitions of 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. The Chairman of our Board of Directors, Mr. Eli Hurvitz, is an experienced pharmaceutical industry veteran and the current Chairman of the Board and former President and Chief Executive Officer of Teva. In February 2008, we appointed Professor Roger D. Kornberg, a renowned biochemist and laureate of the Nobel Prize in Chemistry, to our Board of Directors. We will continue to leverage their experience and established track record 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 July 2007, we reached an agreement with the United States Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of prGCD, through the FDA s special protocol assessment (SPA) process. We completed enrollment of all the patients required for our phase III pivotal clinical trial of prGCD in December 2008 and expect to announce results of the clinical trial in the second half of 2009. We anticipate submitting a New Drug Application (NDA) to the FDA and comparable regulatory agencies in other countries in the fourth quarter of 2009. During the third quarter of 2008, we initiated a double blind, follow-on extension study as part of the phase III clinical trial in which patients that successfully completed treatment in the trial were given the opportunity to continue to be treated with prGCD at the same dose that they received in the trial. We are compiling additional information relating to the long term safety and efficacy of prGCD through the follow-on study. In addition, in the fourth quarter of 2008 we announced the enrollment of the first patient in a worldwide, multi-center, open-label, switch-over trial which has been reviewed by the FDA and is designed to assess the safety and efficacy of prGCD. The switch-over trial, which is not a pre requisite for approval, is designed to include 15 patients with Gaucher disease that are currently undergoing enzyme replacement therapy with imiglucerase (Cerezyme). 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

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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.

In addition, we are developing a new method for delivering active recombinant proteins systemically through oral administration of transgenic plant cells expressing biotherapeutic proteins. If proven effective, we intend to apply this breakthrough technology to prGCD before we apply it to any other product candidates. If proven effective, our experimental oral prGCD would be the first protein to be administered orally rather than through intravenous therapy. We are developing our oral prGCD product candidate to be used in enzyme replacement therapy, not as a small molecule. This differentiates our oral product candidate from other early clinical stage, experimental, small molecule, oral drugs which are being developed for the treatment of Gaucher disease by Amicus Therapeutics, Inc. and Genzyme. Small molecule based treatments for Gaucher disease, such as Zavesca, are different in their mechanism of action from treatments through enzyme replacement therapy, and may be associated with a number of side effects. In connection with such new method for protein delivery, we have filed patent applications in other countries with commercially significant markets.

Gaucher Disease Background

Gaucher disease, a hereditary, genetic disorder with severe and debilitating symptoms, is the most prevalent lysosomal storage disorder in humans. Lysosomal storage disorders are metabolic disorders in which a lysosomal enzyme, a protein that degrades cellular substrates in the lysosomes of cells, is mutated or deficient. 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. In some cases, the patient may suffer an impairment of the central nervous system.

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. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are injected into patients in whom the enzyme is lacking or dysfunctional. 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 over 5,000 patients and had annual sales of approximately $1.2 billion in 2008. 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 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 40.1 million (approximately $34.2 million) in 2008.

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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. The primary efficacy endpoint for our pivotal study is the reduction in size of spleen and the secondary endpoints for our pivotal study include increase in platelet and hemoglobin counts and reduction in liver size, all of which are generally well-established and accepted by regulatory agencies and specifically agreed to by the FDA in the special protocol assessment (SPA) of the final design of our pivotal phase III clinical trial for prGCD. See Phase III Clinical Trial. The primary end point for our switch-over study, which is not a prerequisite for approval, is non deterioration in the patient s clinical condition as measured through significant, well established end points such as platelet and hemoglobin counts and spleen and liver size.

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.

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

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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 based upon data 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.

Figure 3: prGCD and Cerezyme Half-Life Data

	prGCD	**Cerezyme**
Primates	~13.0-20.0 minutes	~ 6.8-8.0 minutes (1)
Humans	~10.5-14.5 minutes	~3.6-10.4 minutes (2)

(1) Source: Cerezyme NDA PharmTox review

(2) Source: Cerezyme labeling approved by FDA for package insert

Prior to submitting an NDA for prGCD, 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.

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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	15 U/kg	30 U/kg	60 U/kg	Placebo	Events Severity	Total
Unrelated to drug (1)	0; 0 (0%)	0; 0 (0%)	2; 1 (17%)	0; 0 (0%)	Moderate	2
Remotely related to drug (2)	4; 2 (33%)	1; 1 (17%)	2; 1 (17%)	1; 1 (17%)	Mild	8
Possibly related to drug (3)	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)		0
Probably related to drug (4)	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)	0; 0 (0%)		0
Related to drug (5)	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, based upon data 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 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 and in the third quarter of 2007 we initiated enrollment and treatment of patients in the phase III clinical trial. According to the SPA, the phase III clinical

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trial is to include at least 30 naive 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 commenced enrollment and treatment of patients in our phase III clinical trial in the third quarter of 2007 and completed enrollment in the fourth quarter of 2008. During the third quarter of 2008, we initiated a double blind, follow-on extension study as part of our phase III clinical trial in which patients that successfully completed treatment in the trial were given the opportunity to continue to be treated with prGCD at the same dose that they received in the trial. We are compiling additional information relating to the long term safety and efficacy of prGCD through the follow-on study. In addition, in the fourth quarter of 2008, we announced the enrollment of the first patient in a worldwide, multi-center, open-label, switch-over trial to assess the safety and efficacy of prGCD. The switch-over trial, which is not a pre requisite for approval, is designed to include 15 patients with Gaucher disease that are currently undergoing enzyme replacement therapy with imiglucerase (Cerezyme). We are currently conducting the phase III clinical trial in selected medical centers worldwide, in North America, South America, Israel, Europe and South Africa.

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. In the past, we were developing variants of Follicle Stimulating Hormone (FSH), a human fertility hormone targeted at the female infertility market but have since determined not to expend additional resources for those projects. We are also 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 2009. Last, 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. These symptoms may lead to kidney failure and increased risk of heart attack and stroke. 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 $494 million in worldwide sales of Fabrazyme in 2008. The other approved drug for the treatment of Fabry disease in the European Union is Replagal, which is sold by Shire plc. Shire reported $176.1 million in sales of Replagal in 2008.

We are currently in the animal evaluation testing phase of the development of PRX-102, which tests are based on a well established mouse model for Fabry disease. We expect to file an IND with the FDA for PRX-102 following the completion of the animal studies. 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 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.

Acetylcholinesterase

In August 2007, we entered into an agreement with the Yissum Research and Development Company and the Boyce Thompson Institute, Inc. 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 and an organophosphate-based pesticide treatment program. Pursuant to the terms of the agreement, we have received an exclusive, worldwide right and license to certain technology, including patents and certain patent applications relating to AChE for the therapeutic and prophylactic indications as well as an exclusive license not limited to such indications with

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respect to certain of those patents and patent applications. In consideration for those licenses, we have agreed to make certain regulatory milestone payments, a sales-based milestone payment, a license maintenance fee and a royalty on net sales of any products developed with the licensed technology.

In January 2008, we expanded the scope of our acetylcholinesterase program with Yissum after we achieved proof of concept results in an animal study conducted as part of the program. In our animal study, the plant cell expressed form of the acetylcholinesterase protein demonstrated full protection from organophosphate poisoning, stimulating the capacity of the plant cell expressed acetylcholinesterase protein to treat nerve gas and pesticide poisoning. Under our agreement with Yissum, we intend to conduct a collaborative research program in the laboratory of Professor Hermona Soreq, a world leader in the field of acetylcholinesterase research and Dean of the Faculty of Science at the Hebrew University.

To date, our in vitro experiments have shown that the acetylcholinesterase expressed in our ProCellEx protein expression system demonstrates promising biological activity on biochemical and cellular levels. In addition, early animal studies demonstrated that the acetylcholinesterase expressed in our ProCellEx protein expression system was able to treat successfully animals exposed to the nerve gas agent analogs, both when injected with our acetylcholinesterase product candidate immediately before exposure or when injected after exposure. We recently held a pre-IND meeting with the FDA to clarify the requirements and scope of the clinical studies required for regulatory approval of our acetylcholinesterase product candidate. We plan to submit an IND application for acetylcholinesterase during 2009, and to initiate a clinical study immediately after our IND is accepted, if at all.

PRX-111

In the past were developing variants of Follicle Stimulating Hormone (FSH), a human fertility hormone targeted at the female infertility market. Although we believe that our in vitro experiments with these hormones demonstrated equivalent to superior biochemical and cellular results when compared to the currently marketed biotherapeutic hormones used in approved female infertility treatments, we have determined not to proceed with this project due to the current, general market conditions.

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 animal studies with respect to one protein under the agreement and we expect to launch feasibility studies with respect to the second protein during 2009. 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. See Risk Factors 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.

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 the first generation treatments used today. The technology licensed from Yeda provides a methodology for the rational design of an improved drug for the 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 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

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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. See Risk Factors 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.

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 14 granted patents and 56 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, two are expected to reach the national phase during 2009. We also have one joint patent with a third party and hold licensed rights to four 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 glycosilated proteins in a plant culture, particularly proteins having a terminal mannose glycosilation, 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 patent family 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 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 9,000 sq/ft of clean rooms built according to industry standards, to develop, process and manufacture prGCD

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and other recombinant proteins. In January 2008, we signed a lease agreement for additional space as part of the expansion of our manufacturing and research facility. The expanded space, located in our existing facility, provides us with approximately three times our current manufacturing space. In January 2009 we commenced the final upgrade of the manufacturing space within our facility to ensure that the manufacturing space will be able to comply with the good laboratory, clinical and manufacturing practices required by the FDA and other comparable regulatory authorities for production of pharmaceutical products on a commercial scale. We intend to use our current manufacturing space to produce all of the prGCD we need in the near future. In addition, we recently held a design review meeting with the FDA to obtain the FDA s input on the facility design. We intend to use our expanded facility to house the laboratory space necessary for further development of other product candidates in our pipeline. Total expected cost for such expansion is estimated to be approximately $5 million and the process is expected to be completed by the end of 2009.

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. Upon the approval of prGCD, if at all, we are planning to expand our existing manufacturing space further to satisfy our entire production needs for the product worldwide. 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. See Risk Factors 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.

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.

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 much lesser extent, Actelion Ltd. Shire plc is currently developing a gene-activated GCD enzyme expressed in human cancer cells to treat Gaucher disease. In addition, we are aware of other early clinical stage, experimental, small molecule, oral drugs which are being developed for the treatment of Gaucher disease by Amicus Therapeutics, Inc. and Genzyme. We also

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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, including a drug being developed by Amicus Therapeutics.

We also face competition from companies that are developing other platforms for the expression of recombinant therapeutic pharmaceuticals. We are aware of companies that are developing alternative technologies to develop and produce therapeutic 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 Symbiosys, none of which are cell-based. Rather, such companies base their product development on transgenic plants or whole plants.

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. See Risk Factors 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.

Scientific Advisory Board

Members of our scientific advisory board, who are experts in the fields of plant molecular and cell biology as well as Gaucher disease and various hematological and genetic disorders, consult with our management within their professional areas of expertise; exchange strategic and business development ideas with our management; attend scientific, medical and business meetings with our management, such as meetings with the FDA and comparable foreign regulatory authorities, meetings with strategic or potential strategic partners and other meetings relevant to their areas of expertise; and attend meetings of our scientific advisory board. We expect our scientific advisory board to convene at least twice annually, and we frequently consult with the individual members of our Scientific Advisory Board. Our scientific advisory board currently includes the following people:

Name	Affiliation
Professor Aaron Ciechanover, M.D., D.Sc.	Laureate of the Nobel Prize in Chemistry
	Distinguished research Professor at the Cancer and Vascular Biology Research Center of the Rappaport Research Institute and Faculty of Medicine at the Technion
	American Academy of Arts and Sciences, Member
Professor Gad Galili, Ph.D.	Chairman of the Department of Plant Sciences, The Weizmann Institute of Science, Rehovot, Israel
Professor Ari Zimran, M.D.	Director of the Gaucher Clinic, Shaare Zedek Medical Center, Jerusalem, Israel
	Associate Professor of Medicine, Hebrew University-Hadassah Medical School, Jerusalem, Israel

We were saddened by the death of Professor Ernest Beutler, one of our Scientific Advisory Board members, during 2008.

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

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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.

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 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, approved products are subject to continual review and holders of an approved product are required, for example, to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for the product. Also, quality control and manufacturing procedures relating to a product must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to comply with cGMP and other aspects of regulatory compliance. The later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements with respect to any product may result in restrictions on the marketing of the product or withdrawal of the product from the market as well as possible civil or criminal sanctions. See also International Regulation.

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

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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 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 or in a centralized procedure to the European Medicines Agency (EMEA). 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 29% 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 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.

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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 in 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:

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

Our original 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.

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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.

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, 2008, the OCS approved grants in respect of Protalix Ltd. s continuing operations totaling approximately $11.0 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, 2008, Protalix Ltd. had not paid or accrued royalties and Protalix Ltd. s contingent liability to the OCS with respect to grants received was approximately $10.6 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

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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.

- 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

Protalix Ltd. is 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.

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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

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., 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 prohibited 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 was permitted, under the terms of the lock-up agreements and the tax ruling described below, to sell an aggregate of 10% of each such shareholder s original number of locked-up shares.

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 were required to maintain our holding of at least 51% of Protalix Ltd. and certain of our shareholders at the time of the consummation of the merger were required to maintain, in the

aggregate, holdings of at least 51% of our outstanding share capital. See Risk Factors Trading of our common stock is limited.

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Notwithstanding the limitations described above, the following transactions were not 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.

Subject to further clarification from the Israeli tax authorities regarding the tax ruling, our Board of Directors terminated the lock-up agreements for holders of 5% or less of our outstanding shares as of the closing of the merger. Such termination allowed 22,929,381 shares of our common stock to become eligible for sale on the public market in advance of the expiration of the lock-up agreements on January 1, 2009. See also Risk factors Future sales of our common stock could reduce our stock price.

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. was 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.
- 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.

These limitations expired on January 1, 2009.

Employees

As of December 31, 2008, we had 138 employees, of whom 24 have an M.D. or a Ph.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 set forth below. Our executive offices and our main research manufacturing facility are located at that address. Our telephone number is +972-4-988-9488. From May 2001 through December 31, 2006, our company had no operations. We were originally formed as Embassy Acquisition Corp., a Florida corporation, in November 2005 and changed our name to Orthodontix, Inc., in April, 1992. 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. In connection with the merger, we completed 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 NYSE Alternext US (then, the American Stock Exchange) under the symbol PLX.

On October 25, 2007, we issued and sold 10,000,000 shares of our common stock in an underwritten public offering at a price of $5.00 per share. The net proceeds to us were approximately $46 million after deducting underwriting

discounts, commissions and offering expenses.

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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 annual report belongs to its respective holder.

Available Information

Our corporate website is www.protalix.com. We make available on our website, free of charge, our Securities and Exchange Commission, or the 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. Additionally, from time to time, we provide notifications of material news including press releases and conferences on our website. Webcasts of presentations made by our company at certain conferences may also be available on our website, to the extent the webcasts are available. The content of our website is not intended to be incorporated by reference into this report or in any other report or document we file and any references to these websites are intended to be inactive textual references only.

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. 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, 2008 was $75.0 million. For the years ended December 31, 2008, 2007 and 2006, we had net losses of $22.4 million, $32.1 million and $9.4 million, respectively, primarily as a result of expenses incurred through a combination of research and development activities and expenses supporting those activities, which includes share-based compensation expense. 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 $13 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 approximately the next 24 months. However, changes may occur that could consume our existing capital at a faster rate than projected, including, among others, changes in the progress of our research and development efforts, the cost and timing of regulatory approvals and the costs of protecting our intellectual property rights. We may seek additional financing to implement and fund product development, preclinical studies and clinical trials for the drugs in our pipeline, as well as additional drug candidates and other research and development projects. If we are unable to secure additional financing in the future on acceptable terms, or at all, we may be unable to commence or complete planned preclinical and clinical trials or obtain approval of our drug candidates from the FDA and other regulatory authorities. In addition, we may be forced to reduce or discontinue product development or product licensing, reduce or forego sales and marketing efforts and other commercialization activities or forego attractive business opportunities in order to improve our liquidity and to enable us to continue operations which would have a material adverse effect on our business and results of operations. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our shareholders.

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

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

- continue to undertake preclinical development and clinical trials for our current and new drug candidates;
- seek regulatory approvals for our drug candidates;
- implement additional internal systems and infrastructure;
- seek to license-in additional technologies to develop; and
- hire additional personnel.

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

could negatively impact the value of our common stock.

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

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

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

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

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

Our ProCellEx protein expression system is based on our proprietary plant cell-based expression technology. Our business is dependent upon the successful development and approval of our product candidates produced through our protein expression system. Our ProCellEx protein expression system is novel and is still in the early stages of development and optimization, and, accordingly, is subject to certain risks. Mammalian cell-based protein expression systems have been used in connection with recombinant therapeutic protein expression for more than 20 years and are the subject of a wealth of data; in contrast, there is not a significant amount of data generated regarding plant cell-based protein expression and, accordingly, plant cell-based protein expression systems may be subject to unknown risks. In addition, the protein glycosilation pattern created by our protein expression system is not identical to the natural human glycosilation 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;
- maintaining the cGMP compliance of our manufacturing facility or establishing manufacturing arrangements with third parties;
- the successful audit of our facilities by the FDA and other foreign regulatory authorities;

the development of a successful sales and marketing organization;

the availability of reimbursement to patients from healthcare payors for our drug products, if approved;

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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, or a Biologic License Application, a BLA, 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

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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 we will be able to complete our current phase III clinical trial of prGCD and file an NDA by the end of the second half of 2009. Other clinical trials of prGCD, will conclude somewhat after, and any of our other potential drug candidates will take at least several years to complete. Preliminary and initial results from a clinical trial do not necessarily predict final results, and failure can occur at any stage of the trials. We may encounter problems that cause us to abandon or repeat preclinical studies or clinical trials. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. 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.

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.

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

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

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

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

- perceptions by physicians, patients, third party payors and others in the medical community, about the safety and effectiveness of our drug candidates;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the prevalence and severity of any side effects, including any limitations or warnings contained in our products approved labeling;
- pharmacological benefit of our products relative to competing products and products under development;
- the efficacy and potential advantages relative to competing products and products under development;
- relative convenience and ease of administration;
- effectiveness of education, marketing and distribution efforts by us and our licensees and distributors, if any;
- publicity concerning our products or competing products and treatments;
- reimbursement of our products by third party payors; and
- the price for our products and competing products.

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

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

We depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials. These collaborators are not our employees, and we cannot control the amount or

timing of resources that they devote to our clinical development programs. The investigators may not assign as great a priority to our clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly. If outside collaborators fail to devote sufficient time and resources to our clinical development programs, or if their performance is substandard, the approval of our FDA and other applications, if any, and our introduction of new drugs, if any, may be delayed which could impair our clinical development programs and would have a material adverse effect on our business and results of operations. The collaborators may also have relationships with other commercial

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entities, some of whom may compete with us. If our collaborators also assist our competitors, our competitive position could be harmed.

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

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

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

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

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

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

product revenues.

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

We currently have no sales, marketing or distribution capabilities and no experience in building a sales force and distribution capabilities. To commercialize our product candidates, we must either develop internal sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services. If we decide to market any of our products directly, we must commit significant financial and managerial resources to

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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.

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

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any co-promotion arrangements, and the terms of any co-promotion arrangements we enter into may not be favorable to us.

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

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

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

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

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

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

developing drugs;

undertaking preclinical testing and human clinical trials;

obtaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

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

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

As of December 31, 2008, we had 56 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

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eventually issued will be as broad as requested in the patent application or sufficient to protect our technology. Any modification required to a current patent application may delay the approval of such patent application which would have a material adverse effect on our business and results of operations. In addition, there are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications to not be granted, including known or unknown prior art, deficiencies in the patent application or the lack of originality of the technology.

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

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

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

Furthermore, the life of our patents is limited. The patents we hold relating to our ProCellEx protein expression system will expire in 2016. If patents issue from other currently pending patent applications, those patents will expire between 2023 and 2028.

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.

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

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

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

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

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

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

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

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

In addition to our own internally developed drug candidates, we proactively seek opportunities to in-license and advance other drug candidates that are strategic and have value-creating potential to take advantage of our development know-how and technology. If we in-license any additional drug candidates, our capital requirements may increase significantly. In addition, in-licensing additional drug candidates may place a strain on the time of our

existing personnel, which may delay or otherwise adversely affect the development of our existing drug candidates or cause us to re-prioritize our drug pipeline if we do not have the necessary capital resources to develop all of our drug candidates, which may delay the development of our drug candidates and negatively impact our business, results of operations and financial condition.

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

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

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

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

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

We are highly dependent upon the principal members of our management team, especially our President and Chief Executive Officer, Dr. David Aviezer, Ph.D., as well as our directors, including Eli Hurvitz, the Chairman of our Board of Directors, our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved with us for many years and have played integral roles in our progress, and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have employment agreements with Dr. Aviezer and four other officers that may be terminated by us or the applicable officer at any time with varying notice periods of 60 to 90 days. Although these employment agreements generally include non-competition covenants and provide for severance payments that are contingent upon the applicable employee s refraining from competition with us, the applicable noncompetition provisions can be difficult and costly to monitor and enforce. The loss of any of these persons services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key-man life insurance.

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

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

We work with chemists, biologists and other scientists at academic and other institutions, and consultants who assist us in our research, development, regulatory and commercial efforts, including the members of our scientific advisory board. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice on our programs. These scientists and consultants are not our employees, may have other commitments that would limit their

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future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product or compound that is more scientifically interesting to his or her professional interests, his or her availability to remain involved in such clinical trials could be restricted or eliminated.

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

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

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

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

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

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

commenced efforts to have our product candidates reimbursed by government or third-party payors. If reimbursement is not available or is available only to limited levels, the sales of our products, if approved may be diminished or we may not be able to sell such products profitably.

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

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

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

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

Risks Relating to Our Operations in Israel

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

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

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

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

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

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

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

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

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

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

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

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

we may be required to pay the OCS a portion of the consideration we receive upon any sale of such technology to an entity that is not Israeli. The scope of the support received, the royalties that were paid by us, the amount of time that elapses between the date on which the know-how is transferred and the date on which the grants were received, as well as the sale price, will be taken into account in order to calculate the amount of the payment; and

the transfer of manufacturing rights could be conditioned upon an increase in the royalty rate and payment of increased aggregate royalties (up to 300% of the amount of the grant plus interest, depending on the percentage of the manufacturing that is foreign).

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

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

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

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

the judgment was rendered by a court which was, according to the laws of the state of the court, competent to render the judgment;

the judgment may no longer be appealed;

the obligation imposed by the judgment is enforceable according to the rules relating to the enforceability of judgments in Israel and the substance of the judgment is not contrary to public policy; and

the judgment is executory in the state in which it was given.

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

the judgment was obtained by fraud;

there is a finding of lack of due process;

the judgment was rendered by a court not competent to render it according to the laws of private international law in Israel;

the judgment is at variance with another judgment that was given in the same matter between the same parties and that is still valid; or

at the time the action was brought in the foreign court, a suit in the same matter and between the same parties was pending before a court or tribunal in Israel.

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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;
- results of our ongoing phase III clinical trial for our lead product candidate prGCD;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- developments in the biotechnology industry; and
- general market conditions and other factors, including factors unrelated to our operating performance.

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

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

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

Trading of our common stock is limited.

Our common stock began trading on the NYSE Alternext US, formerly, 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 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.

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 prohibited 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. During such period, each such former Protalix Ltd. shareholder was permitted, under the terms of the lock-up agreements and the tax ruling described below, to sell an aggregate of 10% of each such shareholder s original number of locked-up shares. On June 11, 2008,

after completing discussions with the Israeli tax authorities regarding the tax ruling, we approved the early termination of the lock-up

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agreements for holders of 5% or less of our outstanding shares as of the closing of the merger which allowed an additional 22,929,381 shares of our common stock to become eligible for sale on the public market. The lock-up agreements expired as of January 1, 2009 according to their terms which freed an additional 35,875,319 shares of our common stock and options and warrants to purchase 3,046,052 shares of our common stock, for sale by the holders thereof.

Under applicable Israeli tax law incorporated by reference into the tax ruling obtained by Protalix Ltd. from the Israeli tax authorities in connection with the merger, until January 1, 2009, we were required to maintain at least 51% of Protalix Ltd. and our shareholders at the time of the consummation of the were required to maintain, in the aggregate, holdings of at least 51% of our outstanding share capital. This restriction limited, to an extent, the volume of our shares available for public trading. These restrictions expired as of January 1, 2009.

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

Sales by shareholders of substantial amounts of our shares, the issuance of new shares by us or the perception that these sales may occur in the future, could affect materially and adversely the market price of our common stock. As described in this Annual Report, substantially all of the former shareholders of Protalix Ltd. (holding at that time, in the aggregate, 65,094,232 shares of our common stock and options and warrants to purchase 3,628,826 shares of our common stock) entered into lock-up agreements with respect to their securities of our company to satisfy Israeli tax laws and contractual obligations. The lock-up agreements prohibited 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. On June 11, 2008, we approved the early termination of the lock-up agreements for holders of 5% or less of our outstanding shares as of the closing of the merger which allowed an additional 22,929,381 shares of our common stock to become eligible for sale on the public market. The lock-up agreements expired as of January 1, 2009 according to their terms which freed an additional 35,875,319 shares of our common stock and options and warrants to purchase 3,046,052 shares of our common stock, for sale by the holders thereof, subject in most cases to the limitations of either Rule 144 or Rule 701 under the Securities Act.

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

Our directors, executive officers, principal shareholders and affiliated entities beneficially own, in the aggregate, approximately 58% 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 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. We continuously monitor our existing internal controls over financial reporting systems to confirm that they 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, at any time, 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. 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

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independent auditors. Failure to 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 NYSE Alternext US 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 on 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.

The issuance of preferred stock or additional shares of common stock could adversely affect the rights of the holders of shares of our common stock.

Our board of directors is authorized to issue up to 100,000,000 shares of preferred stock without any further action on the part of our shareholders. Our Board of Directors has the authority to fix and determine the voting rights, rights of redemption and other rights and preferences of preferred stock. Currently, we have no shares of preferred stock outstanding.

Our board of directors may, at any time, authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, before the redemption of our common stock, which may have a material adverse effect on the rights of the holders of our common stock. In addition, our board of directors, without further shareholder approval, may, at any time, issue large blocks of preferred stock. In addition, the ability of our board of directors to issue shares of preferred stock without any further action on the part of our shareholders may impede a takeover of our company and may prevent a transaction that is favorable to our shareholders.

Item 1B. Unresolved Staff Comments

On June 26, 2008, we received a comment letter from the Commission related to various issues with respect to our Annual Report on Form 10-K for the year ended December 31, 2007, including our accounting of certain stock-based compensation of non-employees. We responded to the Commission on July 11, 2008. Subsequently, on October 2,

2008, we received an additional comment letter from the Commission and on December 4, 2008, January 22, 2009, February 18, 2009, March 3, 2009, and March 5, 2009, we received verbal comments from the Commission on these and other related matters. We responded to these comment letters on October 16, 2008, December 23, 2008, February 5, 2009, and March 4, 2009, respectively, and provided the Commission with supplemental responses and information requested by the Commission in the written and verbal comments.

As of the date of the filing of this Annual Report on Form 10-K, we are responding to the verbal comments received on March 5, 2009, and have not resolved the comments described above. We determined to restate certain financial statements for our fiscal year 2007 in this Annual Report on Form 10-K as a result of our review of the financial statements in response to the Commission s comments. We also intend to restate our financial statements for each of the first, second and third quarter of 2007. We will continue to work to resolve the comments with the Commission.

Item 2. Properties

Our manufacturing facility and executive offices, which are leased for a period ending in 2010, are located in Carmiel, Israel. The facilities currently contain approximately 13,500 sq/ft of laboratory and office space and are leased at a rate of approximately $14,000 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 January

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2008, we entered into an additional lease agreement with the same lessor for approximately three times our current manufacturing space in our existing manufacturing and research facility. The base rent for the additional space is approximately $27,000 per month. As of December 31, 2008, the monthly rent for the additional space will be approximately $41,000 due to the enhancements to the facility performed by the lessor. The term of the new lease is 7.5 years with three options exercisable by us to extend the term, each for a five-year period, for an aggregate of 15 additional years. In connection with the new lease, the original lease was amended to provide us with the same options to extend the original lease as provided in the new lease. Upon the exercise of each option to extend the term of the new lease, if any, the then current base rent shall be increased by 10%. We also lease an office in Ramat Gan, Israel, for approximately $1,700 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

At our Annual Meeting of Shareholders held on November 9, 2008, the following matters were voted on by our shareholders: (i) the election of 10 directors; and (ii) the approval of the appointment of Kesselman & Kesselman, Certified Public Accountant (Isr.), A member of PricewaterhouseCoopers International Limited, as our independent registered public accounting firm for the fiscal year ended December 31, 2008. The results of such shareholder votes are as follows:

(i) Election of Directors

	For	Withheld
Eli Hurvitz	58,516,636	64,789
David Aviezer, Ph.D., MBA	58,535,944	45,481
Yoseph Shaaltiel, Ph.D.	58,534,944	46,481
Alfred Akirov	58,535,984	45,441
Amos Bar-Shalev	58,500,857	80,568
Zeev Bronfeld	57,762,672	818,753
Yodfat Harel Gross	58,499,857	81,568
Roger D. Kornberg, Ph.D.	58,535,944	45,481
Eyal Sheratzky	58,500,857	80,568
Sharon Toussia-Cohen	58,453,709	127,716

(ii) Approval of Kesselman & Kesselman, Certified Public Accountant (Isr.), A member of PricewaterhouseCoopers International Limited, as our independent registered public accounting firm for the fiscal year ended December 31, 2008.

For	Against	Abstain
58,522,738	58,587	100

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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 NYSE Alternext US (then known as 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:

	2008		2007	
Quarter Ended	**High**	**Low**	**High**	**Low**
March 31	$3.59	$2.60	$35.00	$15.75
June 30	$3.70	$2.56	$31.40	$19.50
September 30	$3.06	$2.08	$45.72	$13.46
December 31	$2.17	$0.96	$37.95	$ 3.20

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 53 holders of record of our common stock at March 3, 2009. A substantially greater number of holders of our common stock are street name or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions. 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, 2008 with respect to the shares of our common stock that may be issued under our existing equity compensation plan.

	A	B	C
Plan Category	**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	7,179,058	$ 1.79	2,056,623
Equity Compensation Plans Not Approved by Shareholders	4,016,368	$ 1.61	
Total	11,195,426	$ 1.72	2,056,623

STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total shareholder return data for our common stock from December 31, 2003 through December 31, 2008 to the cumulative return over such time period of (i) The AMEX Composite Index and (ii) The AMEX Biotechnology Index. The graph assumes an investment of $100 on December 31, 2003 in each of our common stock, and the stocks comprising the AMEX Composite Index and the stocks comprising the AMEX Biotechnology Index, including dividend reinvestment, if any.

The stock price performance shown on the graph below represents historical price performance and is not necessarily indicative of any future stock price performance. Specifically, during the period of December 31, 2003 through December 31, 2006, our company did not have any operations and our common stock was quoted on the OTC® Bulletin Board. The historical performance of our common stock prior to January 2, 2007, represents the performance of our company prior to the merger on December 31, 2006, and, therefore, is not indicative of the performance of our common stock after the merger or the performance of our common stock after it was listed for trade on the NYSE Alternext US (then, the American Stock Exchange) on March 12, 2007.

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COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Protalix BioTherapeutics, Inc., The AMEX Composite Index
And The AMEX Biotechnology Index

* $100 invested on December 31, 2003 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

Notwithstanding anything to the contrary set forth in any of our previous filings under the Securities Act of 1933, as amended, or the Exchange Act, which might incorporate future filings made by us under those statutes, this Stock Performance Graph will not be incorporated by reference into any of those prior filings, nor will such report or graph be incorporated by reference into any future filings made by us under those Acts.

Use of Proceeds

The effective date of our first registration statement, filed on Form S-3 under the Securities Act of 1933, which was accompanied by a registration statement on Form S-3 filed pursuant to Rule 462(b) under the Securities Act (Nos. 333-144801 and 333-146919), relating to a public offering of our common stock, was September 26, 2007 and the offering date was October 25, 2007. The sole book-running manager of the offering was UBS Investment Bank and CIBC World Markets (now Oppenheimer & Co., Inc.) served as the co-manager. In the offering we sold 10,000,000 shares of common stock at a price per share of $5.00. Our aggregate net proceeds (after underwriting discounts and expenses) amounted to approximately $46 million. The offering closed on October 30, 2007.

The amount of the underwriting discount paid by us was $3.5 million and the expenses of the offering, not including the underwriting discount, were approximately $810,000.

To date, the net proceeds of the offering were invested in accordance with our investment policy in short-term deposits. We intend to use the proceeds in the manner set forth in our prospectus of October 25, 2007.

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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, 2008, 2007 and 2006 and for the period from December 27, 1993 through December 31, 2008 and the selected consolidated balance sheet data as of December 31, 2008 and 2007, are derived from the audited consolidated financial statements included elsewhere in this Annual Report. The selected consolidated statements of operations data for the year ended December 31, 2007 and the selected consolidated balance sheet data as of December 31, 2007 have been adjusted to reflect the restatement of our financial results. The statement of operations data for the years ended December 31, 2003 and 2004 and the balance sheet data as of December 31, 2004, 2005 and 2006 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,					
	2004	2005	2006	2007(1) (restated)	2008	Period from Dec. 27, 1993 through Dec. 31, 2008
	(in thousands, except share and per share amounts)					
Consolidated Statement of Operations Data:						
Revenues	$ 430	$ 150				$ 830
Cost of revenues	120	35				206
Gross profit	310	115				624
Research and development expenses, net	1,920	3,773	$ 5,246	$ 13,570	$ 17,401	43,516
General and administrative expenses	807	2,131	4,525	20,594	6,770	36,660
Finance expense (income)	4	(43)	(344)	(2,080)	(1,757)	(4,205)
Net loss before change in accounting principle	$ 2,421	$ 5,746	$ 9,427	$ 32,084	$ 22,414	$ 75,047
Cumulative effect of change in accounting principle			(37)			(37)
Net loss	$ 2,421	$ 5,746	$ 9,390	$ 32,084	$ 22,414	$ 75,010
Net loss per share of common stock, basic and diluted (2)	$ 0.13	$ 0.31	$ 0.32	$ 0.48	$ 0.30	
Weighted average number of shares of common stock used in computing net loss per share of common stock (3)	18,801,527	18,801,527	29,300,987	67,187,329	75,892,344	
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 1,477	$ 4,741	$ 15,378	$ 61,813	$ 42,596	
Other assets	2,478	2,484	11,610	6,324	8,215	

Total assets	3,955	7,225	26,988	68,137	50,811
Current liabilities	1,246	845	2,268	3,762	5,527
Liabilities	2,480	1,130	2,704	4,452	6,464
Shareholders equity	1,475	6,095	24,284	63,685	44,347

* Represents less than $1.

(1) We have restated our consolidated balance sheet at December 31, 2007, statements of operations, changes in shareholders equity and cash flows for the year ended December 31, 2007 to change the accounting treatment of certain stock-based compensation of non-employees required by SFAS 123(R), *Share-Based Payment*, for certain transactions with nonemployees. See Note 2 to the consolidated financial statements for further information.

(2) Reflects the retroactive effects of the impact of our merger with Protalix Ltd. and the resulting

exchange of shares of common stock for the ordinary shares of Protalix Ltd. at an exchange ratio of approximately 61.08 shares of our common stock per ordinary share of Protalix Ltd. for all periods presented.

(3) In connection with the merger, we completed a one-for-ten reverse stock split, therefore all share numbers presented in this Annual Report on Form 10-K give retroactive effect to the reverse stock split.

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read Risk Factors in Item 1A of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Restatement

On February 23, 2009, our management concluded, with the concurrence of the Audit Committee of our Board of Directors to amend and restate our financial statements for the year ended December 31, 2007, and each of the fiscal quarters of 2007. We have restated our consolidated balance sheet at December 31, 2007, statements of operations, changes in shareholders equity and cash flows for the year ended December 31, 2007 to change the accounting treatment of certain stock-based compensation of non-employees required by SFAS 123(R), *Share-Based Payment*, or SFAS 123R, for certain transactions with nonemployees. See Note 2 to the consolidated financial statements for further information.

All amendments and restatements to the financial statements affected are non-cash in nature.

Statement of Financial Accounting Standards No. 123 (Revised 2004) Share-Based Payment, or SFAS 123R, requires the use of the fair-value-based method to measure the value of stock-based compensation. In our application of SFAS 123R, we took the position that an active market for our common stock did not exist for the first quarter of 2007, and that better information existed for the first and third quarters of 2007, due to the limited public float and trading volume in the market. We used alternative valuation methods to calculate the fair value of the common stock underlying certain stock-based compensation awards granted to non-employees during the first and third quarters of 2007. The alternative valuation methods included a retrospective valuation conducted by a third-party specialist in the first quarter, and for the third quarter we had used the public offering price of the shares of our common stock sold in the underwritten public offering completed by us on October 25, 2007. For purposes of the second quarter of 2007, we used the traded market value of the common stock to calculate the fair value of the common stock underlying certain stock-based compensation awards granted to non-employees because we did not believe that there was a preferred, alternative valuation mechanism available for that quarter. However, we concluded that we must rely on the traded market value of the common stock for the first and third quarters of 2007. We recalculated the compensation expense for non-employees for the first and third quarters of 2007 based on the traded market price of the common stock on the applicable measurement dates and determined that the resulting increase to the compensation expense for the applicable periods was material. On that basis, we recommended to the Audit Committee that a restatement is required.

SFAS 123R requires that share-based transactions with nonemployees to be measured based on the fair value of the goods or services received or the fair value of the equity instruments, whichever is more reliably measurable. EITF 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, specifies that the measurement date for such share-based transactions should be the earlier of (1) a performance commitment, or (2) the date at which the counterparty s performance is complete. We had previously issued 2,148,569 shares of equity instruments (stock options and restricted common stock) whose terms indicated that performance was not complete until the applicable vesting requirements were fulfilled. Accordingly, the measurement of the share-based compensation expense was determined based on the fair value of those equity instruments at each quarterly vesting date.

When preparing the consolidated financial statements for the first and third quarters of 2007, we utilized a fair value of our common stock of $6.19 and $5.00 per share, respectively. The reported traded prices of our common stock on the NYSE Alternext US were $31.32 and $34.56 at the end of the first and third quarters of 2007, respectively. We subsequently concluded that we should have used the reported traded prices as the valuation methodology for those equity instruments. Accordingly, we have restated the amounts previously reported for share-based compensation.

Overview

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx[tm] protein expression system. Using our ProCellEx system, we are developing a pipeline of proprietary and biosimilar or generic versions of 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

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genetic disorders, such as Gaucher disease and Fabry disease. 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 primarily 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 completely 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. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. 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. In July 2007, we reached an agreement with the United States Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of prGCD, through the FDA s special protocol assessment (SPA) process. We completed enrollment of patients in the phase III clinical trial in December 2008 and expect to report results of the clinical trial in the second half of 2009. We anticipate submitting a New Drug Application (NDA) for prGCD to the FDA and other comparable regulatory agencies in other countries in the fourth quarter of 2009. In addition to our phase III clinical trial, we initiated, during the third quarter of 2008, a double-blind, follow-on extension study as part of our phase III clinical trial. In December 2008, we also initiated a clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with prGCD. The current standard of care for Gaucher patients is enzyme replacement therapy with Cerezyme which is produced by Genzyme Corporation and currently the only approved enzyme replacement therapy for Gaucher disease. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are injected into patients in whom the enzyme is lacking or dysfunctional. The switch-over study is not a prerequisite for approval of prGCD.

Although Gaucher disease is a relatively rare disease, it represents a large commercial market due to the severity of the symptoms and the chronic nature of the disease. The annual worldwide sales of Cerezyme were approximately $1.2 billion in 2008 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, which is a mammalian cell expressed version of the same protein. We believe prGCD may prove more cost-effective than the currently marketed alternative due to the cost benefits of expression through our ProCellEx protein expression system. In addition, based on our laboratory testing, preclinical and clinical results, we believe that prGCD may have the potential for increased potency and efficacy compared to the existing enzyme replacement therapy for Gaucher disease, which may translate into lower dosages and/or less frequent treatments.

In addition to prGCD, we are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates, therapeutic protein candidates for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, an acetylcholinesterase enzyme-based therapy for biodefense and intoxication treatments and an additional undisclosed therapeutic protein, all of which are currently being evaluated in animal studies. We plan to file an investigational new drug application (IND) with the FDA with respect to at least one additional product during 2009 and to initiate human clinical studies immediately thereafter. We believe that we may be able to reduce the development risks and time to market for our product candidates as our product candidates are based on well-understood proteins with known biological mechanisms of actions. 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. In addition we are continuously evaluating potential strategic marketing partnerships.

Our business is conducted by our wholly-owned subsidiary, Protalix Ltd., which we acquired through a reverse merger transaction effective December 31, 2006. The merger transaction was treated as a recapitalization for accounting purposes and, as such, the results of operations discussed below are those of Protalix Ltd. Prior to the merger transaction, we had not conducted any operations for several years. Protalix Ltd. was originally incorporated in Israel in December 1993. Since its inception in December 1993, Protalix Ltd. has generated significant losses in

connection with its research and development, including the clinical development of prGCD. At December 31, 2008, we had an accumulated deficit of $75.0 million. Since we do not generate revenue from any of our product candidates, we expect to continue to generate losses in connection with the continued clinical development of prGCD and the research and development activities relating to our technology and other drug candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we believe that our operating losses are likely to be substantial over the next several years. We will need to obtain additional funds for the commercialization of our lead product, prGCD, and to further develop the research and clinical development of our other programs.

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Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing at the end of this Annual Report. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Functional Currency

The currency of the primary economic environment in which our operations are conducted is the dollar. As a development stage company with no significant source of revenues, we considered the currency of the primary economic environment to be the currency in which we expend cash. Most of our expenses and capital expenditures are incurred in dollars, and a significant source of our financing has been provided in U.S. dollars.

Research and Development Expense

We expect our research and development expense to remain our primary expense in the near future as we continue to develop our product candidates. Research and development expense consists of:

- internal costs associated with research and development activities;
- payments made to third party contract research organizations, investigative sites and consultants;
- manufacturing development costs;
- personnel-related expenses, including salaries, benefits, travel, and related costs for the personnel involved in research and development;
- activities relating to the advancement of product candidates through preclinical studies and clinical trials; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, as well as laboratory and other supplies.

The following table identifies our current major research and development projects:

Project	Status	Expected Near Term Milestone
prGCD for the treatment of Gaucher disease	Phase III	Results of Phase III in second half of 2009
PRX 102 alpha Galactosidase enzyme	Research	Pre Clinical during 2009
Acetylcholinesterase	Research	IND application during 2009

All of our projects, other than our phase III clinical trial of prGCD, are in the research phase with relatively immaterial costs. Most of our research and development costs were incurred in connection with our phase III clinical trial of prGCD. Our internal resources, employees and infrastructure are not tied to any individual research project and are typically deployed across all of our projects. We currently do not record and maintain research and development costs per project.

The costs and expenses of our projects are partially funded by grants we have received from the OCS. Each grant is deducted from the related research and development expenses as the costs are incurred. For additional information regarding the grant process, see Business Israeli Government Programs Encouragement of Industrial Research and Development Law, 1984 in Item 1 of this Annual Report. There can be no assurance that we will continue to receive

grants from the OCS in amounts sufficient for our operations, if at all.

At this time, due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of the product candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. While we are currently

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focused on advancing each of our product development programs, our future research and development expenses will depend on the clinical success of each product candidate, as well as ongoing assessments of each product candidate s commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See Risk Factors 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 and 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 expect our research and development expenses to increase in the future as we continue the advancement of our clinical trials and preclinical product development programs. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expense to increase and, in turn, have a material adverse effect on our operations. If our phase III clinical trial or prGCD produces favorable results, we expect to file a New Drug Application, an NDA, for prGCD with the FDA in the last quarter of 2009. Because of the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects. See Risk Factors 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.

General and Administrative Expense

General and administrative expense consists primarily of salaries and other related costs, including share-based compensation expense, for persons serving as our executive, finance, accounting and administration functions. Other general and administrative expense includes facility-related costs not otherwise included in research and development expense, costs associated with industry and trade shows and professional fees for legal and accounting services. We expect that our general and administrative expenses will increase as we add additional personnel and continue to comply with the reporting and other obligations applicable to public companies in the United States. From inception in December 1993 through December 31, 2008, we have spent $36.4 million on general and administrative expense, including share-based compensation expense of $22.8 million for options granted to employees and consultants.

Financial Expense and Income

Financial Expense and Income consists of the following:

- interest earned on our cash and cash equivalents;
- interest expense on short term bank credit and loan; and
- expense or income resulting from fluctuations of the New Israeli Shekel (NIS), in which a portion of our assets and liabilities are denominated, against the United States Dollar and other foreign currencies.

Share-Based Compensation

The discussion below regarding share-based compensation relates to share-based compensation paid by Protalix Ltd., our wholly-owned subsidiary.

We apply Emerging Issue Task Force 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, or EITF 96-18, with respect to options granted in consideration of services performed by consultants. In accordance with EITF 96-18, we record the benefit of any grant to a non-employee and remeasure the benefit in any future vesting period for the unvested portion of the grants, as applicable. In addition, we use the straight-line accounting method for recording the benefit of the entire grant, unlike the graded method we use to record grants made to employees.

We apply SFAS 123R which requires measurement of share-based compensation cost for all share-based awards at the fair value on the grant date and recognition of share-based compensation over the service period for awards that we expect will vest. The fair value of stock options is determined based on the number of shares granted and the price of our ordinary shares, and calculated based on the Black-Scholes valuation model, which is consistent with our

valuation techniques previously utilized for options in footnote disclosures required under SFAS 123, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. We recognize such value as expense over the service period,

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net of estimated forfeitures, using the accelerated method under SFAS 123R. The cumulative effect of our adoption of SFAS 123R, as of January 1, 2006, was not material.

Protalix Ltd. had multiple classes of stock before the conversion of all preferred shares into ordinary shares in September 2006. Through December 31, 2005, Protalix Ltd. considered the three commonly used methods described by the American Institute of Certified Public Accountants, or the AICPA, practice aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, and determined that the Probability-Weighted Expected Return Method is the appropriate method to value its securities. We chose this method because it is forward-looking and incorporates future economic events and outcomes into the determination of value at the time of calculation. The method is limited, as are all forward-looking methods, in that it relies on a number of assumptions.

Under the Probability-Weighted Expected Return Method, the value of the ordinary shares of Protalix Ltd. is estimated based upon an analysis of future values for the enterprise assuming various future outcomes. Share value is based upon the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available to the enterprise, as well as the rights of each share class. Although the future outcomes considered in any given valuation model will vary based upon the enterprise s facts and circumstances, common future outcomes modeled might include an initial public offering, merger or sale, dissolution or continued operation as a viable private enterprise.

The Probability-Weighted Expected Return Method analysis presents value afforded to shareholders under four possible scenarios. Three of the scenarios assume a shareholder realization, either through an initial public offering, sale, merger or liquidation. The last scenario assumes operations continue as a private company and no realization transaction occurs. Fair value calculations of the ordinary shares of Protalix Ltd. were performed for dates close to the dates on which preferred shares were issued to third parties. We considered the issuance price of each series of preferred shares to third parties in the calculation of the fair value of the ordinary shares. For each of the first three realization scenarios, estimated future and present values for each of the share classes were calculated utilizing assumptions which consisted of the following:

- expected pre-money value at the realization date;
- standard deviation around the above pre-money value;
- expected date of the realization scenario occurring;
- standard deviation around the expected realization scenario occurrence date (in days); and
- an appropriate risk-adjusted discount rate.

For purposes of determining the fair value of the options and shares of restricted common stock granted to employees and non-employees during the fiscal year ended December 31, 2008, including shares held by non employees that vested during such period, our management used the fair value of our common stock which was the closing sale price of our common stock on the NYSE Alternext US LLC on the date of calculation.

SFAS 123R allows companies to estimate the expected term of the option rather than simply using the contractual term of an option. Because of lack of data on past option exercises by employees, the expected term of the options could not be based on historic exercise patterns. Accordingly, we adopted the simplified method as stipulated in the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 107, Share-Based Payment (SAB 107), according to which companies may calculate the expected term as the average between the vesting date and the expiration date, assuming the option was granted as a plain vanilla option.

SAB 107 defines plain vanilla share options as those having the following characteristics:

- share options are granted at the money;
- exercisability is conditional only on performing service through the vesting date;
- if an employee terminates service prior to vesting, the employee forfeits the share options;

if an employee terminates service after vesting, the employee has a limited period of time (typically 30-90 days) to exercise the share options; and

share options are nontransferable and nonhedgeable.

All of the outstanding options granted by Protalix Ltd. were granted at an exercise price that was lower than the then share price. Accordingly, we assumed that the exercise period will on average be shorter than the average period between the vesting and the expiration of the options. However, due to the lack of information regarding exercise behavior, we implemented the methodology proposed above for the calculation of the expected term for all grants including those that were in the money.

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In performing the valuation, we assumed an expected 0% dividend yield in the previous years and in the next years. We do not have a dividend policy and given our development stage, dividends are not expected in the foreseeable future, if at all. SFAS 123R stipulates a number of factors that should be considered when estimating the expected volatility, including the implied volatility of traded options, historical volatility and the period that the shares of the company are being publicly traded. As we do not have any traded shares or options, the expected volatility figures used in this valuation have been calculated by using the historical volatility of traded shares of similar companies. In addition, we examined the standard deviation of shares of similar biotechnology companies that engage in research and development, generally in the development stage. We found that the standard deviation of the shares of comparable companies was in the range of 40%-60% over periods of three to six years. The volatility used for each grant differed based on its expected term. For the term of each grant of our options, the historical volatility was calculated based upon the overall trading history of the common stock of comparable companies.

The risk-free interest rate in the table above has been based on the implied yield of U.S. federal reserve zero-coupon government bonds. The remaining term of the bonds used for each valuation was equal to the expected term of the grant. This methodology has been applied to all grants valued by us. SFAS 123R requires the use of a risk-free interest rate based on the implied yield currently available on zero-coupon government issues of the country in whose currency the exercise price is expressed, with a remaining term equal to the expected life of the option being valued. This requirement has been applied for all grants valued as part of this report.

Results of Operations

Year Ended December 31, 2008 Compared to the Year Ended December 31, 2007

Revenues

No revenues were recorded during the years ended December 31, 2008 or 2007.

Research and Development Expenses

Research and development expenses were $22.1 million for the year ended December 31, 2008, an increase of $7.5 million, or 51%, from $14.6 million for the year ended December 31, 2007. The increase resulted primarily from the increase of $1.8 million in development expenses related to salaries for personnel involved in research and development and $2.1 million in related subcontractors and consultants expenses, mainly in connection with our on-going phase III clinical trial of prGCD. The increase in research and development expenses was partially offset by the recognition of grants equal to $4.7 million from the OCS during 2008, an increase of approximately $3.6 million compared to the recognition of grants equal to $1.1 million during 2007.

We expect research and development expenses to continue to be our primary expense as we enter into a more advanced stage of clinical trials for our product candidates, especially with respect to the anticipated continued progress in our phase III clinical trial for prGCD.

General and Administrative Expenses

General and administrative expenses were $6.8 million for the year ended December 31, 2008, a decrease of $13.8 million, or approximately 67%, from $20.6 million for the year ended December 31, 2007. The decrease resulted primarily from a $15.0 million decrease in share-based compensation during 2008.

Financial Expenses and Income

Financial income was $1.8 million for the year ended December 31, 2008, a decrease of $323,000, or approximately 16%, compared to $2.1 million for the year ended December 31, 2007. The decrease resulted primarily from a lower interest rate for deposits in 2008 and the devaluation of the NIS against USD, both of which contributed to lower financial income during 2008.

Year Ended December 31, 2007 Compared to the Year Ended December 31, 2006

Revenues

No revenues were recorded during the years ended December 31, 2007 or 2006.

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Research and Development Expenses

Research and development expenses were $14.6 million for the year ended December 31, 2007, an increase of $7.6 million, or 109%, from $7.0 million for the year ended December 31, 2006. The increase resulted primarily from the increase of $4.7 million in development expenses related to salaries for personnel involved in research and development and $1.3 million in related subcontractors and consultants expenses. The increase in research and development expenses included the recognition of grants equal to $1.1 million from the OCS during 2007, a decrease of approximately $700,000 compared to the recognition of grants equal to $1.8 million during 2006.

We expect research and development expenses to continue to increase as we enter into a more advanced stage of clinical trials for our product candidates, especially with respect to the anticipated continued progress in our phase III clinical trial for prGCD.

General and Administrative Expenses

General and administrative expenses were $20.6 million for the year ended December 31, 2007, an increase of $16.1 million, or approximately 355%, from $4.5 million for the year ended December 31, 2006. The increase resulted primarily from a $14 million increase in share-based compensation due to the application of SFAS 123R, resulting from additional stock option awards granted in 2007 and higher share price at the measurement dates for certain options held by nonemployees that vested during 2007.

Financial Expenses and Income

Financial income was $2.1 million for the year ended December 31, 2007, an increase of $1.7 million, compared to $344,000 for the year ended December 31, 2006. The increase resulted primarily from a higher balance of cash and cash equivalents during the latter period, primarily the result of the proceeds generated from our underwritten public offering in October 2007, which resulted in higher interest income.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since our inception. To date, we have funded our operations primarily with proceeds equal to $31.3 million from the sale of shares of our common stock and from sales of convertible preferred and ordinary shares of Protalix Ltd., and an additional $14.2 million in connection with the exercise of warrants issued in connection with the sale of such ordinary shares, through December 31, 2008. In addition, on October 25, 2007, we generated gross proceeds of $50 million in connection with an underwritten public offering of our common stock. We believe that the funds currently available to us as are sufficient to satisfy our capital needs for approximately the next 24 months.

The following table summarizes our past funding sources:

Security	Year	Number of Shares	Amount(1)
Ordinary Shares	1996-2000	18,801,527(2)	$ 1,100,000
Series A Convertible Preferred Shares	2001	11,635,090	$ 2,000,000
Series B Convertible Preferred Shares(3)	2004-2005	7,225,357	$ 4,500,000
Series C Convertible Preferred Shares(4)	2005	5,513,422	$ 7,700,000
Ordinary Shares(5)	2006	10,637,686	$16,000,000
Common Stock	2007	10,000,000	$50,000,000

(1) Gross proceeds; does not include proceeds from warrant exercises.

(2)

Includes the issuance of ordinary shares to founders.

(3) During 2005, 1,035,569 Series B Preferred Shares were converted on a 1:1 basis into Series C Preferred Shares for no additional consideration. Also, in connection with such funding, warrants to purchase 181,228 Series B Preferred Shares were issued for no additional consideration with an aggregate exercise price of $100,000. As of the closing date of the

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merger, 168,034 of such warrants were exercised for net proceeds equal to approximately $96,000 and 13,194 of such warrants were forfeited.

(4) In connection with such funding, warrants to purchase an additional 8,862,803 Series C Preferred Shares were granted to the investors for no additional consideration with a total exercise price equal to $9.0 million. As of the closing date of the merger, 5,296,279 of such warrants were exercised for net proceeds equal to $8.7 million, 3,384,502 were assumed by our company and 182,022 expired.

(5) In connection with such funding, warrants to purchase 3,875,416

ordinary shares were issued for no additional consideration with an aggregate exercise price equal to $5.3 million. These warrants were exercised in full on January 31, 2007.

Cash Flows

Net cash used in operations was $16.0 million for the year ended December 31, 2008. The net loss for 2008 of $22.4 million was mainly offset by non-cash charges for share-based compensation of $3.1 million, and depreciation of $1.3 million. Net cash used in investing activities for 2008 was $3.7 million and consisted primarily of purchases of property and equipment. Net cash used by financing activities for 2008 was approximately $51,000 due to certain fundraising costs incurred in 2008 in connection with the offering of 2007.

Net cash used in operations was $10.4 million for the year ended December 31, 2007. The net loss for 2007 of $32.0 million was mainly offset by non-cash charges for share-based compensation of $20.4 million, an increase in accounts payable of $0.9 million and depreciation of $759,000. Net cash used in investing activities for 2007 was $2.4 million and consisted primarily of purchases of property and equipment. Net cash provided by financing activities for 2007 was $58.6 million, consisting mainly of net proceeds of $45.7 million from the public underwritten offering and $12.9 million from the exercise of warrants.

Future Funding Requirements

We expect to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to the hiring of personnel and the advancement of our additional pipeline of product candidate into the various clinical trials. We expect that general and administrative expenses will also increase as we expand our finance and administrative staff, add infrastructure, and incur additional costs related to the preparation of the Company to its commercial phase for its lead product candidate, prGCD. In addition, we are considering a new manufacturing facility that would meet the FDA requirements for the manufacture of our product candidates, which would increase our capital expenditures significantly, the first phase of which has commenced in January 2009 and estimated to cost approximately $5 million.

We believe that our existing cash and cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for approximately the next 24 months. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many factors, including the progress and results of our clinical trials, costs of commercialization activities, including product marketing, sales and distribution and whether these efforts will be performed internally or through some form of collaboration with third parties, the duration and cost of discovery and preclinical development, and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights and the number and development requirements of other product candidates that we pursue.

We will need to finance our future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. We currently do not have any commitments for future external funding. We

may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. The sale of additional equity or debt securities will likely result in dilution to our shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our

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planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Effects of Inflation and Currency Fluctuations

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the years ended December 31, 2006, 2007 or 2008. Currency fluctuations could affect us by increased or decreased costs mainly for goods and services acquired outside of Israel. We do not believe currency fluctuations have had a material effect on our results of operations during the years ended December 31, 2006, 2007 or 2008.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2007 and 2008. See Note 4 of the consolidated financial statements for a full description of certain contingent royalty payments.

Recently Issued Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board, or the FASB, issued Statement of Financial Accounting Standards No. 141 (revised 2007), Business Combinations, or SFAS 141(R). SFAS 141(R) changes the accounting for business combinations, including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer s income tax valuation allowance and income tax uncertainties. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Early application is prohibited. We have adopted SFAS 141(R) as of January 1, 2009.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 160, Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51, or SFAS 160. SFAS 160 amends ARB 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Ownership interests in subsidiaries held by parties other than its parent company are required to be presented in the consolidated statement of financial position within equity, but separate from the parent company s equity. SFAS 160 requires that changes in a parent company s ownership interest while the parent company retains its controlling financial interest in its subsidiary should be accounted for in a manner similar to the accounting treatment of equity transactions. When a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary should be initially measured at fair value, with any gain or loss recognized in earnings.

SFAS 160 requires consolidated net income to be reported in amounts that include the amounts attributable to both the parent company and the noncontrolling interest. It also requires disclosure, on the face of the consolidated income statement, of the amounts of consolidated net income attributable to both parent companies and the noncontrolling interests.

SFAS 160 is effective for fiscal years (including interim periods within those fiscal years) beginning on or after December 15, 2008. Earlier adoption is prohibited. SFAS 160 is required to be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirement which shall be applied retrospectively for all periods presented. We have adopted SFAS 160 as of January 1, 2009. We are currently assessing the impact that SFAS 160 may have on our results of operations and financial position.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133, or SFAS 161, which requires additional disclosures about the objectives of using derivative instruments; the method by which the derivative instruments and related hedged items are accounted for under FASB Statement No.133 and its related interpretations; and the effect of derivative instruments and related hedged items on financial position, financial performance and cash flows. SFAS 161 also requires disclosure of the fair values of derivative instruments and their gains and losses in a tabular format. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early adoption encouraged. We will be required to adopt SFAS 161 as of January 1, 2009. SFAS 161 will not impact the consolidated financial results as it is disclosure-only in nature.

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In March 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles, or SFAS 162, which identifies a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with U.S. generally accepted accounting principles for nongovernmental entities. The hierarchy of SFAS 162 is consistent with that previously defined in the AICPA Statement on Auditing Standards No. 69, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. SFAS 162 is effective 60 days following the Commission s approval of the Public Company Accounting Oversight Board amendments to U. S. Auditing Standards Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. We do not believe the adoption of this pronouncement will have a material impact our results of operations, financial position or cash flows.

In December 2007, the FASB ratified EITF Issue No. 07-01, Accounting for Collaborative Arrangements, or EITF 07-01. EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-01 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-01 is effective for fiscal years beginning after December 15, 2008 (January 1, 2009, for our company). Companies are required to apply EITF 07-01 using a modified version of retrospective transition for those arrangements in place at the effective date. In addition, companies are required to report the effects of the application of EITF 07-01 as a change in accounting principle through retrospective application to all prior periods presented for all arrangements existing as of the effective date, unless it is impracticable to apply the effects of the change retrospectively. We are currently assessing the impact that EITF 07-01 may have on our results of operations and financial position.

Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2008:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$ 4,308	$ 923	$ 1,850	$ 1,535	
Purchase obligations (1)	$ 5,830	$ 5,830			
Certain Clinical contract obligations	$ 2,556	$ 2,045	511		
Other long term liabilities reflected on the balance sheet under GAAP	$ 937				$ 937
Total	$ 13,631	$ 8,798	$ 2,361	$ 1,535	$ 937

(1) Represents open purchase orders issued to certain suppliers and other vendors mainly in connection with certain improvements to our manufacturing facility, that were outstanding as of December 31,

2008.

Selected Quarterly Financial Data (unaudited)

	Three Months Ended On							
	2007 (1) (restated)				2008			
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31
Net loss	$8,549	$9,014	$11,820	$2,701	$5,113	$4,229	$6,496	$6,576
Net loss per share of common stock, basic and diluted	$ 0.13	$ 0.14	$ 0.18	$ 0.04	$ 0.07	$ 0.06	$ 0.09	$ 0.09

(1) Our selected quarterly data includes restated financial data that was restated to change the accounting treatment of certain stock-based compensation of non-employees required by SFAS 123(R), *Share-Based Payment*, for certain transactions with nonemployees.

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Quarterly Effects of the Restatement

	Three Months Ended On							
	March 31, 2007		June 30, 2007		Sept. 30, 2007		Dec. 31, 2007	
	As previously reported	As restated	As previously reported	As restated	As previously reported	As restated	As previously reported	As restated
Research and development	1,794	2,488			3,445	3,460		
General and administrative	1,987	6,392	6,503	6,363	1,986	9,045	1,224	(1,206)
Net loss	3,450	8,549	9,154	9,014	4,746	11,820	5,131	2,701
Net loss per share of common stock, basic and diluted	0.05	0.13	0.14	0.14	0.07	0.18	0.07	0.04

We have restated our consolidated financial statements at December 31, 2007 to change the accounting treatment of certain stock-based compensation of non-employees required by SFAS 123(R), *Share-Based Payment*, for certain transactions with nonemployees. As a result of the restatement, in each of the first and third quarter of 2007, our net research and development expenses increased by $694,000 and $15,000, respectively, and our general and administrative expenses increased by $4.4 million and $7.1 million, respectively. The increases resulted from the higher value attributed to the shares of our common stock underlying such stock-based compensation for the applicable measurement dates during the first and third quarters of 2007. In each of the second and fourth quarter of 2007, our general and administrative expenses decreased by $140,000 and $2.4 million, respectively. The decreases resulted from the remeasurement of certain stock-based compensation of non-employees that were measured, on an interim basis, for the first quarter of 2007. Under applicable accounting guidance, we are required to remeasure the entire cumulative vesting expense of certain stock-based compensation of non-employees for each accounting period according to the fair market value of such compensation at the end of the applicable accounting period. See Note 2 to the consolidated financial statements for further information.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Currency Exchange Risk

The currency of the primary economic environment in which our operations are conducted is the dollar. We are currently in the development stage with no significant source of revenues; therefore we consider the currency of the primary economic environment to be the currency in which we expend cash. Approximately 50% of our expenses and capital expenditures are incurred in dollars, and a significant source of our financing has been provided in U.S. dollars. Since the dollar is the functional currency, monetary items maintained in currencies other than the dollar are remeasured using the rate of exchange in effect at the balance sheet dates and non-monetary items are remeasured at historical exchange rates. Revenue and expense items are remeasured at the average rate of exchange in effect during the period in which they occur. Foreign currency translation gains or losses are recognized in the statement of operations.

Approximately 35% of our costs, including salaries, expenses and office expenses, are incurred in New Israeli Shekels, the NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A revaluation of 1% of the NIS will affect our income before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Year Ended December 31,		
	2006	**2007**	**2008**
Average rate for period	4.4565	4.1081	3.5878
Rate at year-end	4.2250	3.8460	3.8020

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 due to the impact of inflation in Israel.

Interest Rate Risk

Our exposure to market risk is confined to our cash and cash equivalents. We consider all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase, that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents. The

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primary objective of our investment activities is to preserve principal while maximizing the interest income we receive from our investments, without increasing risk. We invest any cash balances primarily in bank deposits and investment grade interest-bearing instruments. We are exposed to market risks resulting from changes in interest rates. We do not use derivative financial instruments to limit exposure to interest rate risk. Our interest gains may decline in the future as a result of changes in the financial markets.

Item 8. Financial Statements and Supplementary Data

See the Index to Consolidated Financial Statements on Page F-1 attached hereto.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-K. The controls evaluation was conducted under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the Commission s rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

The evaluation of our disclosure controls and procedures included a review of the controls objectives and design, our implementation of the controls and their effect on the information generated for use in this Form 10-K. In the course of the controls evaluation, we reviewed identified data errors, control problems or acts of fraud, and sought to confirm that appropriate corrective actions, including process improvements, were being undertaken. This type of evaluation will be performed on a quarterly basis so that the conclusions of management, including the Chief Executive Officer and Chief Financial Officer, concerning the effectiveness of the disclosure controls and procedures can be reported in our periodic reports on Form 10-Q and Form 10-K. The overall goals of these various evaluation activities are to monitor our disclosure controls and procedures, and to modify them as necessary. Our intent is to maintain the disclosure controls and procedures as dynamic systems that change as conditions warrant.

Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Form 10-K, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the Commission, and that material information related to our company and our consolidated subsidiary is made known to management, including the Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

In connection with the restatement, our management has assessed the effectiveness of our disclosure controls and procedures, and our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2007 and the date of this filing. We believe that, as a result of management s in-depth review of its accounting processes, especially as those processes relate to the application of SFAS 123R and the utilization of external resources, there are no material inaccuracies or omissions of material fact in this Form 10-K and we believe that the consolidated financial statements included in this Form 10-K fairly present in all material respects the financial condition, results of operations and cash flows of our company in conformity with United States generally accepted accounting principles.

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Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of management and our directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Management assessed our internal control over financial reporting as of December 31, 2008, the end of our fiscal year. Management based its assessment on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management s assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies and our overall control environment.

Based on our assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles. We reviewed the results of management s assessment with the Audit Committee of our Board of Directors.

Our independent registered public accounting firm, Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited (PwC), has audited our internal control over financial reporting, and issued an unqualified opinion dated March 6, 2009 on our internal control over financial reporting, which opinion is included in this Annual Report on Form 10-K.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Controls

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the period ended December 31, 2008 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Management Consideration of Restatement

On February 23, 2009, our management concluded, with the concurrence of the Audit Committee of our Board of Directors to amend and restate our financial statements for the year ended December 31, 2007, and the first three fiscal quarters of 2007 to change the accounting treatment of certain stock-based compensation of non-employees

required by SFAS 123R for certain transactions with nonemployees. The change in accounting treatment affected our consolidated balance sheet at December 31, 2007, statements of operations, changes in shareholders equity and cash flows for the year ended December 31, 2007, the quarters ended March 31, 2007 and September 30, 2007 and for the period from December 27, 1993 through September 30, 2008. As a result of the effect of the change in accounting treatment on our consolidated financial statements, we have restated our previously issued condensed consolidated financial statements for the year ended December 31, 2007 in this Annual Report on Form 10-K and for each of the first three fiscal quarters of 2008.

In coming to the conclusion that our disclosure controls and procedures and our internal controls over financial reporting were effective as of December 31, 2008, our management considered, among other things, its decision to restate our financial statements in connection with its calculation of stock-based compensation awards. Our Chief Executive Officer and Chief Financial Officer determined that they needed to change the accounting treatment. However, the need to restate our previously issued financial statements did not constitute a material weakness as of December 31, 2008. They have determined that, as of December 31, 2008, there were controls designed and in place to prevent or detect a material misstatement and therefore, there was no reasonable possibility that the computation of stock-based compensation awards will be materially misstated.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

Our directors and executive officers, their ages and positions as of March 1, 2009, are as follows:

Name	Age	Position
Directors		
Eli Hurvitz	76	Chairman of the Board
David Aviezer, Ph.D., MBA	44	Director, President and Chief Executive Officer
Yoseph Shaaltiel, Ph.D.	55	Director and Executive VP, Research and Development
Alfred Akirov	65	Director
Amos Bar-Shalev (1)(2)(3)	56	Director
Zeev Bronfeld	57	Director
Yodfat Harel Gross (2)(3)	36	Director
Roger D. Kornberg, Ph.D.	61	Director
Eyal Sheratzky (1)(3)	40	Director
Sharon Toussia-Cohen (1)(2)	49	Director
Executive Officers		
Einat Brill Almon, Ph.D.	49	Vice President, Product Development
Yossi Maimon, CPA	38	Vice President, Chief Financial Officer, Treasurer and Secretary

(1) Member of Nominating Committee

(2) Member of Audit Committee

(3) Member of Compensation Committee

Eli Hurvitz. Mr. Hurvitz serves as Chairman of our Board of Directors and has served as a director of Protalix Ltd. since 2005 and as our director since December 31, 2006. Mr. Hurvitz has served as Chairman of the Board of Teva since April 2002. Previously, he served as Teva s President and Chief Executive Officer for over 25 years and has been employed at Teva in various capacities for over 40 years. He serves as Chairman of the Board of The Israel Democracy Institute (IDI), Chairman of the Board of NeuroSurvival Technologies Ltd. (a private company) and a director of Vishay Intertechnology. He served as Chairman of the Israel Export Institute from 1974 through 1977 and as the President of the Israel Manufacturers Association from 1981 through 1986. He served as Chairman of the Board of Bank Leumi Ltd. from 1986 through 1987. He was a director of Koor Industries Ltd. from 1997 through 2004 and a member of the Belfer Center for Science and International Affairs at the John F. Kennedy School of Government at Harvard University from 2002 through 2005. He received his B.A. in Economics and Business Administration from the Hebrew University of Jerusalem in 1957.

David Aviezer, Ph.D., MBA. Dr. Aviezer has served as Chief Executive Officer of Protalix Ltd. since 2002 and its director since 2005 and as our director since December 31, 2006. On December 31, 2006, he became our President and Chief Executive Officer. Dr. Aviezer has over a decade of experience in biotechnology management, advancing products from early-stage research up to their regulatory approval and commercialization. Prior to joining Protalix Ltd., from 1996 to 2002, he served as General Manager of ProChon Biotech Ltd., an Israeli company focused on orthopedic disorders. Previously, Dr. Aviezer was a visiting scientist at the Medical Research Division of American

Cyanamid, a subsidiary of Wyeth (NYSE:WEY), in New York. Since 1996, Dr. Aviezer has served as an Adjunct Lecturer at Bar Ian University. Dr. Aviezer is the recipient of the Clore Foundation Award and the J.F. Kennedy Scientific Award. He holds a Ph.D. in Molecular Biology and Biochemistry from the Weizmann Institute of Science and an M.B.A. from the Bar Ilan University Business School.

Yoseph Shaaltiel, Ph.D. Dr. Shaaltiel founded Protalix Ltd. in 1993 and has served as a member of our Board of Directors and as our Vice President, Research and Development since December 31, 2006. Prior to establishing Protalix Ltd., from 1988 to 1993, Dr. Shaaltiel was a Research Associate at the MIGAL Technological Center. He also served as Deputy Head of the Biology Department of the Biological and Chemical Center of the Israeli Defense Forces and as a Biochemist at Makor Chemicals Ltd. Dr. Shaaltiel was a Postdoctoral Fellow at the University of California at Berkeley and at Rutgers University in New Jersey. He has co-authored over 40 articles and abstracts on plant biochemistry and holds seven patents. Dr. Shaaltiel received his Ph.D. in Plant Biochemistry from the Weizmann Institute of Science, an M.Sc. in Biochemistry from the Hebrew University and a B.Sc. in Biology from the Ben Gurion University.

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Alfred Akirov. Mr. Akirov has served as our director since January 2008. Mr. Akirov is the founder, chairman of the Board of Directors and chief executive officer of the Alrov Group (TASE: ALRO), an Israeli publicly-traded company that is listed on the Tel Aviv Stock Exchange. Mr. Akirov founded the Alrov Group in 1978 and it is currently one of Israel s largest real-estate companies. The Alrov Group holds 80% of the capital stock of Techno-Rov Holdings (1993) Ltd., one of our shareholders. Mr. Akirov serves in different capacities, including chairman, chief executive officer and director, for a number of private companies in the Alrov Group and Techno-Rov portfolios. Mr. Akirov serves on the Executive Council and the Board of Governors of the Tel Aviv University.

Amos Bar-Shalev. Mr. Bar-Shalev has served as our director since July 2008. Mr. Bar-Shalev served as a director of Protalix Ltd. from 2005 through January 31, 2008, and as our director from December 31, 2006 through January 31, 2008. Mr. Bar Shalev was not nominated for reelection at our annual meeting of shareholders on January 31, 2008. On July 14, 2008, our board of directors appointed Mr. Bar-Shalev to our board of directors. Mr. Bar Shalev brings to us extensive experience in managing technology companies. Currently, Mr. Bar-Shalev manages the Technorov portfolio. Until 2004, he was the Managing Director of TDA Capital Partners, a management company of the TGF (Templeton Tadiran) Fund. Prior to that, from 2004 through 2007, he was the President of Win Buyer Ltd. From 2000 through 2007, Mr. Bar-Shalev served the Director of Technorov Holdings (1993) Ltd. and from 2004 through 2007 he served as the Director of Golden Wings Investment Company Ltd. He has served on the board of directors of many companies, such as Golden Wings Investment Company Ltd., Win Buyer Ltd. and Sun Light. He received his B.Sc. in Electrical Engineering from the Technion, Israel in 1978 and M.B.A. from the Tel Aviv University in 1981. He holds the highest award from the Israeli Air Force for technological achievements.

Zeev Bronfeld. Mr. Bronfeld has served as a director of Protalix Ltd. since 1996 and as our director since December 31, 2006. Mr. Bronfeld brings to us vast experience in management and value building of biotechnology companies. Mr. Bronfeld is an experienced businessman who is involved in a number of biotechnology companies. He is a co-founder of Biocell Ltd., an Israeli publicly traded holding company specializing in biotechnology companies and has served as its Chief Executive Officer since 1986. Mr. Bronfeld currently serves as a director of Biocell Ltd., D. Medical Industries Ltd., and Biomedix Incubator Ltd., all of which are public companies traded on the Tel Aviv Stock Exchange. Mr. Bronfeld is also a director of each of the following privately-held companies: Meitav Technological Incubator Ltd., Ecocycle Israel Ltd., Contipi Ltd., Nilimedix Ltd., G-Sense Ltd., Sindolor Medical Ltd., L.N. Innovative Technologies, A.T.I Ashkelon Industries Information Technologies Ltd., T.I.F. Ventures Ltd., MOFET B Yehuda Industrial Research & Development in Judea Ltd., Incubator for Management of Technological Entrepreneurship Misgav Ltd., A.Y.M.B. Holdings and Investments Ltd., Macrocure Ltd., Medx-set Ltd., Braintact Ltd., Active P Ltd., and Angio B Ltd. Mr. Bronfeld received a B.A. in Economics from the Hebrew University in 1975.

Yodfat Harel Gross. Ms. Harel Gross has served as our director since June 2007. Since 2006, Ms. Harel Gross has been a Managing Director of Tamares Capital Ltd., a private investment group with interests in real estate, technology, manufacturing, leisure and media. At Tamares Capital, Ms. Harel Gross serves as the Business Development Director and the head of the Israel office. Prior to joining Tamares Capital, from 2004 to 2006, she was the Head of the Medical Desk of Orbotech, Ltd., a company providing high-tech inspection and imaging solutions for bare printed circuit board (PCB), flat panel display (FPD) and PCB assembly manufacturing worldwide. Prior to that, from 1994 to 2003, she was a Managing Director of Harel-Hertz Investment House Ltd., a business investment company with offices in Tel Aviv, Israel and Tokyo, Japan. In 2002, Harel-Hertz Investment House became the Israeli representative office for ITX Corporation, a publicly-traded company in Japan. Ms. Harel Gross currently serves on the board of directors of Tamares Capital, Tamares Hotels, Tamares Real Estate, Storewiz and Halman-Aldubi Provident Funds, Ltd. Ms. Harel Gross holds a B.A. in Communication and Political Science from Bar Ilan University and an executive M.B.A. from Bradford University, Great Britain. She has also completed programs in Directors Studies and Advanced Advertising and Marketing at the Israel Management Center.

Roger D. Kornberg, Ph.D. Professor Kornberg has served as our director since February 2008. He has served as a director of Teva since 2007. Professor Kornberg is a member of the U.S. National Academy of Sciences and the Winzer Professor of Medicine in the Department of Structural Biology at Stanford University, Stanford, California. He has been a member of the faculty of Stanford University since 1972. Prior to that, he was a professor at Harvard

Medical School. In 2006, Professor Kornberg was awarded the Nobel Prize in Chemistry in recognition for his studies of the molecular basis of eukaryotic transcription, the process by which DNA is copied to RNA. Professor Kornberg is also the recipient of several awards, including the 2001 Welch Prize, the highest award granted in the field of chemistry in the United States, and the 2002 Leopold Mayer Prize, the highest award granted in the field of biomedical sciences from the French Academy of Sciences. He received his B.S. in Chemistry from Harvard University in 1967 and his Ph.D. in Chemistry from Stanford University in 1972. He holds honorary degrees from universities in Europe and Israel, including the Hebrew University in Jerusalem, where he currently is a visiting professor.

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Eyal Sheratzky. Mr. Sheratzky has served as a director of Protalix Ltd. since 2005 and as our director since December 31, 2006. Mr. Sheratzky has served as a director of Ituran Location & Control, a publicly-traded company quoted on the Nasdaq, since 1995 and as a Co-Chief Executive Officer since 2003. Prior to such date, he served as an alternate Chief Executive Officer of Ituran from 2002 through 2003 and as Vice President of Business Development from 1999 through 2002. Mr. Sheratzky is the Chairman of the Board of Directors of Biocell and serves as a director of Moked Ituran Ltd. and of Ituran s subsidiaries. From 1994 to 1999 he served as the Chief Executive Officer of Moked Services, Information and Investments Ltd. and as legal advisor to several of Ituran s affiliated companies. Mr. Sheratzky holds LL.B and LL.M degrees from Tel Aviv University School of Law and an Executive M.B.A. degree from Kellogg University.

Sharon Toussia-Cohen. Mr. Toussia-Cohen has served as a director of Protalix Ltd. since 2004 and as our director since December 31, 2006. Mr. Toussia-Cohen is the President, Chief Executive Officer and a director of Marathon Investments, an Israeli publicly-traded company since 2004. During the period from 1996 to 2002, he served as the Chief Executive Officer of the Aleppo Group and also as Managing Director of Israel s Airport City Project. From the years 2002 through 2004, Mr. Toussia-Cohen was a partner and Managing Director of the Tiv Taam Group and from the years 2004 through 2006 he was the Chief Executive Officer and a director of ISRI Investments Ltd. Mr. Toussia-Cohen currently serves on the Board of Directors of Bioview, an Israeli company traded on the Tel Aviv Stock Exchange, and several privately-held companies including Nanomotion, Margan Business Development Ltd., Pegasus, Chromat Ltd., and Yeulit. Mr. Toussia-Cohen is certified in Bank Management by the First International Bank of Israel and the Republic National Bank of New York. He was also the co-owner and director of a strategic consulting firm in Israel. Mr. Toussia-Cohen holds a Bachelor s degree in Economics and Political Science and an M.B.A. from the Hebrew University.

Einat Brill Almon, Ph.D. Dr. Almon joined Protalix Ltd. in December 2004 as its Vice President, Product Development and became our Vice President, Product Development on December 31, 2006. Dr. Almon has many years of experience in the management of life science projects and companies, including biotechnology and agrobiotech, with direct experience in clinical, device and scientific software development, as well as a strong background and work experience in Intellectual Property. Prior to joining Protalix Ltd., from 2001 to 2004, she served as Director of R&D and IP of Biogenics Ltd., a company that developed an autologous platform for tissue based protein drug delivery. Biogenics, based in Israel, is a wholly-owned subsidiary of Medgenics Inc. Dr. Almon has trained as a biotechnology patent agent at leading IP firms in Israel. Dr. Almon holds a Ph.D. and an M.Sc. in molecular biology of cancer research from the Weizmann Institute of Science, a B.Sc. from the Hebrew University and has carried out Post-Doctoral research at the Hebrew University in the area of plant molecular biology.

Yossi Maimon, CPA. Mr. Maimon joined Protalix Ltd. on October 15, 2006 as its Chief Financial Officer and became our Vice President and Chief Financial Officer on December 31, 2006. Prior to joining Protalix, from 2002 to 2006, he served as the Chief Financial Officer of Colbar LifeScience Ltd., a biomaterial company focusing on aesthetics, where he led all of the corporate finance activities, fund raisings and legal aspects of Colbar including the sale of Colbar to Johnson and Johnson. Mr. Maimon has a B.A. in accounting from the City University of New York and an M.B.A. from Tel Aviv University, and he is a Certified Public Accountant in the United States (New York State) and Israel.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the Commission reports regarding their ownership and changes in ownership of our equity securities. Dr. Aviezer, Dr. Shaaltiel, Dr. Almon and Mr. Maimon each filed a late Form 4 in connection with the grant of options in February 2008. Each of Mr. Bar-Shalev, Mr. Akirov and Dr. Kornberg filed late Forms 3 in connection with their becoming directors of our company in 2008. Last, Dr. Kornberg filed a late Form 4 in connection with the options granted to him in 2008. Otherwise, we believe that all Section 16 filings requirements were met during 2007. In making this statement, we have relied solely upon examination of the copies of Forms 3, 4 and 5 provided to us and the written representations of our former and current directors, officers and 10% shareholders.

Audit Committee

We require that all Audit Committee members possess the required level of financial literacy and at least one member of the Committee meet the current standard of requisite financial management expertise as required by the NYSE Alternext US and applicable Commission rules and regulations. Messrs. Bar-Shalev and Toussia-Cohen and Ms. Harel Gross have been appointed by the Board of Directors to serve on the Audit Committee.

Our Audit Committee operates under a formal charter that governs its duties and conduct.

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All members of the Audit Committee are independent from our executive officers and management.
Our independent registered public accounting firm reports directly to the Audit Committee.
Our Audit Committee meets with management and representatives of our registered public accounting firm prior to the filing of officers certifications with the Commission to receive information concerning, among other things, effectiveness of the design or operation of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002.
Our Audit Committee has adopted a Policy for Reporting Questionable Accounting and Auditing Practices and Policy Prohibiting Retaliation against Reporting employees to enable confidential and anonymous reporting of improper activities to the Audit Committee.
Messrs. Bar-Shalev and Toussia-Cohen qualify as financial experts under the applicable rules of the Commission. In making the determination as to these individuals status as financial experts, our Board of Directors determined they have accounting and related financial management expertise within the meaning of the aforementioned rules, as well as the listing standards of the NYSE Alternext US.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that includes provisions ranging from restrictions on gifts to conflicts of interest. All of our employees and directors are bound by this Code of Business Conduct and Ethics. Violations of our Code of Business Conduct and Ethics may be reported to the Audit Committee.
The Code of Business Conduct and Ethics includes provisions applicable to all of our employees, including senior financial officers and members of our Board of Directors and is posted on our website (www.protalix.com). We intend to post amendments to or waivers from any such Code of Business Conduct and Ethics.

Item 11. Executive Compensation

Compensation Discussion and Analysis

The primary goals of the Compensation Committee of our Board of Directors with respect to executive compensation are to attract and retain the most talented and dedicated executives possible, to tie annual and long-term cash and stock incentives to achievement of specified performance objectives, and to align executives incentives with shareholder value creation. To achieve these goals, the Compensation Committee intends to implement and maintain compensation plans that tie a portion of executives overall compensation to key strategic goals such as developments in our clinical path, the establishment of key strategic collaborations, the build-up of our pipeline and the strengthening of our financial position. The Compensation Committee evaluates individual executive performance with a goal of setting compensation at levels the committee believes are comparable with executives in other companies of similar size and stage of development operating in the biotechnology industry while taking into account our relative performance and our own strategic goals.

Elements of Compensation

Executive compensation consists of following elements:

Base Salary. Base salaries for our executives are established based on the scope of their responsibilities taking into account competitive market compensation paid by other companies for similar positions. Generally, we believe that executive base salaries should be targeted near the median of the range of salaries for executives in similar positions with similar responsibilities at comparable companies. Base salaries are usually reviewed annually, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. The review for 2008 took place in February 2009. The base salaries of our executive officers are set forth in Employment Arrangements.

In February 2009, our Board of Directors, acting upon the resolution of a majority of our independent directors, resolved to maintain for 2009 the monthly salaries of our Chief Executive Officer, our Executive Vice President, Research and Development, our Vice President, Product Development, and our Vice President and Chief Financial Officer, at the same level of 2008.

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Annual Bonus. The Compensation Committee has the authority to award discretionary annual bonuses to our executive officers. It has not established a formal bonus plan. These awards are intended to compensate officers for achieving financial, clinical and operational goals and for achieving individual annual performance objectives. These objectives vary depending on the individual executive, but relate generally to strategic factors such as developments in our clinical path, the establishment of key strategic collaborations, the build-up of our pipeline and to financial factors such as raising capital.

For each year, the Compensation Committee will select, in its discretion, the executive officers of our company or our subsidiary who are eligible to receive bonuses. Any bonus granted by the Compensation Committee will generally be paid in the first quarter following completion of a given year. Similar to bonuses paid in the past, the actual amount of discretionary bonus will be determined following a review of each executive s individual performance and contribution to our goals. The Compensation Committee has not fixed a minimum or maximum payout for any officer s annual discretionary bonus, unless specified in an executive s employment agreement.

Pursuant to each officer s employment agreement, the executive officer is eligible for a discretionary annual bonus. The Compensation Committee determines the discretionary annual bonus to be paid to our executive officers, and the discretionary bonus to be awarded to certain officers in 2008 for performance in 2008. The actual amount of the discretionary bonus to be paid to each executive officer is determined following a review of the executive s individual performance and contribution to our strategic goals conducted during the first quarter of each fiscal year. The Compensation Committee has not fixed a minimum or a maximum amount for any officer s annual discretionary bonus.

In February 2009, our Board of Directors, acting upon the resolution of a majority of our independent directors, awarded approximately $29,000 to our Vice President, Product Development for her performance during the year 2008. It was further agreed that discussion regarding all other Named Executives bonuses for their performances during the year 2008 will be deferred to January 2010.

Options. Our 2006 Stock Option Plan authorizes us to grant options to purchase shares of common stock to our employees, directors and consultants. Our Compensation Committee is the administrator of the stock option plan. Stock option grants are generally made at the commencement of employment and following a significant change in job responsibilities or to meet other special retention or performance objectives. The Compensation Committee reviews and approves stock option awards to executive officers based upon a review of competitive compensation data, its assessment of individual performance, a review of each executive s existing long-term incentives, and retention considerations. The exercise price of stock options granted under the 2006 Stock Incentive Plan must be equal to at least 100% of the fair market value of our common stock on the date of grant; however, in certain circumstances, grants may be made at a lower price to Israeli grantees who are residents of the State of Israel.

In February 2009, our Board of Directors, acting upon the resolution of a majority of our independent directors, granted stock options to our Chief Executive Officer, our Executive Vice President, Research and Development, our Vice President, Product Development, and our Vice President and Chief Financial Officer. The number of shares of common stock underlying the option grants was 100,000, 50,000, 50,000 and 50,000, respectively. The options have an exercise price of $2.65 per share and are vested immediately upon the achievement of certain milestones. The grants of stock options to such officers were in recognition their ongoing efforts in achieving our milestones regarding clinical developments, research and development, financial developments and other factors during 2008, and partially as compensation for the lack of annual bonuses or increase in base salary during 2008.

Severance and Change in Control Benefits. Pursuant to the employments agreements entered into with each of our executive officers, the executive officer is entitled to be insured by Protalix Ltd. under a Manager s Policy in lieu of severance. The intention of such Manager s Policies is to provide the officers with severance protection of one month s salary for each year of employment. In addition, the stock option agreements provide for the acceleration of the vesting periods of options in the event of a termination without cause following a change in control of our company. In addition, stock option agreements with each of our named executive officers, as amended, provide that all of the outstanding options of each named executive officer are subject to accelerated vesting immediately upon a change in control of our company.

Other Compensation. Consistent with our compensation philosophy, we intend to continue to maintain our current benefits for our executive officers; however, the Compensation Committee in its discretion may revise, amend, or add to the officer s executive benefits if it deems it advisable. As an additional benefit to all of our Named Executive Officers and for most of our employees, we generally contribute to certain funds amounts equaling a total of approximately 15% of their gross salaries for certain pension and other savings plans for the benefit of the Named Executive Officers. However, the Compensation Committee determined to reduce our contributions in 2009 for the benefit of each respective Named Executive Officer to such pension and other savings plans by approximately 50% due to the economic conditions in Israel and

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worldwide. In addition, in accordance with customary practice in Israel, our executives agreements require us to contribute towards their vocational studies, and to provide annual recreational allowances, a company car and a company phone. We believe these benefits are currently equivalent with median competitive levels for comparable companies.

Executive Compensation. We refer to the Summary Compensation Table set forth in Section 11 below for information regarding the compensation earned during the fiscal year ended December 31, 2008 by our Chief Executive Officer, our Executive Vice President, Research and Development, our Vice President, Product Development, Vice President and Chief Financial Officer and our Vice President of Operations. There are no other executive officers for 2008 whose total compensation exceeded $100,000 during that fiscal year other than those set forth below. We refer to our Chief Executive Officer, our Executive Vice President, Research and Development, our Vice President, Product Development and Vice President and Chief Financial Officer as our Named Executive Officers.

Compensation Committee Report

The above report of the Compensation Committee does not constitute soliciting material and shall not be deemed filed or incorporated by reference into any other filing by us under the Securities Act of 1933 or the Securities Exchange Act of 1934.

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis set forth below with our management. Based on this review and discussion, the Compensation Committee has recommended to our Board of Directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K and our annual proxy statement on Schedule 14A.

Respectfully submitted on February 26, 2009, by the members of the Compensation Committee of the Board of Directors.

Yodfat Harel Gross
Eyal Sherazky
Amos Bar Shalev

Summary Compensation Table

The following table sets forth a summary for the fiscal years ended December 31, 2008 and 2007 respectively, of the cash and non-cash compensation awarded, paid or accrued by Protalix Ltd. to our Named Executive Officers. There were no restricted stock awards, long-term incentive plan payouts or other compensation paid during fiscal years 2008 and 2007 by Protalix Ltd. to the Named Executive Officers, except as set forth below. The Named Executive Officers are employees of our subsidiary, Protalix Ltd. All currency amounts are expressed in U.S. dollars.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Award(s) ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compen-sation ($)(1)	Total ($)
David Aviezer, Ph.D., MBA	2008	486,305			565,394			93,224	1,144,923
President and CEO	2007	341,074	239,210		351,343			67,990	999,617
Yoseph Shaaltiel, Ph.D.	2008	226,652			163,328			54,704	444,684
Executive Vice President	2007	177,297	50,000		2,420			47,339	277,056
Einat Brill Almon, Ph.D.	2008	195,559	28,932		253,862			51,223	529,576
VP, Product Development	2007	153,254	65,171		94,482			42,282	355,189
Yossi Maimon, CPA	2008	203,097	30,659		238,194			83,808	555,758
Chief Financial Officer	2007	156,444	77,223		247,815			41,975	523,457
Iftah Katz(2)	2008	131,524			1,323,587			35,215	1,490,326
Vice President of Operations	2007	114,087			2,254,567			36,117	2,404,771

(1) Includes employer contributions to pension and/or insurance plans and other miscellaneous payments.

(2) Iftah Katz joined our company as our Vice President of Operations on February 28, 2007 and terminated on May 6, 2008.

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The following table summarizes the grant of awards made to the Named Executive Officers during 2008 as of December 31, 2008.

GRANTS OF PLAN-BASED AWARDS

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units	All other Option Awards: Number of Securities Underlying Options	Exercise or Base Price of Option Awards	Grant Date fair Value of Stock and Option Awards
		Threshold($)	Target($)	Maximum($)	Threshold($)	Target($)	Maximum($)				
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
David Aviezer											
Yoseph Shaaltiel											
Einat Brill											
Almon Yossi Maimon											
Iftah Katz											

(1) Represents outstanding options at December 31, 2008.

(2) Represents the range of the exercise price of the stock options.

(3) Represents the fair value as recorded on the grant date of the stock options.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information with respect to the Named Executive Officers concerning equity awards as of December 31, 2008.

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	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
David Aviezer	807,858			0.120	8/1/2013				
	610,810	366,486		0.972	9/10/2016				
	66,668	533,332		5.00	2/7/2018				
Yoseph Shaaltiel	244,324			0.001	6/30/2011				
	29,304	234,424		5.00	2/7/2018				
Einat Brill Almon	251,593			0.399	5/23/2006				
	85,514	146,594		0.972	8/13/2016				
	34,584	276,688		5.00	2/7/2018				
Yossi Maimon	262,558	271,238		0.972	9/19/2016				
	19,444	155,556		5.00	2/7/2018				
Iftah Katz	76,631	127,720		4.33	5/30/2017				

Option exercises during 2008 and vested stock awards for Named Executive Officers as of December 31, 2008 were as follows:

OPTION EXERCISES AND STOCK VESTED

	Option Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Received on Exercise($)	Number of Shares Acquired on Vesting (#)	Value Received on Vesting($)

(a)	(b)	(c)	(d)	(e)
David Aviezer				
Yossi Maimon(1)	86,176			
Yoseph Shaaltiel				
Einat Brill				
Almon Iftah Katz	48,370			

(1) Options were exercised through net exercise with no value received by our company in connection with the exercise.

Potential Payments upon Termination or Change-in-Control

We do not provide any change in control benefits to our executive officers except that their stock option agreements, as amended, provide that all of the outstanding options of each named executive officer are subject to accelerated vesting immediately upon a change in control of our company.

Employment Arrangements

David Aviezer, Ph.D., MBA. Dr. Aviezer originally served as Protalix Ltd. s Chief Executive Officer on a consultancy basis pursuant to a Consulting Services Agreement between Protalix Ltd. and Agenda Biotechnology Ltd., a company wholly-owned by Dr. Aviezer. On September 11, 2006, Protalix Ltd. entered into an employment agreement with Dr. Aviezer pursuant to which he agreed to be employed as Protalix Ltd. s President and Chief Executive Officer, which agreement supersedes the Consultancy Services Agreement. Dr. Aviezer currently serves as our President and Chief Executive Officer. Dr. Aviezer s current monthly base salary is NIS 136,000 (approximately $32,870) and he is entitled to an annual bonus at the Board s discretion. The monthly salary is subject to cost of living adjustments from time to time. Dr. Aviezer is eligible to receive a substantial bonus in the event of certain public offerings or acquisition transactions, which bonus shall be at the discretion of the Board, and certain specified bonuses in the event Protalix achieves certain specified milestones. In connection with the employment agreement, in addition to other options already held by Dr. Aviezer granted

to Dr. Aviezer options to purchase 16,000 ordinary shares of Protalix Ltd. at an exercise price equal to $59.40 per share, which we assumed as options to purchase 977,297 shares of our common stock at $0.97 per share. Such options vest quarterly retroactively from June 1, 2006, over a four-year period. In addition, in 2008 we granted to Dr. Aviezer an option to purchase 600,000 shares of our common stock at an exercise price equal to $5.00 per share. The option vests variably over a five-year period that commenced on January 1, 2008. Dr. Aviezer s employment agreement is terminable by either party on 90 days written notice for any reason and we may terminate the agreement for cause without notice. Dr. Aviezer is entitled to be insured by Protalix Ltd. under a Manager s Policy in lieu of severance, company contributions towards vocational studies, annual recreational allowances, a company car and a company phone. Dr. Aviezer is entitled to 24 working days of vacation. All stock options that have not vested as of the date of termination shall be deemed to have expired.

Yoseph Shaaltiel, Ph.D. Dr. Shaaltiel founded Protalix Ltd. in 1993 and currently serves as our Executive Vice President, Research and Development. Dr. Shaaltiel entered into an employment agreement with Protalix Ltd. on September 1, 2001. Pursuant to the employment agreement, his current monthly base salary is NIS 60,500 (approximately $14,658) per month. The employment agreement is terminable by Protalix Ltd. on 90 days written notice for any reason and we may terminate the agreement for cause without notice. In 2008 we granted to Dr. Shaaltiel an option to purchase 263,728 shares of our common stock at an exercise price equal to $5.00 per share. The option vests variably over a five-year period that commenced on January 1, 2008. Dr. Shaaltiel is entitled to be insured by Protalix Ltd. under a Manager s Policy in lieu of severance, company contributions towards vocational studies, annual recreational allowances, a company car and a company phone. Dr. Shaaltiel is entitled to 24 working days of vacation.

Einat Brill Almon, Ph.D. Dr. Brill Almon joined Protalix Ltd. on December 19, 2004 as its Vice President, Product Development, pursuant to an employment agreement effective on December 19, 2004 by and between Protalix Ltd. and Dr. Brill Almon, and currently serves as our Senior Vice President, Product Development. Pursuant to the employment agreement, her current monthly base salary is NIS 55,000 per month (approximately $13,325). She is also entitled to certain specified bonuses in the event that Protalix achieves certain specified clinical development milestones within specified timelines. In connection with the employment agreement, Protalix agreed to grant to Dr. Brill Almon options to purchase 7,919 ordinary shares of Protalix Ltd. at exercise prices equal to $24.36 and $59.40 per share, which we assumed as options to purchase 483,701 shares of our common stock at $0.40 and $0.97 per share. The options vest over four years. In addition, in 2008 we granted to Dr. Almon an option to purchase 311,272 shares of our common stock at an exercise price equal to $5.00 per share. The option vests variably over a five-year period that commenced on January 1, 2008. The employment agreement is terminable by either party on 60 days written notice for any reason and we may terminate the agreement for cause without notice. Dr. Brill Almon is entitled to be insured by Protalix Ltd. under a Manager s Policy in lieu of severance, company contributions towards vocational studies, annual recreational allowances, a company car and a company phone at up to NIS 1,000 per month. Dr. Brill Almon is entitled to 22 working days of vacation. All stock options that have not vested as of the date of termination shall be deemed to have expired.

Yossi Maimon, CPA. Mr. Maimon joined Protalix Ltd. as its Chief Financial Officer pursuant to an employment agreement effective as of October 15, 2006 by and between Protalix Ltd. and Mr. Maimon and currently serves as our Chief Financial Officer. Pursuant to the employment agreement, his current monthly base salary is NIS 55,000 (approximately $13,325) and Mr. Maimon is entitled to an annual discretionary bonus and additional discretionary bonuses in the event Protalix achieves significant financial milestones, subject to the Board s sole discretion. The monthly salary is subject to cost of living adjustments from time to time. In connection with the employment agreement, Protalix agreed to grant to Mr. Maimon options to purchase 10,150 ordinary shares of Protalix Ltd. at an exercise price equal to $59.40 per share, which we assumed as options to purchase 619,972 shares of our common stock at $0.97 per share. The first 25% of such options shall vest on the first anniversary of the grant date and the remainder shall vest quarterly in 12 equal increments. In addition, in 2008 we granted to Mr. Maimon an option to purchase 175,000 shares of our common stock at an exercise price equal to $5.00 per share. The option vests variably over a five-year period that commenced on January 1, 2008. The employment agreement is terminable by either party on 60 days written notice for any reason and we may terminate the agreement for cause without notice. Mr. Maimon is

entitled to be insured by Protalix Ltd. under a Manager s Policy in lieu of severance, company contributions towards vocational studies, annual recreational allowances, a company car and a company phone. Mr. Maimon is entitled to 24 working days of vacation. All stock options that have not vested as of the date of termination shall be deemed to have expired.

2006 Stock Incentive Plan

Our Board of Directors and a majority of our stockholders approved our 2006 Stock Incentive Plan on December 14, 2006 and cancelled our 1998 stock option plan (no options were outstanding under the 1998 plan at that time). We have reserved 9,741,655 shares of our common stock for issuance, in the aggregate, under the 2006 Stock Incentive Plan, subject to

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adjustment for a stock split or any future stock dividend or other similar change in our common stock or our capital structure. As of February 1, 2009, options to acquire 2,056,623 shares of common stock remain available to be granted under our 2006 Stock Incentive Plan.

Our 2006 Stock Incentive Plan provides for the grant of stock options, restricted stock, restricted stock units, stock appreciation rights and dividend equivalent rights, collectively referred to as awards. Stock options granted under the 2006 Stock Incentive Plan may be either incentive stock options under the provisions of Section 422 of the Internal Revenue Code, or non-qualified stock options. Incentive stock options may be granted only to employees. Awards other than incentive stock options may be granted to employees, directors and consultants. The 2006 Stock Incentive Plan is also in compliance with the provisions of the Israeli Income Tax Ordinance New Version, 1961 (including as amended pursuant to Amendment 132 thereto) and is intended to enable us to grant awards to grantees who are Israeli residents as follows: (i) awards to employees pursuant to Section 102 of the Tax Ordinance (definition refers only to employees, office holders and directors of our company or a related entity excluding those who are considered Controlling Shareholders pursuant to the Tax Ordinance); and (ii) awards to non-employees pursuant to Section 3(I) of the Tax Ordinance. In accordance with the terms and conditions imposed by the Tax Ordinance, grantees who receive awards under the 2006 Stock Incentive Plan may be afforded certain tax benefits in Israel as described below.

Our Board of Directors or the Compensation Committee, referred to as the plan administrator, will administer our 2006 Stock Incentive Plan, including selecting the grantees, determining the number of shares to be subject to each award, determining the exercise or purchase price of each award, and determining the vesting and exercise periods of each award.

The exercise price of stock options granted under the 2006 Stock Incentive Plan must be equal to at least 100% of the fair market value of our common stock on the date of grant; however, in certain circumstances, grants may be made at a lower price to Israeli grantees who are residents of the State of Israel. If, however, incentive stock options are granted to an employee who owns stock possessing more than 10% of the voting power of all classes of our stock or the stock of any parent or subsidiary of our company, the exercise price of any incentive stock option granted must equal at least 110% of the fair market value on the grant date and the maximum term of these incentive stock options must not exceed five years. The maximum term of all other awards must not exceed 10 years. The plan administrator will determine the exercise or purchase price (if any) of all other awards granted under the 2006 Stock Incentive Plan.

Under the 2006 Stock Incentive Plan, incentive stock options and options to Israeli grantees may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised during the lifetime of the participant only by the participant. Other awards shall be transferable by will or by the laws of descent or distribution and to the extent and in the manner authorized by the plan administrator by gift or pursuant to a domestic relations order to members of the participant s immediate family. The 2006 Stock Incentive Plan permits the designation of beneficiaries by holders of awards, including incentive stock options.

In the event the service of a participant in the 2006 Stock Incentive Plan is terminated for any reason other than cause, disability or death, the participant may exercise awards that were vested as of the termination date for a period ending upon the earlier of 12 months or the expiration date of the awards unless otherwise determined by the plan administrator.

In the event of a corporate transaction or a change of control, all awards will terminate unless assumed by the successor corporation. Unless otherwise provided in a participant s award agreement, in the event of a corporate transaction for the portion of each award that is assumed or replaced, then such award will automatically become fully vested and exercisable immediately upon termination of a participant s service if the participant is terminated by the successor company or us without cause within 12 months after the corporate transaction. For the portion of each award that is not assumed or replaced, such portion of the award will automatically become fully vested and exercisable immediately prior to the effective date of the corporate transaction so long as the participant s service has not been terminated prior to such date.

In the event of a change in control, except as otherwise provided in a participant s award agreement, following a change in control (other than a change in control that also is a corporate transaction) and upon the termination of a participant s service without cause within 12 months after a change in control, each award of such participant that is

outstanding at such time will automatically become fully vested and exercisable immediately upon the participant s termination.

Under our 2006 Stock Incentive Plan, a corporate transaction is generally defined as:

a merger or consolidation in which we are not the surviving entity, except for the principal purpose of changing our company s state of incorporation;

the sale, transfer or other disposition of all or substantially all of our assets;

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the complete liquidation or dissolution of our company;

any reverse merger in which we are the surviving entity but our shares of common stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or in which securities possessing more than forty percent (40%) of the total combined voting power of our outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger; or

acquisition in a single or series of related transactions by any person or related group of persons of beneficial ownership of securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities but excluding any such transaction or series of related transactions that the plan administrator determines not to be a corporate transaction (provided however that the plan administrator shall have no discretion in connection with a corporate transaction for the purchase of all or substantially all of our shares unless the principal purpose of such transaction is changing our company s state of incorporation).

Under our 2006 Stock Incentive Plan, a change of control is defined as:

the direct or indirect acquisition by any person or related group of persons of beneficial ownership of securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities pursuant to a tender or exchange offer made directly to our shareholders and which a majority of the members of our board (who have generally been on our board for at least 12 months) who are not affiliates or associates of the offeror do not recommend shareholders accept the offer; or

a change in the composition of our board over a period of 12 months or less, such that a majority of our board members ceases, by reason of one or more contested elections for board membership, to be comprised of individuals who were previously directors of our company.

Unless terminated sooner, the 2006 Stock Incentive Plan will automatically terminate in 2016. Our Board of Directors has the authority to amend, suspend or terminate our 2006 Stock Incentive Plan. No amendment, suspension or termination of the 2006 Stock Incentive Plan shall adversely affect any rights under awards already granted to a participant. To the extent necessary to comply with applicable provisions of federal securities laws, state corporate and securities laws, the Internal Revenue Code, the rules of any applicable stock exchange or national market system, and the rules of any non-U.S. jurisdiction applicable to awards granted to residents therein (including the Tax Ordinance), we shall obtain shareholder approval of any such amendment to the 2006 Stock Incentive Plan in such a manner and to such a degree as required.

Impact of Israeli Tax Law

The awards granted to employees pursuant to Section 102 of the Tax Ordinance under the 2006 Stock Incentive Plan may be designated by us as approved options under the capital gains alternative, or as approved options under the ordinary income tax alternative.

To qualify for these benefits, certain requirements must be met, including registration of the options in the name of a trustee. Each option, and any shares of common stock acquired upon the exercise of the option, must be held by the trustee for a period commencing on the date of grant and deposit into trust with the trustee and ending 24 months thereafter.

Under the terms of the capital gains alternative, we may not deduct expenses pertaining to the options for tax purposes.

Under the 2006 Stock Incentive Plan, we may also grant to employees options pursuant to Section 102(c) of the Tax Ordinance that are not required to be held in trust by a trustee. This alternative, while facilitating immediate exercise of vested options and sale of the underlying shares, will subject the optionee to the marginal income tax rate of up to 50% as well as payments to the National Insurance Institute and health tax on the date of the sale of the shares or options. Under the 2006 Stock Incentive Plan, we may also grant to non-employees options pursuant to Section 3(I) of the Tax Ordinance. Under that section, the income tax on the benefit arising to the optionee upon the exercise of options and the issuance of common stock is generally due at the time of exercise of the options.

These options shall be further subject to the terms of the tax ruling that has been obtained by Protalix Ltd. from the Israeli tax authorities in connection with the merger. Under the tax ruling, the options issued by us in connection with the assumption of Section 102 options previously issued by Protalix Ltd. under the capital gains alternative shall be

issued to a trustee, shall

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be designated under the capital gains alternative and the issuance date of the original options shall be deemed the issuance date for the assumed options for the calculation of the respective holding period.

Compensation of Directors

The following table sets forth information with respect to compensation of our directors during fiscal year 2008. The fees to our current directors were paid by Protalix Ltd. Prior to the merger, Protalix Ltd. compensated only certain of its directors, which compensation was limited to the granting of options under its employee stock option plan. The former directors were our directors who resigned during fiscal year 2008.

Name	Fees Earned or Paid in Cash($)	Stock Award($)	Option Awards($)	Non-Equity Incentive Plan Compensation($)	Nonqualified Deferred Compensation Earnings($)	All Other Compensation($)	Total($)
Current Directors							
Eli Hurvitz(1)	33,000		936,116				969,116
Alfred Akirov	33,000						33,000
Amos Bar-Shalev	15,125						15,125
Zeev Bronfeld	33,000						33,000
Yodfat Harel Gross	33,000						33,000
Roger D. Kornberg	29,590						29,590
Eyal Sheratzky	33,000						33,000
Sharon Toussia-Cohen	33,000						33,000

(1) Represents amounts paid to Pontifax Management Company, Ltd. pursuant to a management consulting agreement.

Our Board of Directors will review director compensation annually and adjust it according to then current market conditions and corporate governance guidelines.

Compensation Committee Interlocks and Insider Participation

Our Compensation Committee currently consists of Messrs. Bar Shalev, Sherazky and Ms Harel Gross, who were appointed to the Committee as of May 6, 2008. In addition, until May 6, 2008, Mr. Toussia Cohen served on our Compensation Committee. No member of our Compensation Committee or any executive officer of our company or of Protalix Ltd. has a relationship that would constitute an interlocking relationship with executive officers or directors of another entity. No Compensation Committee member is or was an officer or employee of ours or of Protalix Ltd. Further, none of our executive officers serves on the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our Board of Directors or Compensation Committee.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information, as of March 1, 2009, regarding beneficial ownership of our common stock:

- each person who is known by us to own beneficially more than 5% of our common stock;

each director;

each of our executive officers; and

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all of our directors and executive officers collectively.

Unless otherwise noted, we believe that all persons named in the table have sole voting and investment power with respect to all shares of our common stock beneficially owned by them. For purposes of these tables, a person is deemed to be the beneficial owner of securities that can be acquired by such person within 60 days from March, 2009 upon exercise of options, warrants and convertible securities. Each beneficial owner s percentage ownership is determined by assuming that options, warrants and convertible securities that are held by such person (but not those held by any other person) and that are exercisable within such 60 days from such date have been exercised.

The address for all directors and officers is c/o Protalix BioTherapeutics, Inc., 2 Snunit Street, Science Park, POB 455, Carmiel, Israel, 20100.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class
Board of Directors and Executive Officers		
Eli Hurvitz	6,270,949(1)	8.1%
David Aviezer, Ph.D., MBA	1,579,752(2)	2.0
Yoseph Shaaltiel, Ph.D.	1,668,172(3)	2.2
Alfred Akirov	6,186,046(4)	8.2
Amos Bar-Shalev		
Zeev Bronfeld	14,466,319(5)	19.1
Yodfat Harel Gross		
Roger D. Kornberg. Ph.D.	15,625(6)	*
Eyal Sheratzky		
Sharon Toussia-Cohen	6,556,381(7)	8.6
Einat Brill Almon, Ph.D.	388,983(8)	*
Yossi Maimon	357,153(9)	*
All executive officers and directors as a group (12 persons)	37,489,400(10)	45.8
5% Holders		
Biocell Ltd.	14,466,319(11)	19.1
Pontifax G.P. Ltd.	6,270,949(12)	8.1
Techno-Rov Holdings (1993) Ltd.	6,186,046(13)	8.2
Marathon Investments Ltd.	6,556,381(14)	8.6
Frost Gamma Investment Trust	9,781,273(15)	12.9

* less than 1%.

(1) Consists of 2,994,378 shares of our common stock held by Pontifax (Cayman) L.P., 1,378,278 of which shares are owned of record and 1,616,100 of which shares

are issuable upon exercise of options that are exercisable within 60 days of March 1, 2009, and 3,276,571 shares of our common stock held by Pontifax (Israel) L.P., 1,508,169 of which shares are owned of record and 1,768,402 of which shares are issuable upon exercise of options that are exercisable within 60 days of March 1, 2009. Mr. Hurvitz is the chairman of Pontifax G.P. Ltd.

(2) Consists of 1,579,752 shares of our common stock issuable upon exercise of outstanding options within 60 days of March 1, 2009. Does not include 705,401 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2009.

(3) Consists of 1,502,054 shares of our common stock held by Dr. Shaaltiel and 166,118 shares of our common stock issuable upon exercise of outstanding options within 60 days of March 1, 2009. Does not include 219,772 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2009.

(4) Consists of 6,186,046 shares of our common stock held by Techno-Rov Holdings (1993) Ltd. Mr. Akirov is the Chief Executive Officer of Techno-Rov Holdings and has the power to control its investment decisions.

(5) Consists of 14,466,319 shares of our common stock

held by Biocell Ltd. Mr. Bronfeld is a director and Chief Executive Officer of Biocell. Mr. Bronfeld disclaims beneficial ownership of these shares.

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(6) Consists of 15,625 shares of our common stock issuable upon exercise of outstanding options within 60 days of March 1, 2009. Does not include 34,375 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2009.

(7) Consists of 6,556,381 shares of our common stock held by Marathon Investments Ltd. Mr. Toussia-Cohen is a director and Chief Executive Officer of Marathon Investments Ltd. Mr. Toussia-Cohen disclaims beneficial ownership of these shares.

(8) Consists of 388,983 shares of our common stock issuable upon exercise of outstanding

options within 60 days of March 1, 2009. Does not include 354,114 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2009.

(9) Consists of 26,700 outstanding shares of our common stock and 330,473 shares of our common stock issuable upon exercise of outstanding options within 60 days of March 1, 2009. Does not include 349,158 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2009.

(10) Consists of 31,623,947 shares of our common stock and 5,865,453 shares of our common stock issuable upon

exercise of options within 60 days of March 1, 2009. Does not include 1,662,819 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2009.

(11) The address is Moshe Aviv Tower, 7 Jabotinsky Street, Ramat Gan, Israel. Biocell Ltd. s investment and voting decisions are made collectively by its board of directors.

(12) The address of Pontifax (Israel) L.P. and Pontifax (Cayman) L.P. is 8 Hamenofim Street, Herzliya Pituach 46725, Israel. Consists of 2,994,378 shares of our common stock held by Pontifax (Cayman) L.P., 1,378,278 of which shares are owned of record and 1,616,100 of which shares

are issuable upon exercise of options that are exercisable within 60 days of March 1, 2009, and 3,276,571 shares of our common stock held by Pontifax (Israel) L.P., 1,508,169 of which shares are owned of record and 1,768,402 of which shares are issuable upon exercise of options that are exercisable within 60 days of March 1, 2009. Pontifax (Cayman) L.P. and Pontifax (Israel) L.P. are governed by Pontifax Management L.P. Pontifax G.P. Ltd. is the general partner of Pontifax Management L.P. Pontifax G.P. Ltd. s investment and voting decisions are made collectively by its board of directors.

(13) The address is Alrov Tower, 46 Rothschild Blvd., Tel Aviv, Israel. Mr. Akirov is the Chief

Executive Officer of Techno-Rov Holdings (1993) Ltd. and has the power to control its investment decisions.

(14) The address is 7 Hanagar Street, Holon, Israel. Marathon Investments Ltd. s investment and voting decisions are made collectively by its board of directors.

(15) The address is 4400 Biscayne Blvd., Miami, Florida 33137. Frost Gamma, L.P. is the sole and exclusive beneficiary of Frost Gamma Investments Trust. Dr. Phillip Frost is the sole limited partner of Frost Gamma, L.P. The general partner of Frost Gamma, L.P. is Frost Gamma, Inc. and the sole shareholder of Frost Gamma, Inc. is Frost-Nevada Corporation. Dr. Frost is also the sole

shareholder of Frost-Nevada Corporation.

Item 13. Certain Relationships and Related Transactions, and Director Independence

On March 17, 2005, Protalix Ltd. entered into a Management Services Agreement with Pontifax Management Company, Ltd. in connection with the purchase of Protalix s Series B Preferred Shares by the Pontifax Funds. Pursuant to the Management Services Agreement, Mr. Hurvitz serves as a member of the Board of Directors. Further, Protalix agreed not to designate a permanent chairman of the Board of Directors until Pontifax Management Company chose to nominate Mr. Hurvitz as the Chairman of the Board in 2006. In consideration for Mr. Hurvitz s services, Protalix is required to pay Pontifax Management Company a fee equal to $3,000 per month plus required taxes on such payment. In addition, in connection with the execution of the Management Services Agreement, Protalix issued to Pontifax options to purchase a number of its Series B Preferred Shares equal to 3.5% of the then outstanding share capital with an exercise price equal to the par value of the shares. Lastly, upon the appointment of Mr. Hurvitz as Chairman of the Board of Directors, Protalix issued to Pontifax additional warrants for Series B Preferred Shares equal to 3.76% of the then outstanding share capital of Protalix. In connection with the merger, we assumed the Management Services Agreement and all options granted under the Management Services Agreement have been converted into options to purchase 3,384,502 shares of our common stock. Under the terms of the assumed Management Services Agreement, we are obligated only to use our best efforts to nominate Mr. Hurvitz for election to our Board of Directors, which remains subject to the review and approval of the Nominating Committee of the Board of

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Directors and the entire Board of Directors, as applicable. For 2009, the fee payable under this agreement will be $33,000, which is the same fee payable to the other non-executive directors.

On September 14, 2006, Protalix Ltd. entered into a collaboration and licensing agreement with Teva for the development and manufacture of two proteins using ProCellEx. Mr. Hurvitz, the Chairman of our Board of Directors, is the Chairman of Teva s Board of Directors, and Phillip Frost M.D., a former director and a major shareholder of our company, is the Vice Chairman of Teva s Board of Directors and Professor Roger D. Kornberg, a member of our board of directors also serves as a member of the board of directors of Teva. Pursuant to the agreement, we will collaborate on the research and development of two proteins using ProCellEx. Protalix Ltd. has granted to Teva an exclusive license to commercialize the products developed under the collaboration in return for royalty and milestone payments payable upon the achievement of certain pre-defined goals. Protalix Ltd. 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 thereafter.

All related party transactions are reviewed and approved by the Audit Committee, as required by the audit committee charter.

Corporate Governance and Independent Directors

Our common stock began trading on the NYSE Alternext US, formerly the American Stock Exchange, under the ticker symbol PLX on March 12, 2007. In compliance with the listing requirements of the NYSE Alternext US, we have a comprehensive plan of corporate governance for the purpose of defining responsibilities, setting high standards of professional and personal conduct and assuring compliance with such responsibilities and standards. We currently regularly monitor developments in the area of corporate governance to ensure we are in compliance with the standards and regulations required by the NYSE Alternext US. A summary of our corporate governance measures follows.

Independent Directors

We believe a majority of the members of our Board of Directors are independent from management. When making determinations from time to time regarding independence, the Board of Directors will reference the listing standards adopted by the NYSE Alternext US as well as the independence standards set forth in the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the Commission under that Act. In particular, our Audit Committee periodically evaluates and reports to the Board of Directors on the independence of each member of the Board. We anticipate our audit committee will analyze whether a director is independent by evaluating, among other factors, the following:

- Whether the member of the Board of Directors has any material relationship with us, either directly, or as a partner, shareholder or officer of an organization that has a relationship with us;

- Whether the member of the Board of Directors is a current employee of our company or our subsidiaries or was an employee of our company or our subsidiaries within three years preceding the date of determination;

- Whether the member of the Board of Directors is, or in the three years preceding the date of determination has been, affiliated with or employed by (i) a present internal or external auditor of our company or any affiliate of such auditor or (ii) any former internal or external auditor of our company or any affiliate of such auditor, which performed services for us within three years preceding the date of determination;

- Whether the member of the Board of Directors is, or in the three years preceding the date of determination has been, part of an interlocking directorate, in which any of our executive officers serve on the Compensation Committee of another company that concurrently employs the member as an executive officer;

- Whether the member of the Board of Directors receives any compensation from us, other than fees or compensation for service as a member of the Board of Directors and any committee of the Board of Directors and reimbursement for reasonable expenses incurred in connection with such service and for reasonable educational expenses associated with Board of Directors or committee membership matters;

Whether an immediate family member of the member of the Board of Directors is a current executive officer of our company or was an executive officer of our company within three years preceding the date of determination;

Whether an immediate family member of the member of the Board of Directors is, or in the three years preceding the date of determination has been, affiliated with or employed in a professional capacity by (i) a

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present internal or external auditor of ours or any of our affiliates or (ii) any former internal or external auditor of our company or any affiliate of ours which performed services for us within three years preceding the date of determination; and

Whether an immediate family member of the member of the Board of Directors is, or in the three years preceding the date of determination has been, part of an interlocking directorate, in which any of our executive officers serve on the Compensation Committee of another company that concurrently employs the immediate family member of the member of the Board of Directors as an executive officer.

The above list is not exhaustive and we anticipate that the Audit Committee will consider all other factors which could assist it in its determination that a director will have no material relationship with us that could compromise that director s independence.

Under these standards, our Board of Directors has determined that Messrs. Sheratzky and Toussia-Cohen and Ms. Harel Gross are considered independent pursuant to the rules of the NYSE Alternext US and Section 10A(m)(3) of the Securities Exchange Act of 1934, as amended. In addition, our Board of Directors has determined that at least two of these directors are able to read and understand fundamental financial statements and have substantial business experience that results in their financial sophistication, qualifying them for membership on any audit committee we form. Our Board of Directors has also determined that Messrs. Akirov, Bar-Shalev, Bronfeld, Sheratzky and Toussia-Cohen, Ms. Harel Gross and Dr. Kornberg are independent pursuant to the rules of the NYSE Alternext US.

Our non-management directors hold formal meetings, separate from management, at least twice per year. We have no formal policy regarding attendance by our directors at annual shareholders meetings, although we encourage such attendance and anticipate most of our directors will attend these meetings. Messrs. Hurvitz, Bronfeld, Bar-Shalev, Sheratzky, Akirov, Toussia-Cohen, Aviezer and Shaaltiel, and Ms. Harel Gross, attended our 2008 annual meeting of shareholders.

Item 14. Principal Accountant Fees and Services

The following table sets forth fees billed to us by our independent registered public accounting firm during the fiscal years ended December 31, 2008 and 2007 for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements; (ii) services by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees; (iii) services rendered in connection with tax compliance, tax advice and tax planning; and (iv) all other fees for services rendered.

	Year ended December 31,	
	2008	2007
Audit Fees	$249,000	$393,000
Audit Related Fees	$ 49,000	$ 77,000
Tax Fees	$ 76,000	$ 76,000
All Other Fees	$	$ 70,000

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

Prior to entering into the engagement letter with our independent registered accountants, our Audit Committee approved the 2008 audit fees. For fiscal year 2009, our Audit Committee has approved fees for certain services to be rendered by our independent registered accounting firm.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. *Financial Statements*. The following Consolidated Financial Statements of Protalix BioTherapeutics, Inc. are included in Item 8 of this Annual Report on Form 10-K:

2. *Financial Statement Schedule.* Financial statement schedules have been omitted since they are either not required, are not applicable or the required information is shown in the consolidated financial statements or related notes.

3. *Exhibits.*

Exhibit Number	Exhibit Description	Method of Filing
3.1	Amended and Restated Articles of Incorporation of the Company	Incorporated by reference to our Registration Statement on Form S-4 filed on March 26, 1998, SEC File No. 333-48677
3.2	Article of Amendment to Articles of Incorporation dated June 9, 2006	Incorporated by reference to our Registration Statement on Form 8-A filed on March 9, 2007
3.3	Article of Amendment to Articles of Incorporation dated December 13, 2006	Incorporated by reference to our Registration Statement on Form 8-A filed on March 9, 2007
3.4	Article of Amendment to Articles of Incorporation dated December 26, 2006	Incorporated by reference to our Registration Statement on Form 8-A filed on March 9, 2007
3.5	Article of Amendment to Articles of Incorporation dated February 26, 2007	Incorporated by reference to our Registration Statement on Form 8-A filed on March 9, 2007
3.6	Amended and Restated Bylaws of the Company	Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 8, 2008

10.1	2006 Stock Incentive Plan	Incorporated by reference to our Amended Annual Report on Form 10-K/A for the year ended December 31, 2006, filed on July 13, 2007

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Exhibit Number	Exhibit Description	Method of Filing
10.2	Employment Agreement between Protalix Ltd. and Yoseph Shaaltiel, dated as of September 1, 2004	Incorporated by reference to our Current Report on Form 8-K filed on January 8, 2007
10.3	Employment Agreement between Protalix Ltd. and Einat Almon, dated as of December 19, 2004	Incorporated by reference to our Current Report on Form 8-K filed on January 8, 2007
10.4	Employment Agreement between Protalix Ltd. and David Aviezer, dated as of September 11, 2006	Incorporated by reference to our Current Report on Form 8-K filed on January 8, 2007
10.5	Employment Agreement between Protalix Ltd. and Yossi Maimon, dated as of October 15, 2006	Incorporated by reference to our Current Report on Form 8-K filed on January 8, 2007
10.6	License Agreement entered into as of April 12, 2005, by and between Icon Genetics AG and Protalix Ltd.	Incorporated by reference to our Amended Current Report on Form 8-K/A filed on September 20, 2007
10.7	Research and License Agreement between Yeda Research and Development Company Limited and Protalix Ltd. dated as of March 15, 2006	Incorporated by reference to our Amended Current Report on Form 8-K/A filed on September 20, 2007
10.8	Agreement between Teva Pharmaceutical Industries Ltd. and Protalix Ltd., dated September 14, 2006	Incorporated by reference to our Amended Current Report on Form 8-K/A filed on September 20, 2007
10.9	Lease Agreement between Protalix Ltd. and Angel Science Park (99) Ltd., dated as of October 28, 2003 as amended on April 18, 2005	Incorporated by reference to our Current Report on Form 8-K filed on January 8, 2007
10.10	Merger Agreement and Plan of Reorganization made and entered into as of August 21, 2006, by and among the Company, Protalix Acquisition Co., Ltd. and Protalix Ltd.	Incorporated by reference to our Current Report on Form 8-K filed on January 8, 2007
10.11	Stock Option Award Agreement grant by and between the Company and Steven Rubin, dated as of December 31, 2006	Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2007, filed on March 30, 2007
10.12	First Amendment to the December 31, 2006 Stock Option Award Agreement by and between the Company and Steven Rubin, effective as of February 28, 2007	Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2008 filed on March 30, 2007
10.13	Scientific Advisory Board Agreement dated August 5, 2007 by and between the Company and Aaron Ciechanover, M.D.	Incorporated by reference to our Current Report on Form 8-K filed on August 6, 2007
10.14		

	Research and License Agreement made on August 8, 2007, by and between Yissum Research Development Company of Jerusalem, the Boyce Thompson Institute and Protalix Ltd.	Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, filed on November 14, 2007
10.15	Unprotected Lease Agreement	Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2007, filed on March 17, 2008.
21.1	Subsidiaries	Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2006, filed on March 30, 2007
23.1	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), A member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant	Filed herewith

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Exhibit Number	Exhibit Description	Method of Filing
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer	Filed herewith
32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer	Filed herewith

Portions of this exhibit were omitted and have been filed separately with the Secretary of the Securities and Exchange Commission pursuant to the Registrant s application requesting confidential treatment under Rule 24b-2 of the Exchange Act.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, as of March 6, 2009.

PROTALIX BIOTHERAPEUTICS, INC.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Aviezer, Ph.D. and Yossi Maimon, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David Aviezer David Aviezer, Ph.D.	President, Chief Executive Officer (Principal Executive Officer) and Director	March 6, 2009
/s/ Yossi Maimon Yossi Maimon	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 6, 2009
/s/ Yoseph Shaaltiel Yoseph Shaaltiel, Ph.D.	Executive VP, Research and Development and Director	March 6, 2009
/s/ Eli Hurvitz Eli Hurvitz	Chairman of the Board	March 6, 2009
/s/ Alfred Akirov Alfred Akirov	Director	March 6, 2009
/s/ Amos Bar-Shalev	Director	March 6, 2009

Amos Bar-Shalev		
/s/ Zeev Bronfeld	Director	March 6, 2009
Zeev Bronfeld		
/s/ Yodfat Harel Gross	Director	March 6, 2009
Yodfat Harel Gross		

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Signature	Title	Date
/s/ Eyal Sheratzky Eyal Sheratzky	Director	March 6, 2009
/s/ Roger D. Kornberg Roger D. Kornberg, Ph.D.	Director	March 6, 2009
/s/ Sharon Toussia-Cohen Sharon Toussia-Cohen	Director	March 6, 2009

PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONSOLIDATED FINANCIAL STATEMENTS
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The dollar amounts are stated in U.S. dollars ($)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

PROTALIX BIOTHERAPEUTICS, INC.

(A Development stage company)

In our opinion, the consolidated balance sheets and the related statements of operations, changes in shareholders equity and cash flows present fairly, in all material respects, the financial position of Protalix BioTherapeutics, Inc. and its subsidiary (a development stage enterprise) at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 and for the period from December 27, 1993 (date of the Company s incorporation) through December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company s internal control over financial reporting based on our audits (which were integrated audits in 2008 and 2007). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2, the Company has restated its 2007 financial statements.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Tel-Aviv, Israel
March 6, 2009

/s/ Kesselman & Kesselman
Kesselman & Kesselman
Certified Public Accountant (Isr.)
A member of PricewaterhouseCoopers
International Limited

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except shares and per share amounts)

	December 31,	
	2007 (restated)	2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 61,813	$ 42,596
Accounts receivable	1,354	793
Total current assets	63,167	43,389
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	464	581
PROPERTY AND EQUIPMENT, NET	4,506	6,841
Total assets	$ 68,137	$ 50,811
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 899	$ 2,235
Other	2,863	3,292
Total current liabilities	3,762	5,527
LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT	690	937
Total liabilities	4,452	6,464
COMMITMENTS		
SHAREHOLDERS EQUITY:		
Common Stock, $0.001 par value: Authorized as of December 31, 2007 and 2008, 150,000,000 shares; Issued and outstanding as of December 31, 2007 and 2008, 75,775,439 and 75,938,059 shares, respectively	76	76

Additional paid-in capital	116,205	119,281
Deficit accumulated during the development stage	(52,596)	(75,010)
Total shareholders equity	63,685	44,347
Total liabilities and shareholders equity	$ 68,137	$ 50,811

The accompanying notes are an integral part of the consolidated financial statements.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except shares and per share amounts)

	Year ended December 31,			Period from December 27, 1993* through December 31,
	2006	2007 (restated)	2008	2008
REVENUES				$ 830
COST OF REVENUES				206
GROSS PROFIT				624
RESEARCH AND DEVELOPMENT EXPENSES	$ 6,997	$ 14,641	$ 22,115	54,417
Less grants	(1,751)	(1,071)	(4,714)	(10,901)
	5,246	13,570	17,401	43,516
GENERAL AND ADMINISTRATIVE EXPENSES	4,525	20,594	6,770	36,360
OPERATING LOSS	9,771	34,164	24,171	79,252
FINANCIAL INCOME NET	(344)	(2,080)	(1,757)	(4,205)
NET LOSS BEFORE CHANGE IN ACCOUNTING PRINCIPLE	9,427	32,084	22,414	75,047
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE	(37)			(37)
NET LOSS FOR THE PERIOD	$ 9,390	$ 32,084	$ 22,414	$ 75,010
NET LOSS PER SHARE OF COMMON STOCK BASIC:				
Prior to cumulative effect of change in accounting principle	$ 0.32	$ 0.48	$ 0.30	
Cumulative effect of change in accounting principle	**			
	$ 0.32	$ 0.48	$ 0.30	

NET LOSS PER SHARE OF COMMON STOCK DILUTED:			
Prior to cumulative effect of change in accounting principle	$ 0.32	$ 0.48	$ 0.30
Cumulative effect of change in accounting principle	**		
	$ 0.32	$ 0.48	$ 0.30
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE OF COMMON STOCK:			
Basic	29,300,987	67,187,329	75,890,633
Diluted	29,300,987	67,187,329	75,890,633

* Incorporation date, see Note 1a.

** Represents an amount less than $0.01.

The accompanying notes are an integral part of the consolidated financial statements.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY
(U.S. dollars in thousands, except share data)

	Common Stock	Convertible preferred shares	Common Stock	Convertible preferred Shares	Warrants	Additional paid-in Capital	Deficit accumulated during development stage	Total
	Number of shares					Amount		
As of December 27, 1993 (1)								
Changes during the period from December 27, 1993 through December 31, 2005:								
Ordinary and convertible preferred A and B shares issued for cash (net of issuance costs of $532)	18,801,527	398,227	19	1	1,027	13,634		14,681
Share-based compensation						2,536		2,536
Net Loss							(11,122)	(11,122)
Balance at December 31, 2005	**18,801,527**	**398,227**	**19**	**1**	**1,027**	**16,170**	**(11,122)**	**6,095**
Changes during 2006:								
Common Stock and warrants issued for cash (net of issuance costs of $236) (see Note 6c)	10,054,600		10		355	14,522		14,887
Merger with a wholly-owned subsidiary of Orthodontix, Inc. (net of issuance cost of $642) (2)	583,280		1			240		241
	2,670,403	847	3			394		397

Exercise of options granted to employees and non-employees								
Share-based compensation						3,421		3,421
Conversion of convertible preferred shares into Common Stock (see Note 6a) (3)	24,375,870	(399,074)	24	(1)		(23)		
Change in accounting principle						(37)	37	
Expiration of warrants (4)					(34)	34		
Exercise of warrants (5)	5,296,279		5		(993)	9,658		8,670
Net Loss							(9,427)	(9,427)