



**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)



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

For the fiscal year ended December 31, 2009

OR

☐

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

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

001-33357

(Commission file number)

**PROTALIX BIOTHERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Florida

State or other jurisdiction  
of incorporation or organization

65-0643773

(I.R.S. Employer  
Identification No.)

2 Snunit Street  
Science Park  
POB 455  
Carmiel, Israel

(Address of principal executive offices)

20100

(Zip Code)

972-4-988-9488

Registrant's telephone number, including area code

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

Title of each class  
Common stock, par value \$0.001 per share

Name of each exchange on which registered  
NYSE AMEX

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 ☐ No ☒

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 ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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

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 ☒

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 ☒

The aggregate market value of the voting stock held by non-affiliates of the Registrant, as of June 30, 2009 was approximately \$162 million (based upon the closing price for shares of the Registrant’s common stock as reported by the NYSE Amex) as of June 30, 2009 of \$4.52). 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 February 15, 2010, approximately 80,745,296 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 our subsidiaries 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 the potential rejection of any applications we file with the U.S. 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 relationship with Pfizer Inc., Teva Ltd. or with any other collaborator, distributor or partner;
- 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 product candidates, 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 subsidiaries, 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 or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated by clinical trials of drug products, the FDA may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. 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™ protein expression system, or ProCellEx. 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 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 (designated this year as taliglucerase alfa) 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. Taliglucerase alfa 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 U.S. Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of taliglucerase alfa, through the FDA’s special protocol assessment (SPA) process. The phase III clinical trial was completed in September 2009 and, on October 15, 2009, we announced positive top-line results from the trial. On December 9, 2009, we filed a New Drug Application (NDA) for taliglucerase alfa. In January 2010, the FDA requested additional data regarding the Chemistry, Manufacturing and Controls (CMC) section of the NDA. No additional clinical or preclinical information was requested. The FDA’s request focused primarily on the validation of the manufacturing process for our upgraded manufacturing facility. A validation plan for our manufacturing process of taliglucerase alfa has already been established and reviewed by the FDA. We are working diligently to provide the requested data to the FDA and anticipate submitting the requested data during the second quarter of 2010. In addition, we expect to submit similar applications with other comparable regulatory agencies in other countries during 2010.

In addition to our recently completed pivotal phase III clinical trial, during the third quarter of 2008, we initiated a double-blind, follow-on extension study as part of this trial. We also initiated a home care treatment program for patients enrolled in the extension study and in December 2008, we initiated a clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with taliglucerase alfa. 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 infused into patients in whom the enzyme is lacking or dysfunctional. The switch-over study is not a prerequisite for marketing approval from the FDA of taliglucerase alfa. In December 2009 we filed a proposed pediatric investigation plan to the Pediatric Committee of the European Medicines Agency, or the EMEA.

In July 2009, following a request by the FDA, we submitted an expanded access program treatment protocol in order to address an expected shortage of the current enzyme replacement therapy approved for Gaucher disease. The treatment protocol was approved by the FDA in August 2009. We are also providing taliglucerase alfa to patients in the European Union under a compassionate use protocol. In August 2009, we received Fast Track Designation for taliglucerase alfa and in September 2009, the FDA’s Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status. The fast track mechanism was created to facilitate the development and approval of new drugs intended for the treatment of life-threatening conditions for which there are no effective treatments and which demonstrate the potential to address unmet medical needs for the conditions. The fast track process includes the scheduling of meetings to seek FDA input into development plans, the option of submitting an NDA serially in sections rather than submitting all components simultaneously, the option to request evaluation of studies using surrogate endpoints, and the potential for a priority review. The fast track designation may be withdrawn by the FDA at any time. The fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that taliglucerase alfa will receive regulatory approval.

The Orphan Drug designation for taliglucerase alfa for the treatment of Gaucher Disease provides special status to taliglucerase alfa provided that it meets certain criteria. As a result of the orphan designation, we are qualified for the tax credit and marketing incentives provided under the Orphan Drug Act of 1983. A marketing application for a prescription drug product that has been designated as a drug for a rare disease or condition is not subject to a prescription drug user fee unless the application includes an indication for other than a rare disease or condition.

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On November 30, 2009, Protalix Ltd. and Pfizer Inc., or Pfizer, entered into an exclusive license and supply agreement pursuant to which Pfizer was granted an exclusive, worldwide license to develop and commercialize taliglucerase alfa. Under the terms and conditions of the Pfizer agreement, Protalix Ltd. retained the right to commercialize taliglucerase alfa in Israel. In connection with the execution of the Pfizer agreement, Pfizer made an upfront payment to Protalix Ltd. of \$60.0 million in connection with the execution of the agreement and subsequently paid to Protalix Ltd. an additional \$5.0 million upon our filing of a proposed pediatric investigation plan to the Pediatric Committee of the EMEA. Protalix Ltd. is also eligible to receive potential milestone payments of up to \$50.0 million, in the aggregate, for the successful achievement of other regulatory-related milestones and to payments equal to 40% of the net profits earned by Pfizer on sales of taliglucerase alfa. In calculating the net profits, there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold. Protalix Ltd. retained the manufacturing rights to taliglucerase alfa and Pfizer and Protalix Ltd. have agreed to a specific allocation of the responsibilities for the continued development efforts for taliglucerase alfa.

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 \$793 million in 2009, compared with \$1.2 billion for the previous year, according to public reports by Genzyme. According to Genzyme, it suffered a temporary interruption in production of Cerezyme in 2009 associated with the remediation of a contamination in one of its manufacturing facilities, and, as a result, shipments of Cerezyme were limited during the second half of 2009. Taliglucerase alfa is a plant cell expressed version of the GCD enzyme, developed through our ProCellEx protein expression system. Taliglucerase alfa 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 taliglucerase alfa 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 taliglucerase alfa may have the potential for increased potency and efficacy in certain parameters compared to the existing enzyme replacement therapy for Gaucher disease.

In addition to taliglucerase alfa, 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, antiTNF, a plant cell expressed recombinant fusion protein made from the soluble form of the human TNF receptor (TNFR), fused to the Fc component of a human antibody IgG1 domain and additional undisclosed therapeutic proteins, most of which are currently being evaluated in animal studies. During the fourth quarter of 2009, we filed an IND (investigational new drug application) with the FDA for our acetylcholinesterase enzyme-based therapy for biodefense applications after successfully completing pre-clinical studies for this indication. We expect to initiate a phase I clinical study for our acetylcholinesterase enzyme-based therapy during the first quarter of 2010. We plan to file an investigational new drug application (IND) with the FDA with respect to an additional product candidate during 2010.

In September 2009, we announced preliminary preclinical data regarding pr-antiTNF, our proprietary product candidate for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing, spondylitis, psoriatic arthritis and plaque psoriasis. Our pr-antiTNF product candidate has an amino acid sequence that is similar to Enbrel™, which is one of the treatments for patients of those diseases. 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 action. Except for the rights to commercialize taliglucerase alfa worldwide (other than Israel) which we licensed to Pfizer, 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 taliglucerase alfa in Israel 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 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 taliglucerase alfa.

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 through clinical and pre clinical studies performed by us to date including the positive efficacy and safety data in our phase III study for taliglucerase alfa, pre clinical results in well-known models in our enzyme for Fabry disease and pr-antiTNF, and extensive animal studies for our acetylcholinesterase enzyme, and by expressing, on an exploratory, research scale, many additional 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 the clinical success of taliglucerase alfa represents 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 identified by Teva and us, using our ProCellEx protein expression system. The agreement also identifies additional matters for collaboration between Teva and us. Subsequently, two proteins were identified to be researched and developed under the agreement but in 2009, both of the projects were terminated for commercial reasons. 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-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 glycosylation (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, and several cases of viral contamination have occurred recently. 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 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 taliglucerase alfa.

***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.

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

***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 taliglucerase alfa in a “ready to use” form that does not require additional glycosilation or other modifications to make taliglucerase alfa 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.

**Broad Range of Expression Capabilities.** Unlike bacterial and yeast cell-based systems, which are unable to produce complex proteins, our ProCellEx protein expression system is able to produce a broad array of complex glycosylated proteins. We have successfully demonstrated the feasibility of our ProCellEx system by producing, on an exploratory, research scale, a variety of therapeutic proteins belonging to different classes of recombinant drugs, such as enzymes, hormones, monoclonal antibodies, cytokines and vaccines. We have demonstrated that the recombinant proteins we have expressed to date 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:

**Facilitate the successful development and commercialization of taliglucerase alfa by Pfizer.** We intend to work with our licensee, Pfizer, to develop and commercialize taliglucerase alfa. We have begun collaborating with Pfizer to facilitate the transition of certain of our taliglucerase alfa assets to Pfizer's organization. We are cooperating with Pfizer with respect to our Expanded Access protocol for taliglucerase alfa in order to facilitate the participation of additional physicians in additional sites in the protocol. Pfizer is promoting the protocol to new clinical sites and is recruiting additional patients. We have also begun to facilitate relationships between Pfizer and the Gaucher community and third-party payors. We intend to actively participate and provide our expertise in Pfizer's development and commercialization efforts with respect to taliglucerase alfa.

**Obtain Regulatory Approval for Taliglucerase Alfa for the Treatment of Gaucher Disease.** We completed successfully our pivotal phase III clinical trial of taliglucerase alfa in September 2009 and announced the positive top-line study results in October 2009 and full study results in February 2010. We filed a New Drug Application (NDA) to the FDA in December 2009 and in January 2010, the FDA requested additional data regarding the Chemistry, Manufacturing and Controls (CMC) section of the NDA. No additional clinical or preclinical information was requested. The FDA's request focused primarily on the validation of the manufacturing process for our upgraded manufacturing facility. A validation plan for our manufacturing process of taliglucerase alfa has already been established and reviewed by the FDA. We are working diligently to provide the requested data to the FDA and anticipate submitting the requested data during the second quarter of 2010. We expect to submit similar applications with other comparable regulatory agencies in other countries during 2010. On February 1, 2010, we held a pre-Marketing Approval Application (MAA) meeting with the EMEA. Our phase III clinical trial was conducted 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 taliglucerase alfa at the same dose that they received in the trial. We are compiling additional information relating to the long term safety and efficacy of taliglucerase alfa 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 taliglucerase alfa. The switch-over trial, which is not a pre requisite for marketing approval from the FDA, was designed to include 15 patients with Gaucher disease that are currently undergoing enzyme replacement therapy with imiglucerase (Cerezyme). Due to the shortage in 2009 of the currently available enzyme replacement therapy for Gaucher disease, after fully enrolling the 15 patients we extended the trial to include up to 30 patients in total. In December 2009, we filed a proposed pediatric investigation plan to the Pediatric Committee of the EMEA. We believe that taliglucerase alfa 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 taliglucerase alfa as a treatment for Gaucher disease, if at all, with its potentially longer acting profile and more cost-effective development process, may lead to an increase in the number of patients who will be able to have access to and afford such treatment, thereby expanding the size of 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 have also identified several other product candidates that are chemical equivalents of approved therapeutic products that will no longer be patent protected within the next couple of years, such as pr-antiTNF, our proprietary product candidate for the treatment of certain immune diseases such as rheumatoid arthritis. We believe our cost-effective technology will be an important asset for the commercialization of such drug candidates. 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.

**Collaborate with Third Party Pharmaceutical Suppliers and build a Targeted Sales and Marketing Infrastructure.** We have licensed to Pfizer the right to commercialize taliglucerase worldwide, except in Israel. We plan to establish our own, internal sales and marketing capabilities for taliglucerase in Israel, and, for our other product candidates, 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 may facilitate our creation of a targeted internal sales force. In addition we are continuously evaluating potential strategic marketing partnerships with respect to our other product candidates.

**Establish Development and Commercialization Alliances with Corporate Partners.** We believe that our technology and know-how has broad applicability to many classes of proteins and can be used to develop and potentially enhance numerous existing marketed protein therapeutics. We intend to leverage our technology and know-how by pursuing development and commercialization alliances with corporate partners for specific products and territories in order to enable us to optimize our resources and effectively penetrate a wider range of target diseases and therapeutic markets. In November 2009, we entered into a license and supply agreement with Pfizer for the development and commercialization of taliglucerase alfa. We entered into an agreement with Teva in September 2006 for the development of two proteins. In 2009, programs relating to two proteins to be developed under the agreement were terminated for commercial reasons. Last, we are in various stages of discussions with a number of multinational pharmaceutical companies regarding additional collaboration agreements.

**Acquire or In-License New Technologies, Products or Companies.** We continuously seek attractive product candidates and innovative technologies to in-license or acquire. We intend to focus on product candidates that would be synergistic with our ProCellEx protein expression system and expertise and that represent large potential market opportunities. We believe that by pursuing selective acquisitions of 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, Taliglucerase Alfa**

Taliglucerase alfa, 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 FDA on the final design of our pivotal phase III clinical trial of taliglucerase alfa through the FDA's special protocol assessment (SPA) process. We successfully completed our phase III pivotal clinical trial of taliglucerase alfa in September 2009 and announced positive top line results of the clinical trial in October 2009 and full study results in February 2010. We submitted a New Drug Application (NDA) to the FDA in December 2009. In January 2010, the FDA requested additional data regarding the Chemistry, Manufacturing and Controls (CMC) section of the NDA. No additional clinical or preclinical information was requested. The FDA's request focused primarily on the validation of the manufacturing process for our upgraded manufacturing facility. A validation plan for our manufacturing process of taliglucerase alfa has already been established and reviewed by the FDA. We are working diligently to provide the requested data to the FDA and anticipate submitting the requested data during the second quarter of 2010. In addition, we expect to submit

similar applications with other comparable regulatory agencies in other countries during 2010. 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 taliglucerase alfa at the same dose that they received in the trial. We are compiling additional information relating to the long term safety and efficacy of taliglucerase alfa 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 taliglucerase alfa. 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). Due to the shortage of the currently available enzyme replacement therapy for Gaucher disease, after fully enrolling the 15 patients we extended the trial to include up to 30 patients in total. In addition, in December 2009, we filed a proposed pediatric investigation plan to the Pediatric Committee of the EMEA. In clinical trials in healthy subjects and in vivo primate studies, taliglucerase alfa 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 taliglucerase alfa, 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 taliglucerase alfa in the subjects' blood serum after infusion showed that the half-life of taliglucerase alfa is significantly longer than that of Cerezyme when measured and compared to publicly available data on Cerezyme.

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

As such, we believe that taliglucerase alfa's potential advantages may lead taliglucerase alfa 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 taliglucerase alfa before we apply it to any other product candidates. If proven effective, our experimental oral taliglucerase alfa would be the first protein to be administered orally rather than through intravenous therapy. We are developing our oral taliglucerase alfa 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., or Amicus Therapeutics, and Genzyme. Small molecule based treatments for Gaucher disease, such as Zavesca, have different mechanisms of action than those associated with enzyme replacement therapy, and may be associated with a number of side effects. We have filed patent applications with respect to this new protein delivery mechanism in other countries with commercially significant markets. Currently, we are the exclusive owners of all rights to this technology.

## 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 had annual sales of approximately \$793 million in 2009, compared to \$1.2 billion in 2008. According to Genzyme it suffered a temporary interruption in production of Cerezyme in 2009 associated with the remediation of a contamination in one of its manufacturing facilities, and, as a result, shipments of Cerezyme were limited during the second half of 2009. 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 and contamination risks. 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 at this time 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 53.1 million (approximately \$51.6 million) in 2009.

### **Taliglucerase Alfa Development Program**

We believe the clinical development path for taliglucerase alfa will be similar to that followed by the existing enzyme replacement therapy currently on the market. The primary efficacy endpoint for our pivotal phase III study was the reduction in size of spleen and the secondary endpoints for our pivotal phase III study included 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 taliglucerase alfa. We met all of the endpoints in our phase III trial which was successfully completed in September 2009. 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 Taliglucerase Alfa**

We conducted several in vitro tests and in vivo preclinical studies of taliglucerase alfa. Our preclinical rodent and primate trials generated extensive toxicological and safety data that demonstrated no adverse effects, even with very high doses of taliglucerase alfa 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.

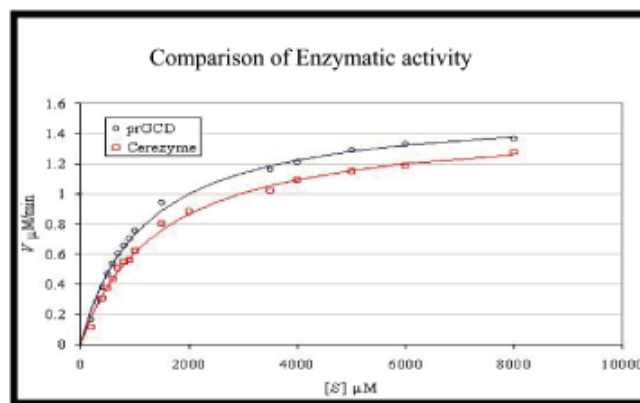
Our laboratory and preclinical data demonstrate that taliglucerase alfa has the potential to be an efficacious enzyme replacement therapy for the treatment of Gaucher disease. Data produced from these preliminary development studies show that, relative to Cerezyme, taliglucerase alfa has:



- 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).

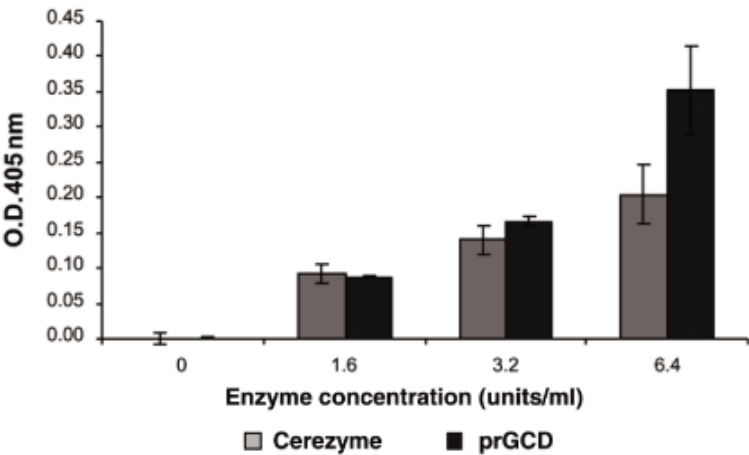
As shown in Figure 1, we compared the enzymatic activity of taliglucerase alfa and Cerezyme using an in vitro assay where increasing amounts of GlcCer substrate (S), provided in millimolar, were degraded by a fixed amount of taliglucerase alfa and Cerezyme, measured in milligrams. Enzymatic activity 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 taliglucerase alfa had enzymatic activity that was equivalent to Cerezyme; the other studies demonstrated superior activity by taliglucerase alfa. Figure 1 demonstrates that the enzymatic activity of taliglucerase alfa was superior to Cerezyme.

**Figure 1: Taliglucerase Alfa and Cerezyme Enzymatic Activity**



As shown in Figure 2, we compared the uptake of increasing amounts of Cerezyme and taliglucerase alfa 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 taliglucerase alfa based on the amount of GlcCer substrate degradation into glucose and ceramide, measured in a microplate absorbance reader, a flat plate with multiple “wells” used as small test tubes, at an optical density of 405 nanometers. The results in Figure 2 demonstrate that the uptake into the macrophage cells of taliglucerase alfa 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 glycosylation of taliglucerase alfa, results in the enhanced uptake of taliglucerase alfa 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 glycosylation patterns and could reduce cellular uptake of Cerezyme.

**Figure 2: Taliglucerase Alfa 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 taliglucerase alfa is significantly longer than that of Cerezyme based upon data disclosed publicly by Genzyme. We believe the extended half-life of taliglucerase alfa relative to Cerezyme is attributable to the different glycoside profile, thereby resulting in the enhanced uptake of taliglucerase alfa into the Gaucher cells.

**Figure 3: Taliglucerase Alfa and Cerezyme Half-Life Data**

	Taliglucerase Alfa	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 the NDA for taliglucerase alfa, we conducted further, standard preclinical studies, mainly reproductive studies, of taliglucerase alfa, which further support the safety profile of taliglucerase alfa.

**Phase I Clinical Trial**

We completed a phase I clinical trial of taliglucerase alfa 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 taliglucerase alfa in healthy subjects. The trial was conducted on healthy subjects over a four-week period in which subjects received three single escalating doses of taliglucerase alfa administered as intravenous infusions.

All doses administered to subjects in the phase I clinical trial, including the highest dose, which was the same dosage currently suggested with respect to the treatment by Cerezyme, demonstrated a strong safety profile. The data from our phase I clinical trial showed that taliglucerase alfa 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 taliglucerase alfa 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.

### 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 taliglucerase alfa 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 taliglucerase alfa. 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 naive patients in the phase III clinical trial. In accordance with the terms of the SPA, the phase III clinical trial was a multi-center, world-wide, randomized, double-blind, parallel group, dose-ranging study to assess the safety and efficacy of taliglucerase alfa in 31 treatment-naive patients suffering from Gaucher disease. In the trial, patients were selected randomly for one of two dosing arms (60 U/kg or 30 U/kg) and received intravenous infusions of taliglucerase alfa once every two weeks for a nine-month period. The primary endpoint of the study was a 20% mean reduction from baseline in spleen volume after nine months, as measured by MRI. Major secondary endpoints were an increase in hemoglobin, decrease in liver volume and increase in platelet count. The trial enrolled patients at 11 centers throughout Europe, Israel, North America, South America and South Africa. 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

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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 taliglucerase alfa at the same dose that they received in the trial. We are compiling additional information relating to the long term safety and efficacy of taliglucerase alfa 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 taliglucerase alfa. The switch-over trial, which is not a pre requisite for approval, was originally designed to include 15 patients with Gaucher disease that are currently undergoing enzyme replacement therapy with imiglucerase (Cerezyme). Due to the shortage of Cerezyme in 2009, after fully enrolling the 15 patients we extended the trial to include up to 30 patients in total. We successfully completed the phase III clinical trial in September 2009.

### **Phase III Clinical Trial Results**

We reported positive top line results of our phase III clinical trial of taliglucerase alfa in October 2009 and full study results in February 2010. In the clinical trial, taliglucerase alfa significantly reduced mean spleen volume after nine months compared with baseline in both treatment groups. The 60 U/kg group demonstrated a statistically significant mean reduction in spleen volume of 38.0% ( $p < 0.0001$ ) and the 30 U/kg group demonstrated a significant mean reduction in spleen volume of 26.9% ( $p < 0.0001$ ). In addition, the primary endpoint was achieved in both treatment groups after only six months of therapy.

Statistically significant improvements were also observed for the secondary endpoints after nine months when compared to baseline for the 60 U/kg dose. Patients demonstrated a mean increase in hemoglobin of 2.2 g/dL or 22.2% ( $p < 0.0001$ ), a mean decrease in liver volume of 11.1% ( $p < 0.0001$ ) and a mean elevation in platelet count of 41,494 ml or 72.1% ( $p = 0.0031$ ). For patients in the 30 U/kg dose, statistically significant improvements after nine months compared with baselines were observed for hemoglobin level (increased 1.6 g/dL or 14.8%;  $p = 0.0010$ ) and liver size (decreased 10.48%;  $p = 0.0041$ ); a nominal elevation in platelet count was also seen (11,427 ml or 13.7%;  $p = 0.0460$ ).

Thirty patients in the trial had Chitotriosidase measurements, a biomarker for clinical symptoms of Gaucher disease. In these patients, Chitotriosidase decreased from baseline in both the 30U/kg and 60U/kg groups by 47.3% and 58.4%, respectively.

The safety analysis for both treatment groups showed that taliglucerase alfa was well tolerated and no serious or severe adverse events were reported. Two patients in the trial developed antibodies to taliglucerase alfa and no patients developed neutralizing antibodies. In addition, two patients experienced hypersensitivity reactions to taliglucerase alfa. No anti-taliglucerase antibodies were detected in these patients and both reactions were treated in the physicians' clinic and reversed.

Most adverse events were considered unrelated to taliglucerase alfa. The most frequent mild to moderate adverse event was headache. Other mild to moderate adverse events included dizziness, muscle spasm, chest discomfort, nausea, skin irritation and arthralgia.

### **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. We are also conducting initial research to evaluate potential programs in the fields of monoclonal antibodies, cytokines and vaccines. We filed an investigational new drug application (IND) with the FDA for our acetylcholinesterase enzyme (AChE) during the last quarter of 2009. In addition, we plan to file an IND with the FDA with respect to our Fabry project during the second half of 2010. 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 \$431 million in worldwide sales of

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Fabrazyme in 2009, compared to \$494 million in 2008. According to Genzyme, it suffered a temporary interruption in production of Fabrazyme in 2009 associated with the remediation of a contamination in one of its manufacturing facilities, and, as a result, shipments of Fabrazyme were limited during the second half of 2009. The other approved drug for the treatment of Fabry disease in the European Union is Replagal, which is sold by Shire plc. Shire reported \$194 million in sales of Replagal in 2009. According to public reports by Shire, it filed a BLA with the FDA for Replagal in the United States in December 2009.

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. Initial pre clinical trial results demonstrate the successful reduction of the GB3 level of mice suffering from Fabry disease when compared to the control. These results are similar to the results of treatment with Fabrazyme. We expect to file an IND with the FDA for PRX-102 in the second half of 2010 following the completion of additional animal studies. As was the case in our development of taliglucerase alfa, 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 taliglucerase alfa 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 Yisum 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 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 Yisum 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 Yisum, 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 enzyme 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 successfully treat animals exposed to the nerve gas agent analogs, both when injected with our acetylcholinesterase product candidate immediately before exposure or when injected after exposure. In December 2009, we submitted an IND application for our acetylcholinesterase enzyme with the FDA, and we intend to initiate a clinical study immediately after our IND is accepted, if at all.

We are currently in discussions with different U.S. civil and military organizations regarding certain grants for which our acetylcholinesterase program is eligible. We anticipate applying for specific grants during 2010 to support the further development of our acetylcholinesterase program.

### **pr-antiTNF**

In September 2009, we announced preliminary preclinical data regarding an antiTNF (Tumor, Necrosis Factor) protein that we are expressing through our proprietary ProCellEx system. We have designed this antiNF as pr-antiNF. pr-antiNF is a candidate for the treatment of certain autoimmune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing, spondylitis, psoriatic arthritis and plaque psoriasis. Amgen Inc. has reported total sales of Enbrel of \$3.5 billion for 2009 and Wyeth Pharmaceuticals has reported total sales of Enbrel of \$1.4 billion for the six months ended June 30, 2009. Wyeth was acquired by Pfizer in 2009.

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pr-antiTNF is a plant cell-expressed recombinant fusion protein made from the soluble form of the human TNF receptor (TNFR), fused to the Fc component of a human antibody domain. pr-antiTNF has an identical amino acid sequence to Enbrel and our in vitro and preclinical animal studies have demonstrated that pr-antiTNF exhibits similar activity to Enbrel. Specifically, pr-antiTNF binds TNF thereby inhibiting it from binding to cellular surface TNF receptors and protects L929 cells from TNF-induced apoptosis in a dose-dependent manner. In a proof-of-concept in vivo study using an established arthritis animal model, pr-antiTNF, when injected in mice, significantly improved the clinical arthritis parameters associated with this accepted arthritis mouse model, including joint inflammation, swelling and tissue degradation. We intend to conduct additional animal studies to collect additional data to form a basis for a discussion with the FDA to explore the regulatory pathway for our antiTNF program. Patents for the Enbrel start to expire as early as 2012, and we expect to use our cost effective manufacturing platform to facilitate entry into this market upon approval of our pr-antiTNF product, if at all.

### **Commercialization Agreement**

On November 30, 2009, Protalix Ltd. and Pfizer entered into a license and supply agreement pursuant to which Pfizer was granted an exclusive, worldwide license to develop and commercialize taliglucerase alfa. Under the terms and conditions of the Pfizer agreement, Protalix Ltd. retained the right to commercialize taliglucerase alfa in Israel. In connection with the execution of the Pfizer agreement, Pfizer made an upfront payment to Protalix Ltd. of \$60.0 million in connection with the execution of the agreement and subsequently paid to Protalix Ltd. an additional \$5.0 million upon our filing of a proposed pediatric investigation plan to the Pediatric Committee of the EMEA. Protalix Ltd. is also eligible to receive potential milestone payments of up to \$50.0 million, in the aggregate, for the successful achievement of other regulatory-related milestones and to payments equal to 40% of the net profits earned by Pfizer on sales of taliglucerase alfa. In calculating the net profits, there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold. Protalix Ltd. retained the manufacturing rights to taliglucerase alfa and Pfizer and Protalix Ltd. have agreed to a specific allocation of the responsibilities for the continued development efforts for taliglucerase alfa. Protalix Ltd. will manufacture all of the taliglucerase alfa needed for all purposes under the agreement and Pfizer will purchase the taliglucerase alfa from Protalix Ltd., subject to certain terms and conditions. The Pfizer agreement also provides for reimbursement by Pfizer of certain costs to be incurred by Protalix Ltd.

In connection with the payments made under the Pfizer agreement, Protalix Ltd. has accrued a sublicense fee equal to \$1.6 million payable to the academic institution from who it licensed certain technology relating to taliglucerase alfa. Future milestone payments will be subject to a 2.5% royalty, and all of the royalty payments we receive under the agreement will be subject to a 0.75% royalty payable to the same institution until 2016, when a patent related to taliglucerase alfa licensed to us will expire. We are also required to pay a royalty equal to 3% of the revenues we record from Pfizer under the Pfizer agreement to the OCS.

We will be subject to a withholding tax on the U.S. revenue source portion of the payments made to us for our share of Pfizer's in net profits under the Pfizer agreement. Currently, the withholding tax rate is 15%.

### **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. The agreement also identifies additional matters for collaboration between Teva and us. Subsequently, two proteins were identified to be researched and developed under the agreement but in 2009, both of the projects were terminated for commercial reasons. These proteins were not part of our current product development pipeline. 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 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 84 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 were filed internationally during the first quarter of 2010. We also have one joint patent with a third party and hold licensed rights to seven patents and five 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, taliglucerase alfa 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 the production of glycosylated proteins in our plant culture platform, particularly proteins having a terminal mannose glycosylation, including taliglucerase alfa. 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 and a patent family related to saccharides containing protein conjugates. Lastly, our patent portfolio includes a patent 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), or Icon, 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**

We are obligated to manufacture all of the taliglucerase alfa drug product needed under the Pfizer agreement, subject to certain terms and conditions. Our drug product candidates, including taliglucerase alfa, 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 20,000 sq/ft of clean rooms built according to industry standards, to develop, process and manufacture taliglucerase alfa and other recombinant proteins. We have completed 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 taliglucerase alfa we need in the near future, including the taliglucerase alfa to be purchased by Pfizer. Current capacity of our facility can serve approximately 20% of the Gaucher disease patients that are currently under treatment. We intend to expand our current facility in order to reach a capacity of approximately 50% of the Gaucher disease patients that are currently under treatment and 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 \$20.0 million and the process is expected to be completed during 2011.

We have entered into a contract with Teva pursuant to which Teva is performing the final filling and freeze drying steps for taliglucerase alfa. According to our agreement with Pfizer, Pfizer will be responsible for the fill and finish activities for taliglucerase alfa.

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. Shire is currently developing a gene-activated enzyme expressed in human cancer cells to treat Gaucher disease. Shire has submitted marketing applications for its enzyme replacement therapy treatment for Gaucher disease. According to public reports by Shire, its application is being reviewed by the FDA under Priority Review with a PDUFA date of February 28, 2010 and the EMEA's Committee for Medicinal Products for Human Use has granted accelerated review for Shire's Marketing Authorization Application. 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, which according to public filings by Amicus Therapeutics has been suspended, and Genzyme. We also face competition from companies with approved enzyme treatments of Fabry disease, including Genzyme and Shire, and we are aware of other early stage drugs which are being developed for the treatment of Fabry disease, 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, 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:

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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

### Government Regulation

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

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

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.”

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to drugs and biological products intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. In September 2009, we received orphan drug designation for taliglucerase alfa for the treatment of Gaucher disease. The FDA grants orphan drug designation to drugs that may provide a significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. Among the other benefits of orphan drug designation are possible funding and tax savings to support clinical trials and for other financial incentives and a waiver of the marketing application user fee and most likely priority review.

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. For a fast track product, the FDA may consider for review on a rolling basis sections of the NDA before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA as they become available and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. We used the rolling submission option for our NDA for our lead product candidate, taliglucerase alfa, which we completed in December 2009.

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

The United States federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the Federal Food, Drug, and Cosmetic Act (FDCA), as well as other relevant laws; (ii) the Center for Medicare & Medicaid Services (CMS), which administers the Medicare and Medicaid programs; (iii) the Office of Inspector General (OIG) which enforces various laws aimed at curtailing fraudulent or abusive practices, including by way of example, the Anti-Kickback Law, the Anti-Physician Referral Law, commonly referred to as Stark, the Anti-Inducement Law, the Civil Money Penalty Law and the laws that authorize the OIG to exclude healthcare providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights, which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All of the aforementioned are agencies within the Department of Health and Human Services (HHS). Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Department of Veterans Affairs, especially through the Veterans Health Care Act of 1992, the Public 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 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. On January 2010, the Committee for Orphan Medicinal Products (COMP) of the EMEA recommended that the European Commission grant orphan drug designation to taliglucerase alfa. Orphan drug designation in the European Union is granted to medicinal products intended for the diagnosis, prevention and treatment of life-threatening diseases and very serious conditions that affect not more than five in 10,000 people in the European Union. Orphan drug designation is generally given to medicinal products that treat conditions for which no current therapy exists or are expected to bring a significant benefit to patients over existing therapies. If granted by the European Commission, orphan drug designation will provide us a centralized procedure for obtaining marketing authorization for taliglucerase alfa, with a single marketing authorization valid throughout all EU Member States. We may also be eligible for a number of additional incentives including protocol assistance, reduction in registration fees and eligibility for grants and initiatives supporting research and development related to the orphan drug designation.

## **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. Additional, gradual corporate tax reductions were adopted in 2008, as follows: 24% for the 2011 tax year; 23% for the 2012 tax year; 22% for the 2013 tax year; 21% for the 2014 tax year; 20% for the 2015 tax year; and 18% thereafter. As discussed below, the corporate tax rate may be less for income derived from an Approved Enterprise. In addition to the corporate taxes in Israel, we are subject to a withholding tax on the U.S. revenue source portion of the payments made to us for our share of Pfizer's net profits under the Pfizer agreement. The withholding tax rate is 15%. See "Business — Commercialization Agreement."

## **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.

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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, or 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:

<b>Percent of Foreign Ownership</b>	<b>Rate of Reduced Tax</b>
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.

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, 2009, the OCS approved grants in respect of Protalix Ltd.'s continuing operations totaling approximately \$16.7 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, 2009, Protalix Ltd. had not paid royalties and Protalix Ltd.'s contingent liability to the OCS with respect to grants received was approximately \$14.8 million, after the accrual of a \$1.9 million royalty payment to the OCS in connection with the \$65.0 million we received in 2009 from Pfizer.

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

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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.
- 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.

### **Employees**

As of December 31, 2009, we had 182 employees, of whom 29 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

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BioTherapeutics, Inc. Unless otherwise indicated, all share numbers in this annual report on Form 10-K give effect to such reverse stock split.

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

ProCellEx™ is our trademark. Each of the other trademarks, trade names or service marks appearing in this Annual Report on Form 10-K belongs to its respective holder.

### **Available Information**

Our corporate website is [www.protalix.com](http://www.protalix.com). We make available on our website, free of charge, our Securities and Exchange Commission, 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



## 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 significant 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 significant revenues from product sales and only minimal revenues from research and development services and other fees. For the years ended December 31, 2009, 2008 and 2007, we had net losses of \$31.4 million, \$22.4 million and \$32.1 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, except for the upfront payment we received in connection with the Pfizer agreement and certain regulatory-related milestone payments in connection with the agreement which we expect to earn prior to any sales of taliglucerase alfa. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from our cash on hand, potential regulatory-related milestone payments under the Pfizer agreement, other licensing fees and grants and the net proceeds of any equity or debt offerings. Over the next 12 months, we expect to spend a minimum of approximately \$30.0 million building an internal sales and marketing force for the sale of taliglucerase alfa in Israel, expanding our manufacturing capacity and on preclinical and clinical development for our products candidates. Based on our current plans and capital resources, we believe that our cash and cash equivalents together with the regulatory milestones payments we anticipate receiving from Pfizer will be sufficient to enable us to meet our planned operating needs for the foreseeable future. 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.

**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, taliglucerase alfa, which trial was completed in August 2009, and we have not commenced the preclinical trial phase of development under Good Laboratory Practice (GLP) standards for any of our other drug candidates. These operations provide a limited basis for investors to assess our ability to commercialize our drug candidates and whether to invest in us.

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

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

**We currently depend heavily on the success of taliglucerase alfa, our lead product candidate. Any failure to commercialize taliglucerase alfa, 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 taliglucerase alfa. Our ability to generate product revenue, depends heavily on the successful development and commercialization of taliglucerase alfa. In November 2009, we granted to Pfizer an exclusive worldwide license to develop and commercialize taliglucerase alfa except in Israel. We retained such rights in Israel. The successful commercialization of taliglucerase alfa will depend on several factors, including the following:

- successful completion of our ongoing studies of taliglucerase alfa;
- 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;

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- Pfizer's efforts under the license and supply agreement we entered into in November 2009;
- our development of a successful sales and marketing organization for taliglucerase in Israel;
- the availability of reimbursement to patients from healthcare payors for our drug products, if approved;
- a continued acceptable safety and efficacy profile of our product candidates following approval; and
- other risks described in these Risk Factors.

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

**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 effect on our revenues.**

Our strategy, in many cases, is to enter into arrangements with pharmaceutical companies to leverage our ProCellEx system to develop additional product candidates. Under these arrangements, we may grant to our partners rights to license and commercialize pharmaceutical products developed under the applicable agreements. Our partners may control key decisions relating to the development of the products and we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our product candidates. The rights of our partners limit our flexibility in considering alternatives for the commercialization of our product candidates. To date, we have entered into a license and supply agreement with Pfizer relating to the development and commercialization of taliglucerase alfa and an agreement with Teva Pharmaceutical Industries Ltd., which relates to the development by us of two proteins, and the licensing by Teva of such proteins in consideration for royalties and milestone payments. Subsequently, two proteins were identified to be researched and developed under the agreement but in 2009, both of the projects were terminated for commercial reasons. We may not identify any additional proteins to be developed in a collaboration between us and Teva under the agreement, which may have a material adverse effect on our business, results of operations and financial condition. If we or any of our partners breach or terminate the agreements that make up such arrangements, our partners otherwise fail to conduct their obligations under such arrangements in a timely manner, there is a dispute about their obligations or if either party terminates the applicable agreement or elects not to continue the arrangement, we may not enjoy the benefits of the agreements or receive a sufficient amount of royalty or milestone payments from them, if any.

**All of our product candidates other than taliglucerase alfa are in pre clinical or 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 taliglucerase alfa. 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.

Any failure to develop or commercialize any of our other product candidates may have a material adverse effect on our business, results of operations and financial condition.

**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. In December 2009 we completed the filing of an NDA for taliglucerase alfa for the treatment of Gaucher disease. 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;
- delay the regulatory-related milestone payments we anticipate receiving from Pfizer;
- 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 the NDA we filed for taliglucerase alfa or one or more of the NDAs we file in the future, if any, or we might not obtain regulatory clearance in a timely manner for taliglucerase alfa or any of our other product candidates. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain FDA approval of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues.

**The “fast track” designation for the development program of taliglucerase alfa for the treatment of Gaucher disease may not lead to a faster development or regulatory review or approval process.**

If a human medicine is intended for the treatment of a serious or life-threatening condition and the medicine demonstrates the potential to address unmet medical needs for this condition, the sponsor of an IND may apply for FDA “fast track” designation for a particular indication. Marketing applications submitted by sponsors of product candidates in fast track development may qualify for expedited FDA review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification. Although the FDA has granted fast track designation for taliglucerase alfa for the treatment of Gaucher disease, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures. In addition, the FDA may withdraw the fast track designation at any time. If the FDA withdraws the fast track designation of taliglucerase alfa, the approval process for taliglucerase alfa may be delayed. In addition, the fast track designation does not guarantee that taliglucerase alfa will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that taliglucerase alfa will receive regulatory approval for the treatment of Gaucher disease.

**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. Other than taliglucerase alfa, our drug candidates

are in early stages of preclinical studies or research stages. Other, ongoing clinical trials of taliglucerase alfa, and anticipated clinical trial of our other potential drug candidates which have not yet been initiated, 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 any clinical trial at any time if it appears that we are exposing participants in the trial 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 the trial. Any suspension of clinical trial may have a material adverse effect on our business, financial condition 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. Results of early clinical trials conducted on a small patient population 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, financial condition and results of operations.

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

Most of the diseases or disorders that our product candidates are intended to treat are relatively rare and we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Given that each of our product candidates other than taliglucerase alfa is in the early stages of preclinical or research stages, we may not be able to initiate 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 trials generally 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 entities, some of whom may compete with us. If our collaborators also assist our competitors, our competitive position could be harmed.

**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 but must be audited in connection with the NDA we submitted for

taliglucerase alfa. 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 taliglucerase alfa, 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. According to our license and supply agreement with Pfizer, Pfizer will be responsible for the fill and finish activities for taliglucerase alfa. Upon our receipt of marketing approval from the FDA or other regulatory authorities for taliglucerase alfa, if at all, we will rely primarily on Pfizer and/or other third-party contractors to perform the final manufacturing steps for taliglucerase alfa 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 taliglucerase alfa and our other potential drug candidates by the FDA or other regulatory authorities, or the commercialization of taliglucerase alfa 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 be able to commercialize taliglucerase alfa upon approval, if at all, in Israel, and to commercialize any of our other 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. In November 2009, we granted to Pfizer an exclusive, worldwide right to develop and commercialize taliglucerase alfa, but retained such rights in Israel. If we decide to market any of our products directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. 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 any of our products upon approval, if at all, and even if we do build a sales force, it may not be successful in marketing our products, which would have a material adverse effect on our business, financial condition and results of operations.

**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.**

The primary 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 taliglucerase alfa in Israel and other product candidates worldwide, 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, such as our license and supply agreement with Pfizer, 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. Any use of distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including the following:

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

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

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

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

We specifically face competition from companies with approved treatments of Gaucher disease, including Genzyme and to a much lesser extent, Actelion. In addition, we are aware of other early stage, experimental, small molecule, oral drugs which are being developed for the treatment of Gaucher disease by Amicus Therapeutics, a trial which Amicus Therapeutics reports has been suspended, and Genzyme. Shire plc is currently developing a gene-activated enzyme expressed in human cancer cells to treat Gaucher disease. Shire has submitted marketing applications in the United States, the European Union and Canada for its enzyme replacement therapy treatment for Gaucher disease. According to public reports by Shire, its application is being reviewed by the FDA under Priority Review with a PDUFA date of February 28, 2010 and the EMEA's Committee for Medicinal Products for Human Use has granted accelerated review for Shire's Marketing Authorization Application. We also face competition from companies with approved treatments of Fabry disease, including Genzyme and Shire, and we are aware of other early stage drugs which are being developed for the treatment of Fabry disease, including a drug being developed by Amicus Therapeutics.

We also face competition from companies that are developing other platforms for the expression of recombinant therapeutic pharmaceuticals. We are aware of companies that are developing alternative technologies to develop and produce therapeutic proteins in anticipation of the expiration of certain patent claims covering marketed proteins. Competitors developing



alternative expression technologies include Crucell N.V., Shire and GlycoFi Inc. (which was acquired by Merck). Other companies are developing alternate plant-based technologies, include Biolex, Inc., Chlorogen, Inc., Greenovation Biotech GmbH and Dow Agrosience.

Several biogeneric companies are pursuing the opportunity to develop and commercialize follow-on versions of other currently marketed biologic products, including growth factors, hormones, enzymes, cytokines and monoclonal antibodies, which are areas that interest us. These companies include, among others, Novartis AG/Sandoz Pharmaceuticals, BioGeneriX AG, 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, financial condition 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, 2009, we had 84 pending patent applications and held licensed rights to five pending patent applications. However, the filing of a patent application does not mean that we will be issued a patent, or that any patent eventually issued will be as broad as requested in the patent application or sufficient to protect our technology. Any modification required to a current patent application may delay the approval of such patent application which would have a material adverse effect on our business and results of operations. In addition, there are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications to not be granted, including known or unknown prior art, deficiencies in the patent application or the lack of originality of the technology.

Our competitive position and future revenues will depend in part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We have filed U.S. and international patent applications for process patents, as well as composition of matter patents, for taliglucerase alfa. 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.

As of December 31, 2009, we hold, or have license rights to, 22 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 U.S. 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 the intellectual property. 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 seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

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

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

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

We have not received to date any claims of infringement by any third parties. However, as our drug candidates progress into clinical trials and commercialization, if at all, our public profile and that of our drug candidates may be raised and generate such claims. Defending against such claims, and occurrence of a judgment adverse to us, could result in unanticipated costs and may have a material adverse effect on our business and competitive position. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we may 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, financial condition 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, or Yissum, the technology transfer arm of the Hebrew University of Jerusalem, Israel, and the Boyce Thompson Institute for Plant Research, at Cornell University, we have received an exclusive worldwide right and license to certain technology, including patents and additional patent applications relating to acetylcholinesterase (AChE), for all therapeutic and prophylactic indications as well as an exclusive license not limited to such indications with respect to certain of these patents and patent applications. Under the agreement with Yissum, we intend to develop a proprietary plant cell-based acetylcholinesterase (AChE) and its molecular variants for the use in several therapeutic and prophylactic indications, including a biodefense program. Our license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. All of these agreements last either throughout the life of the patents that are the subject of the agreements, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

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

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

In addition to our own internally developed drug candidates, we proactively seek opportunities to in-license and advance other drug candidates that are strategic and have value-creating potential to take advantage of our development know-how and technology. If we in-license any additional drug candidates, our capital requirements may increase significantly. In addition, in-licensing additional drug candidates may place a strain on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing drug candidates or cause us to re-prioritize our drug pipeline if we do not have the necessary capital resources to develop all of our drug candidates, which may delay the development of our drug candidates and negatively impact our business, results of operations and financial condition.

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

We have grown rapidly and expect to continue to grow. We expect to hire more employees, particularly in the areas of drug development, manufacturing, 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. 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 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 our 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 demand 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 \$5.0 million per occurrence and \$5.0 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, financial condition 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, financial condition 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. Except with respect to taliglucerase alfa, we have not commenced efforts to have our product candidates reimbursed by government or third-party payors. If reimbursement is not available or is available only to limited levels, the sales of our products, if approved may be diminished or we may not be able to sell such products profitably.

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

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the U.S. healthcare system have been introduced or proposed in the U.S. 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, if approved. 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. If our facilities are damaged as a result of hostile action, our operations may be materially adversely affected.

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

Many of our male employees in Israel, including members of senior management, are obligated to perform up to one month (in some cases more) of annual military reserve duty until they reach the age of 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 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 OCS. We, therefore, must comply with the requirements of the Israeli Law for the Encouragement of Industrial Research and Development, 1984, and related regulations, or the Research Law.

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

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

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

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

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

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

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

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

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

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

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

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

- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- results of our ongoing studies regarding our lead product candidate taliglucerase alfa, or communications from the FDA or other regulatory authorities regarding our NDA for taliglucerase alfa or similar filings;
- 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, stock markets in general, and the market for biotechnology companies in particular, have 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.

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

The market price of our common stock could drop significantly if our existing shareholders sell a large number of shares of our common stock or are perceived by the market as intending to sell them. All of the shares sold in our public offering in October 2007 were freely tradable without restriction or further registration under the federal securities laws, unless purchased by our “affiliates” as that term is defined in Rule 144 under the Securities Act. In addition, all of the outstanding shares of our common stock are freely tradable without restriction or further registration under the federal securities laws, unless owned by our affiliates. At December 31, 2009, there were options issued and outstanding to purchase 6,805,421 shares of our common stock with a weighted average exercise price of \$2.89 per share. Also at December 31, 2009, there were 1,433,623 shares of common stock remaining available for future for issuance in connection with future grants of incentives under our 2006 Stock Incentive Plan.

**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 38% 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 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 Amex 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. 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 U.S. 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**

None.

**Item 2. Properties**

Our manufacturing facility and executive offices are located in Carmiel, Israel. The facilities currently contain approximately 15,000 sq/ft of manufacturing space and additional 40,000 sq/ft of laboratory, warehouse and office space and are leased at a rate of approximately \$63,000 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. We have leased the facility through 2017, subject to three options exercisable by us to extend the term for a five-year period, for an aggregate of 15 additional years. Upon the exercise of each option to extend the term of the 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, 2009, the following matters were voted on by our shareholders: (i) the election of nine 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, 2009. The results of such shareholder votes are as follows:

**(i) Election of Directors**

	For	Withheld
Eli Hurvitz	46,816,221	260,960
David Aviezer, Ph.D., MBA	47,064,250	12,931
Yoseph Shaaltiel, Ph.D.	46,858,832	218,349
Alfred Akirov	46,941,083	136,098
Amos Bar Shalev	46,565,514	511,667
Zeev Bronfeld	45,584,634	1,492,547
Yodfat Harel Gross	46,662,025	415,156
Roger D. Kornberg, Ph.D.	46,859,840	217,341
Eyal Sheratzky	47,061,035	16,146

(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, 2009.

For	Against	Abstain
46,945,171	129,176	2,834
46		

## PART II

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

Our common stock is traded on the NYSE Amex under the symbol PLX. The following table sets forth the quarterly sales price ranges of our common stock for the periods indicated, as reported by the NYSE Amex.

Quarter Ended	2009		2008	
	High	Low	High	Low
March 31	\$ 2.99	\$1.74	\$3.59	\$2.60
June 30	\$ 5.29	\$2.00	\$3.70	\$2.56
September 30	\$ 8.49	\$4.49	\$3.06	\$2.08
December 31	\$12.50	\$6.37	\$2.17	\$0.96

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

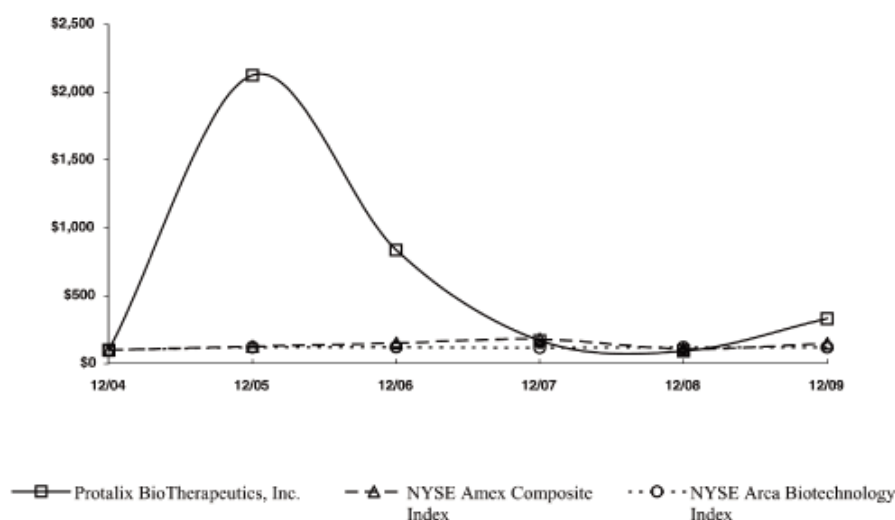
There were approximately 40 holders of record of our common stock at February 15, 2010. A substantially greater number of holders of our common stock are “street name” or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions. To date, we have not declared or paid any cash dividends on our common stock. We do not anticipate paying any dividends on our common stock in the foreseeable future.

### STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total shareholder return data for our common stock from December 31, 2004 through December 31, 2009 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, 2004 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 from December 31, 2004 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 AMEX on March 12, 2007.*

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***  
Among Protalix BioTherapeutics, Inc., The NYSE Amex Composite Index  
and The NYSE Arca Biotechnology Index



\*\$100 invested on 12/31/04 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.

Between October 30, 2007 and December 31, 2009, we have used approximately \$43.7 million of the net proceeds to fund our operating activities, including activities related to the development of our clinical and preclinical product candidates and for working capital, capital expenditures and other general corporate purposes. During the year ended December 31, 2009, our research and development expenses comprised approximately 78% of our operating expenses. We have deposited the net proceeds of the offering in accordance with our investment policy in short-term bank-deposits. There has been no material change in our planned use of proceeds from our public offering as described in our registration statement.

**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, 2009, 2008 and 2007 and for the period from December 27, 1993 through December 31, 2009 and the selected consolidated balance sheet data as of December 31, 2009 and 2008, 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, 2005 and 2006 and the balance sheet data as of December 31, 2005, 2006 and 2007 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,				
	2005	2006	2007	2008	2009
<i>(in thousands, except share and per share amounts)</i>					
<b>Consolidated Statement of Operations Data:</b>					
Revenues	\$ 150	—	—		\$ 388
Cost of revenues	35	—	—		1,625
Gross profit (loss)	115	—	—		(1,237)
Research and development expenses, net	3,773	\$ 5,246	\$ 13,570	\$ 17,401	\$ 23,588
General and administrative expenses	2,131	4,525	20,594	6,770	7,144
Finance expense (income)	(43)	(344)	(2,080)	(1,757)	(529)
Net loss before change in accounting principle	\$ 5,746	\$ 9,427	\$ 32,084	\$ 22,414	\$ 31,440
Cumulative effect of change in accounting principle	—	(37)	—	—	—
Net loss	\$ 5,746	\$ 9,390	\$ 32,084	\$ 22,414	\$ 31,440
Net loss per share of common stock, basic and diluted (1)	\$ 0.31	\$ 0.32	\$ 0.48	\$ 0.30	\$ 0.41
Weighted average number of shares of common stock used in computing net loss per share of common stock (2)	18,801,527	29,300,987	67,187,329	75,890,633,344	76,942,840
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 4,741	\$ 15,378	\$ 61,813	\$ 42,596	\$ 81,266
Other assets	2,484	11,610	6,324	8,215	17,405
Total assets	7,225	26,988	68,137	50,811	98,671
Current liabilities	845	2,268	3,762	5,527	21,530
Liabilities	1,130	2,704	4,452	6,464	82,788
Shareholders’ equity	6,095	24,284	63,685	44,347	15,838

\* Represents less than \$1.

- (1) 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.
- (2) 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, as applicable.

## **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.*

### **Overview**

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx™ protein expression system, or ProCellEx. 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 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 (taliglucerase alfa) 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. Taliglucerase alfa 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 U.S. Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of taliglucerase alfa, through the FDA's special protocol assessment (SPA) process. The phase III clinical trial was completed in September 2009 and, on October 15, 2009, we announced positive top-line results from the trial. On December 9, 2009, we filed our New Drug Application (NDA) for taliglucerase alfa, and in January 2010 the FDA requested additional data regarding the Chemistry, Manufacturing and Controls (CMC) section of our NDA. No additional clinical or preclinical information was requested. The request focused primarily on the validation of the manufacturing process in our upgraded manufacturing facility. A validation plan for our manufacturing process of taliglucerase alfa has already been established and reviewed by the FDA. We are working diligently to provide the requested data to the FDA and anticipate submitting the requested data during the second quarter of 2010. In addition, we expect to submit similar applications with other comparable regulatory agencies in other countries during 2010.

In addition to our recently completed phase III clinical trial, during the third quarter of 2008, we initiated a double-blind, follow-on extension study as part of the trial. We also initiated a home care treatment program for patients enrolled in the extension study and in December 2008, we initiated a clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with taliglucerase alfa. 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 taliglucerase alfa. In December 2009 we filed a proposed pediatric investigation plan to the Pediatric Committee of the EMEA.

On November 30, 2009, Protalix Ltd. and Pfizer entered into an exclusive license and supply agreement pursuant to which Pfizer was granted an exclusive, worldwide license to develop and commercialize taliglucerase alfa. Under the terms and conditions of the Pfizer agreement, Protalix Ltd. retained the right to commercialize taliglucerase alfa in Israel. In connection with the execution of the Pfizer agreement, Pfizer made an upfront payment to Protalix Ltd. of \$60.0 million in connection with the execution of the agreement and subsequently paid to Protalix Ltd. an additional \$5.0 million upon our filing of a proposed pediatric investigation plan to the Pediatric Committee of the EMEA. Protalix Ltd. is also eligible to receive potential milestone payments exceeding \$50.0 million for the successful achievement of other developmental milestones and to royalties equal to 40% of the net profits earned on Pfizer's sales of taliglucerase alfa. Pfizer and Protalix Ltd. have agreed to a specific allocation of the responsibilities for the continued development efforts for taliglucerase alfa.



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 taliglucerase alfa. Since we do not generate significant revenue from any of our product candidates, we expect to continue to generate losses in connection with the continued clinical development of taliglucerase alfa 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, taliglucerase alfa, and to further develop the research and clinical development of our other programs.

### **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 we have 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.

### **Revenues**

We have applied guidance regarding Accounting for Revenue Arrangements with Multiple Deliverables in connection with our receipt of revenues. In accordance with the guidance, we determined that the various deliverables due from us under our license and supply agreement with Pfizer represent separate units of accounting for revenue recognition purposes. The initial, non-refundable upfront license fee payment of \$60.0 million together with the first \$5.0 million milestone will be recognized on a straight line basis as revenue over the estimated relationship period. We have estimated that the performance period under the agreement with Pfizer will be 14 years based on our last relevant patent to expire.

Our deliverables under the agreement with Pfizer primarily include an exclusive license to taliglucerase alfa as an enzyme replacement therapy for the treatment of Gaucher disease, the manufacture of taliglucerase alfa, the performance of certain research and development services as required under the agreement and participation in a joint steering committee. The \$60.0 million up-front payment and the subsequent \$5.0 million milestone payment were recorded as deferred revenue. These amounts will be amortized over the performance period at a rate of approximately \$1.1 million per fiscal quarter, with \$388,000 recorded as revenues in 2009.

### **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;

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- 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
taliglucerase alfa for the treatment of Gaucher disease	NDA Filed	PDUFA date
PRX 102 — alpha Galactosidase enzyme	Pre Clinical	Pre IND meeting with FDA
Acetylcholinesterase	Pre Clinical	IND approval and initiation of phase I clinical trial
pr-antiTNF	Research	Additional animal studies

All of our projects, other than our recently completed phase III clinical trial of taliglucerase alfa, are in the pre clinical or research phase with relatively immaterial costs. Most of our research and development costs were incurred in connection with our phase III clinical trial of taliglucerase alfa. 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 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 taliglucerase alfa 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. We filed a New Drug Application, or NDA, for taliglucerase alfa 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.

### ***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.

In accordance with the guidance, 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 measure 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. We recognize such value as expense over the service period, net of estimated forfeitures, using the accelerated method.

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 Amex on the date of calculation.

The guidance 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, 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.

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 the lack of profitability, dividends are not expected in the foreseeable future, if at all. The guidance 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 with no significant revenues. 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. The guidance 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, 2009 Compared to the Year Ended December 31, 2008***

#### *Revenues*

We recorded revenue of \$388,000 during the year ended December 31, 2009. The revenue represents the pro rata amortization of the \$60.0 million upfront payment and \$5.0 million milestone payment we received in connection with our license and supply agreement with Pfizer. The payments were recorded as deferred revenue and the amounts will be amortized over the performance period, estimated at approximately 14 years, at a rate of approximately \$1.1 million per quarter. No revenues were recorded during the year ended December 31, 2008.

#### *Research and Development Expenses*

Research and development expenses were \$27.4 million for the year ended December 31, 2009, an increase of \$5.3 million, or 24%, from \$22.1 million for the year ended December 31, 2008. The increase resulted primarily from an increase of \$1.2 million in development expenses related to salaries for personnel involved in research and development, and \$2.2 million in related subcontractors and consultants expenses, mainly in connection with our phase III clinical trial of taliglucerase alfa. The increase in research and development expenses was further increased by the recognition of grants equal to \$3.8 million from the OCS during 2009, a decrease of approximately \$912,000, or 19%, compared to the recognition of grants equal to \$4.7 million during 2008.

We expect research and development expenses to continue to be our primary expense as we enter into a more advanced stage of pre clinical trials for certain of our product candidates and into clinical trials for our AChE program.

#### *General and Administrative Expenses*

General and administrative expenses were \$7.1 million for the year ended December 31, 2009, an increase of \$374,000, or approximately 6.0%, from \$6.8 million for the year ended December 31, 2008. The increase resulted primarily from a \$543,000 increase in salaries expenses during 2009.

#### *Financial Expenses and Income*

Financial income was \$529,000 for the year ended December 31, 2009, a decrease of \$1.2 million, or approximately 70.0%, compared to \$1.8 million for the year ended December 31, 2008. The decrease resulted primarily from a lower interest rate for deposits in 2009 which contributed to lower financial income during 2009.

### ***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 taliglucerase alfa. 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 taliglucerase alfa.

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### *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.

### **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. Furthermore, on November 30, 2009, we entered into an exclusive license and supply agreement with Pfizer, pursuant to which Pfizer made an upfront payment to Protalix Ltd. of \$60.0 million in connection with the execution of the agreement and subsequently paid to Protalix Ltd. an additional \$5.0 million upon meeting a certain milestone. Protalix Ltd. is also eligible to receive potential milestone payments of up to \$50.0 million for the successful achievement of other regulatory-related milestones. We are also entitled to payments equal to 40% of the net profits earned by Pfizer on its sales of taliglucerase alfa, if any. In calculating net profits there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold. We believe that the funds currently available to us as are sufficient to satisfy our capital needs for the foreseeable future.

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 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.

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### *Cash Flows*

Net cash provided from operations was \$44.5 million for the year ended December 31, 2009. The net loss for 2009 of \$31.4 million was reversed by \$65.0 million received under the license and supply agreement with Pfizer. Such reversal was partially offset by non-cash charges for share-based compensation of \$2.7 million, and depreciation of \$2.0 million. Net cash used in investing activities for 2009 was \$6.2 million and consisted primarily of purchases of property and equipment. Net cash provided from financing activities for 2009 was approximately \$293,000 due to option exercise.

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.

### *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 our preparation for the commercial phase for our lead product candidate, taliglucerase alfa. In addition, we are working on the expansion of our manufacturing facility that would meet approximately half of the market for our lead product candidate, which would increase our capital expenditures significantly, the first phase of which has commenced in the first quarter of 2010 and estimated to cost approximately \$20.0 million in total.

We believe that our existing cash and cash equivalents and the regulatory milestone payments we anticipate receiving from Pfizer will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for the foreseeable future. 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 may need to finance our future cash needs through public or private equity offerings, debt financings, or additional corporate collaboration and licensing arrangements. We currently do not have any commitments for future external funding, other than the potential regulatory-related milestone payments from Pfizer. 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 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, 2007, 2008 or 2009.

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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, 2007, 2008 or 2009.

### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2008 and 2009. See Note 4 of the consolidated financial statements for a full description of certain contingent royalty payments.

### Recently Issued Accounting Pronouncements

In May 2009, the Financial Accounting Standards Board, or FASB, issued ASC Topic 855 “Subsequent Events” (formerly SFAS No. 165, Subsequent Events). ASC 855 sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. ASC 855 is effective for interim or annual periods ending after June 15, 2009. We adopted the provisions of ASC 855 for the quarter ended June 30, 2009. The adoption of ASC 855 did not have a material impact on our condensed financial statements.

In June 2009, the FASB issued Accounting Standards Update, “Topic 105 — Generally Accepted Accounting Principles” which amended ASC 105 “The FASB Accounting Standards Codification” and the Hierarchy of Generally Accepted Accounting Principles (formerly SFAS No. 168 “The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles – A Replacement of FASB Statement No. 162”). ASU 2009-1 establishes the FASB Accounting Standards Codification™ (Codification) as the single source of authoritative U.S. generally accepted accounting principles (U.S. GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. ASU 2009-1 and the Codification are effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification supersedes all existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. The FASB will no longer issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts. Instead, the FASB will issue Accounting Standards Updates, which will serve only to: (a) update the Codification; (b) provide background information about the guidance; and (c) provide the bases for conclusions on the change(s) in the Codification. The adoption of ASU 2009-1 did not have a material impact on our financial statements.

### Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2009:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	\$ 4,695	\$ 1,136	\$ 2,038	\$ 1,521	—
Purchase obligations (1)	\$ 5,419	\$ 5,419	—	—	—
Certain Clinical contract obligations	\$ 3,693	\$ 2,954	\$ 739	—	—
Other long term liabilities reflected on the balance sheet under GAAP	\$ 1,209	—	—	—	\$ 1,209
Total	<u>\$ 15,016</u>	<u>\$ 9,510</u>	<u>\$ 2,777</u>	<u>\$ 1,521</u>	<u>\$ 1,209</u>

- (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, 2009.



Selected Quarterly Financial Data (unaudited)

	Three Months Ended							
	2008				2009			
	(U. S. dollars in thousands)							
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31
Revenues	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 388
Net loss	\$ 5,113	\$ 4,229	\$ 6,496	\$ 6,576	\$ 5,183	\$ 5,427	\$ 5,894	\$ 14,936
Net loss per share of common stock, basic and diluted	\$ 0.07	\$ 0.06	\$ 0.09	\$ 0.09	\$ 0.07	\$ 0.07	\$ 0.08	\$ 0.19

**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 have 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,		
	2007	2008	2009
Average rate for period	4.1081	3.5878	3.933
Rate at year-end	3.8460	3.8020	3.775

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 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.

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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.

### **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, 2009, 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 has audited management's assessment of our internal control over financial reporting, and issued an unqualified opinion dated February 25, 2010 on such assessment and on our internal control over financial reporting, which opinion is included herein.

### **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, 2009 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

Our directors and executive officers, their ages and positions as of February 15, 2010, are as follows:

Name	Age	Position
<b>Directors</b>		
Eli Hurvitz	77	Chairman of the Board
David Aviezer, Ph.D., MBA	45	Director, President and Chief Executive Officer
Yoseph Shaaltiel, Ph.D.	56	Director and Executive VP, Research and Development
Alfred Akirov (1)(2)(3)	69	Director
Amos Bar Shalev (1)(2)(3)	57	Director
Zeev Bronfeld	58	Director
Yodfat Harel Gross (1)(2)(3)	37	Director
Roger D. Kornberg, Ph.D.	62	Director
Eyal Sheratzky	41	Director
<b>Executive Officers</b>		
Einat Brill Almon, Ph.D.	50	Vice President, Product Development
Yossi Maimon, CPA	39	Vice President, Chief Financial Officer, Treasurer and Secretary
Sandra L Lauterbach	41	Vice President, Sales and Commercial Affairs

- 
- (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 (TASE:TEVA; NASDAQ:TEVA) since April 2002. Previously, he served as Teva's President and Chief Executive Officer for over 25 years and has been involved with Teva in various capacities for over 40 years. Mr. Hurvitz is an experienced veteran of the pharmaceutical industry. In addition, he currently 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 15 years 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 which was subsequently acquired by Pfizer (NYSE:PFE), in New York. Since 1996, Dr. Aviezer has served as an Adjunct Lecturer at Bar Ilan 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 MBA 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.

**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 serve on the board. 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. (TASE:BCEL), 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. (TASE:DMDC), and Biomedix Incubator Ltd. (TASE:BMDX), 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., Macrocare 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. (NASDAQ:ORBK), 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. Professor Kornberg is a renowned biochemist and in 2006 he 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.

**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 (NASDAQ:ITRN), 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.

**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.

**Sandra L. Lauterbach.** Ms. Lauterbach has served as our Vice President, Sales and Commercial Affairs since December 18, 2009. Prior to joining our company, Ms. Lauterbach was the Vice President of Marketing, Endocrinology of EMD Serono, Inc., from July 2008 through July 2009. Prior to that, from August 2003 through July 2008, she served in a number of positions at Genzyme Corporation, the last position being the Senior Director, Global Marketing for Fabrazyme. Ms. Lauterbach holds a B.Sc. in Molecular Biology from the University of Wisconsin and an MBA from the University of South Florida.

## **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. Shaaltiel, and Mr. Bar Shalev each filed a late Form 4 in connection with certain purchases of our common stock in 2009. Otherwise, we believe that all Section 16 filings requirements were met during 2009. 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 Audit Committee meet the current standard of requisite financial management expertise as required by the NYSE Amex and applicable rules and regulations of the SEC. Messrs. Bar-Shalev and Akirov, and Ms. Harel Gross have been appointed by the Board of Directors to serve on the Audit Committee until their respective successors have been duly elected.

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

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.



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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 Akirov qualify as "audit committee financial experts" under the applicable rules of the SEC. In making the determination as to these individuals' status as audit committee 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 Amex.

### **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](http://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 2009 took place during the first quarter of 2010. The base salaries of our Named Executive Officers are set forth in "Employment Arrangements."

On February 25, 2010, our Board of Directors, acting upon the resolution of a majority of our independent directors, resolved to increase for 2010 the monthly salaries of our Named Executive Officers at further described below.

**Annual Bonus.** The Compensation Committee has the authority to award discretionary annual bonuses to our executive officers. It has established a formal bonus plan for certain milestones expected to occur during 2010. 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 execution of license agreement for the commercialization of our lead product candidates, 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, unless such bonuses were specifically granted for a specific milestone achieved during the year which was payable immediately after the achievement of the milestone. 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 determined the discretionary annual bonus to be paid to our executive officers, and the discretionary bonus to be awarded to certain officers in 2010 for performance in 2009 and in 2008. The Compensation Committee elected to pay bonuses to the executive officers for their performance in 2008 as bonuses were not paid in 2009 due to the general market conditions and our cash balance at that time. 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.

On February 25, 2010, our Board of Directors, acting upon the resolution of a majority of our independent directors, awarded a total of approximately \$2.6 million in bonuses to our executive officers, out of which approximately \$1.0 million is to be paid during the first quarter of 2010 for achievements for the years 2008 and 2009 including, among others, the execution of the license and supply agreement for the commercialization of our lead product candidate, the completion of our phase III clinical trial for our lead product candidate and the upgrade of our manufacturing facility. The remaining approximately \$1.5 million is to be paid upon, and subject to, the FDA's approval of taliglucerase alfa and upon the first shipment of taliglucerase alfa, if at all.

**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.

On February 25, 2010, our Board of Directors, acting upon the resolution of a majority of our independent directors, granted stock options to our President and 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 250,000, 145,000, 130,000 and 130,000, respectively. The options have an exercise price of \$6.90 per share and will vest quarterly over three years after the FDA's approval of taliglucerase alfa, if at all. 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 2009 and 2010.

**Severance and Change in Control Benefits.** Pursuant to the employment agreements entered into with each of our executive officers based in Israel, 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 Israel-based officers with severance protection of one month's salary for each year of employment. 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 Israel-based 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. In addition, in accordance with customary practice in Israel, our Israel-based 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 of the Annual Report on Form 10-K for information regarding the compensation earned during the fiscal year ended December 31, 2009 by:

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our President and Chief Executive Officer; our Executive Vice President, Research and Development; our Vice President, Product Development; and our Vice President and Chief Financial Officer, who we refer to collectively as the “Named Executive Officers.” There are no other executive officers for 2009 whose total compensation exceeded \$100,000 during that fiscal year other than the 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 our Annual Report on Form 10-K and our annual proxy statement on Schedule 14A.

Respectfully submitted on February 25, 2010, by the members of the Compensation Committee of the Board of Directors.

*Yodfat Harel Gross*

*Alfred Akirov*

*Amos Bar Shalev*

### Summary Compensation Table

The following table sets forth a summary for the fiscal years ended December 31, 2009 and 2008 respectively, of the cash and non-cash compensation awarded, paid or accrued by us or Protalix Ltd. to each of our President and Chief Executive Officer, our Executive Vice President, Research and Development, our Vice President, Product Development and our Vice President and Chief Financial Officer, who we refer to collectively as the “Named Executive Officers.” There were no restricted stock awards, long-term incentive plan payouts or other compensation paid during fiscal years 2009 and 2008 by us or Protalix Ltd. to the Named Executive Officers, except as set forth below. All of 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 Award(s) (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation \$(1)	Total (\$)
David Aviezer, Ph.D., MBA <i>President and Chief Executive Officer</i>	2009	427,970	500,000		529,951			62,167	1,520,088
	2008	486,305	—		565,394			93,224	1,144,923
	2007	341,074	239,210		351,343			67,990	999,617
Yoseph Shaaltiel, Ph.D. <i>Executive Vice President, Research and Development</i>	2009	196,271	160,000		225,336			37,981	619,588
	2008	226,652	—		163,328			54,704	444,684
	2007	117,297	50,000		2,420			47,339	277,056
Einat Brill Almon, Ph.D. <i>Vice President, Product Development</i>	2009	172,210	160,000		203,388			36,927	652,525
	2008	195,559	28,932		253,862			51,223	529,576
	2007	153,254	65,171		94,482			42,282	355,189
Yossi Maimon, CPA <i>Vice President, Chief Financial Officer</i>	2009	186,478	160,000		253,030			41,051	640,599
	2008	203,097	30,659		238,194			83,808	555,758
	2007	156,444	77,223		247,815			41,975	523,457

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

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The following table summarizes the grant of awards made to the Named Executive Officers during 2009 as of December 31, 2009.

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 (#) (1)	Exercise or Base Price of Option Awards (\$/Sh) (2)	Grant Date fair Value of Stock and Option Awards (\$)(3)
		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											

- (1) Represents outstanding options at December 31, 2009.
- (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, 2009.

Name	Option Awards					Stock Awards			
	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	326,267	—	—	0.120	8/1/2013	—	—	—	—
	855,135	122,162	—	0.972	9/10/2016	—	—	—	—
	200,001	399,999	—	5.00	2/7/2018	—	—	—	—
	100,000	—	—	2.65	2/25/2019	—	—	—	—
Yoseph Shaaltiel	244,324	—	—	0.001	6/30/2011	—	—	—	—
	87,910	175,818	—	5.00	2/7/2018	—	—	—	—
	50,000	—	—	2.65	2/25/2019	—	—	—	—
Einat Brill Almon	4,740	—	—	0.399	5/23/2016	—	—	—	—
	158,811	73,297	—	0.972	8/13/2016	—	—	—	—
	103,756	207,516	—	5.00	2/7/2018	—	—	—	—
	50,000	—	—	2.65	2/25/2019	—	—	—	—
Yossi Maimon	107,488	116,245	—	0.972	9/19/2016	—	—	—	—
	58,333	116,667	—	5.00	2/7/2018	—	—	—	—
	50,000	—	—	2.65	2/25/2019	—	—	—	—

Option exercises during 2009 and vested stock awards for Named Executive Officers as of December 31, 2009 were as follows:

### OPTION EXERCISES AND STOCK VESTED

Name (a)	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#) (b)	Value Received on Exercise(\$) (c)	Number of Shares Acquired on Vesting (#) (d)	Value Received on Vesting(\$) (e)
David Aviezer(1)	469,238-	—	—	—
Yossi Maimon(1)	251,890	—	—	—
Yoseph Shaaltiel	—	—	—	—
Einat Brill Almon(1)	185,000	—	—	—

(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

Each of our Named Executive Officers is entitled to be insured by Protalix Ltd. under a Manager's Policy in lieu of severance upon termination. The intention of such Manager's Policies is to provide the Israel-based officers with severance protection of one month's salary for each year of employment. We do not provide any change in control benefits to our Named Executive Officers except that their stock option agreements, as amended, provide that all of the outstanding options of each Named Executive Officers are subject to accelerated vesting immediately upon a change in control of our company as defined in our 2006 Stock Incentive Plan. If we had experienced a change of control on December 31, 2009, the value of the acceleration of the stock options held by each of Dr. Aviezer, Dr. Shaaltiel, Dr. Brill Almon and Mr. Maimon would be \$1.3 million, \$284,000, \$750,000 and \$846,000, respectively. For a discussion regarding the change of control under our 2006 Stock Incentive Plan, see "—2006 Stock Incentive Plan."

### 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 148,000 (approximately \$39,200) 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. In 2009, we granted Dr. Aviezer an option to purchase 100,000 shares of our common stock at an exercise price equal to \$2.65 per share. As of December 31, 2009, all of those options had fully vested. 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 85,000 (approximately \$22,500) 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. In 2009, we granted Dr. Shaaltiel an option to purchase 50,000 shares of our common stock at an exercise price equal to \$2.65 per share. As of December 31, 2009, all of those options had fully vested. 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 73,500 per month (approximately \$19,500). 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. In 2009, we granted to Dr. Brill Almon an option to purchase 50,000 shares of our common stock at an exercise price equal to \$2.65 per share. As of December 31, 2009, all of those options had fully vested. 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 73,500 (approximately \$19,500) 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. In 2009, we granted to Mr. Maimon an option to purchase 50,000 shares of our common stock at an exercise price equal to \$2.65 per share. As of December 31, 2009, all of those options had fully vested. 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.

**Sandra L. Lauterbach.** Ms. Lauterbach joined our company as our Vice President, Sales and Commercial Affairs, pursuant to an employment agreement effective December 18, 2009. Pursuant to the employment agreement, Ms. Lauterbach's annual base salary is \$180,000 and we may elect to pay her an annual discretionary bonus in an amount and based upon criteria determined by either the Compensation Committee of our Board of Directors, or the entire Board of Directors, at their sole discretion. She is also entitled to certain health care insurance benefits and contributions to retirement plans, and allowances for car and cell phone expenses. In connection with the employment agreement, the Board of Directors granted to Ms. Lauterbach stock options to purchase 160,000 shares of our common stock at an exercise price equal to \$6.81. The options vest over a period of four years, with 25% of the options vesting upon the lapse of one year from the date of grant and the remainder of the options vesting on a quarterly basis in 12 equal installments, commencing on the initial vesting date. The unvested portion of the option will vest automatically upon a change of control of our company. 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.

## **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 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 25, 2010, options to acquire 230,000 of common stock remain available for grant 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,” administers 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.

If 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;



- 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

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 non-employee directors during fiscal year 2009. 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.

Name	Fees Earned or Paid in Cash (\$)	Stock Award (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compen- sation Earnings (\$)	All Other Compen- sation (\$)	Total (\$)
<b>Current Directors</b>							
Eli Hurvitz(1)	33,000	—	—	—	—	—	33,000
Alfred Akirov	33,000	—	—	—	—	—	33,000
Amos Bar Shalev	33,000	—	—	—	—	—	33,000
Zeev Bronfeld	33,000	—	—	—	—	—	33,000
Yodfat Harel Gross	33,000	—	—	—	—	—	33,000
Roger D. Kornberg	33,000	—	—	—	—	—	33,000
Eyal Sheratzky	33,000	—	—	—	—	—	33,000
Sharon Toussia-Cohen(2)	11,000	—	—	—	—	—	11,000

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

(2) Mr. Toussia-Cohen resigned from our Board of Directors on May 10, 2009.

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. Akirov and Bar Shalev and Ms. Harel Gross, who were appointed to the Committee during 2009. In addition, until May 10, 2009, 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 February 15, 2010, 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
- 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 February 15, 2010 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
<b>Board of Directors and Executive Officers</b>		
Eli Hurvitz	455,240	*%
David Aviezer, Ph.D., MBA	1,609,155 (1)	2.0
Yoseph Shaaltiel, Ph.D.	1,573,828 (2)	1.9
Alfred Akirov	6,186,046 (3)	7.7
Amos Bar Shalev	—	—
Zeev Bronfeld	14,466,319 (4)	17.9
Yodfat Harel Gross	—	—
Roger D. Kornberg, Ph.D.	21,875 (5)	*
Eyal Sheratzky	—	—
Einat Brill Almon, Ph.D.	278,590 (6)	*
Yossi Maimon	312,761 (7)	*
Sandra L. Lauterbach	— (8)	—
All executive officers and directors as a group (12 persons)	24,903,814 (9)	29.7
<b>5% Holders</b>		
Biocell Ltd.	14,466,319 (10)	17.9
Techno-Rov Holdings (1993) Ltd.	6,186,046 (11)	7.7
FMR LLC	4,193,555 (12)	5.4
Frost Gamma Investment Trust	7,188,132 (13)	8.9

\* less than 1%.

- (1) Consists of 1,609,155 shares of our common stock issuable upon exercise of outstanding options within 60 days of February 15, 2010. Does not include 394,049 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of February 15, 2010.
- (2) Consists of 1,363,754 shares of our common stock held by Dr. Shaaltiel and 210,074 shares of our common stock issuable upon exercise of outstanding options within 60 days of February 15, 2010. Does not include 225,816 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of February 15, 2010.

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- (3) 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.
- (4) 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.
- (5) Consists of 21,875 shares of our common stock issuable upon exercise of outstanding options within 60 days of February 15, 2010. Does not include 28,125 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of February 15, 2010.
- (6) Consists of 278,590 shares of our common stock issuable upon exercise of outstanding options within 60 days of February 15, 2010. Does not include 319,530 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of February 15, 2010.
- (7) Consists of 312,761 shares of our common stock issuable upon exercise of outstanding options within 60 days of February 15, 2010. Does not include 135,972 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of February 15, 2010.
- (8) Does not include 160,000 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of February 15, 2010.
- (9) Consists of 22,471,359 shares of our common stock and 2,432,455 shares of our common stock issuable upon exercise of options within 60 days of February 15, 2010. Does not include 1,103,852 shares of common stock issuable upon exercise of outstanding options that are not exercisable within 60 days of February 15, 2010.
- (10) 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.
- (11) 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.
- (12) Based solely on a Schedule 13G filed by FMR LLC on February 12, 2010, reporting the above stock ownership as of December 31, 2009. FMR LLC reports that it has the sole power to dispose or to direct the disposition of 4,193,555 shares of common stock. The address is 82 Devonshire Street, Boston, MA 02109.
- (13) 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.

## Equity Compensation Plan Information

The following table provides information as of December 31, 2009 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	6,173,555	\$ 2.13	1,433,623
Equity Compensation Plans Not Approved by Shareholders	631,866	\$ 10.24	—
Total	6,805,421	\$ 2.89	1,433,623

## 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 Directors and the entire Board of Directors, as applicable. For 2010, 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. The agreement provides that we will collaborate with Teva on the research and development of two proteins using ProCellEx. Subsequently, two proteins were identified to be researched and developed under the agreement but in 2009, both of the projects were terminated for commercial reasons. Protalix Ltd. has granted to Teva an exclusive license to commercialize any 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**

In compliance with the listing requirements of the NYSE Amex, 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 Amex. 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 Amex 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 any of our subsidiaries, or was an employee of our company or any of 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;

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- 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 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. Akirov and Bar-Shalev and Ms. Harel Gross are considered "independent" pursuant to the rules of the NYSE Amex 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 and Sheratzky, Ms. Harel Gross and Dr. Kornberg are "independent" pursuant to the rules of the NYSE Amex.

The position of chairman of the board is not held by our chief executive officer at this time. The Board of Directors does not have a policy mandating the separation of these functions. However, when Mr. Hurvitz joined our company in 2005, the Board of Directors at that time determined that it was in our best interest that Mr. Hurvitz serve as the chairman of the board. This decision was based on Mr. Hurvitz's vast experience in the pharmaceutical industry in Israel and globally. 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, Aviezer and Shaaltiel, and Ms. Harel Gross, attended our 2009 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, 2009 and 2008 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,	
	2009	2008
Audit Fees	\$259,000	\$249,000
Audit Related Fees	\$ 78,039	\$ 49,000
Tax Fees	\$197,282	\$ 76,000
All Other Fees	\$ —	\$ —

**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 2009 audit fees. For fiscal year 2010, our Audit Committee has approved fees for certain services to be rendered by our independent registered accounting firm.

## 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:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2008, and 2009	F-3
Consolidated Statements of Operations for the years ended December 31, 2007, 2008, and 2009	F-4
Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2007, 2008, and 2009	F-5
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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*.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Method of Filing</u>
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
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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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Method of Filing</b>
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 Yisum 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.
10.16†	Exclusive License and Supply Agreement dated as of November 30, 2009 between Protalix Ltd. and Pfizer Inc.	Filed herewith
10.17	Employment Agreement by and between the Company and Sandra Lauterbach dated as of December 17, 2009	Incorporated by reference to our Current Report on Form 8-K filed on December 22, 2009
21.1	Subsidiaries	Filed herewith

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Method of Filing</b>
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
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.

## 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 February 25, 2010.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ David Aviezer</u> David Aviezer, Ph.D.	President, Chief Executive Officer (Principal Executive Officer) and Director	February 25, 2010
<u>/s/ Yossi Maimon</u> Yossi Maimon	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	February 25, 2010
<u>/s/ Yoseph Shaaltiel</u> Yoseph Shaaltiel, Ph.D.	Executive VP, Research and Development and Director	February 25, 2010
<u>/s/ Alfred Akirov</u> Alfred Akirov	Director	February 25, 2010
<u>/s/ Amos Bar Shalev</u> Amos Bar Shalev	Director	February 25, 2010
<u>/s/ Zeev Bronfeld</u> Zeev Bronfeld	Director	February 25, 2010
<u>/s/ Yodfat Harel Gross</u> Yodfat Harel Gross	Director	February 25, 2010

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Signature	Title	Date
/s/ Eyal Sheratzky Eyal Sheratzky	Director	February 25, 2010
/s/ Roger D. Kornberg Roger D. Kornberg, Ph.D.	Director	February 25, 2010
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**PROTALIX BIOTHERAPEUTICS, INC.**  
**CONSOLIDATED FINANCIAL STATEMENTS**

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The dollar amounts are stated in U.S. dollars (\$)

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the shareholders of

**PROTALIX BIOTHERAPEUTICS, INC.**

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 subsidiaries at December 31, 2008 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, 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 integrated audits. 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.

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  
February 25, 2010

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

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

	<b>December 31,</b>	
	<b>2008</b>	<b>2009</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 42,596	\$ 81,266
Accounts receivable	793	2,144
Total current assets	<u>43,389</u>	<u>83,410</u>
<b>FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT</b>	581	724
<b>PROPERTY AND EQUIPMENT, NET</b>	<u>6,841</u>	<u>14,537</u>
Total assets	<u>\$ 50,811</u>	<u>\$ 98,671</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accruals:		
Trade	\$ 2,235	\$ 3,406
Other	3,292	13,561
Deferred revenues	—	4,563
Total current liabilities	<u>5,527</u>	<u>21,530</u>
<b>LONG TERM LIABILITIES:</b>		
Deferred revenues		60,049
Liability for employee rights upon retirement	937	1,209
Total long term liabilities	<u>937</u>	<u>61,258</u>
<b>COMMITMENTS</b>		
Total liabilities	<u>6,464</u>	<u>82,788</u>
<b>SHAREHOLDERS' EQUITY:</b>		
Common Stock, \$0.001 par value:		
Authorized — as of December 31, 2008 and 2009, 150,000,000 shares; issued and outstanding — as of		
December 31, 2008 and 2009, 75,938,059 and 80,841,237 shares, respectively	76	81
Additional paid-in capital	119,281	122,252
Accumulated deficit	(75,010)	(106,450)
Total shareholders' equity	<u>44,347</u>	<u>15,883</u>
Total liabilities and shareholders' equity	<u>\$ 50,811</u>	<u>\$ 98,671</u>

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

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

	Year ended December 31,		
	2007	2008	2009
<b>REVENUES</b>	\$ —	\$ —	\$ 388
<b>ROYALTIES EXPENSES</b>	—	—	3,575
	—	—	3,187
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>	14,641	22,115	\$ 27,390
Less — grants	(1,071)	(4,714)	(5,752)
	13,570	17,401	21,638
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	20,594	6,770	7,144
<b>OPERATING LOSS</b>	34,164	24,171	31,969
<b>FINANCIAL INCOME — NET</b>	(2,080)	(1,757)	(529)
<b>NET LOSS FOR THE YEAR</b>	<u>\$ 32,084</u>	<u>\$ 22,414</u>	<u>\$ 31,440</u>
Net loss per share of common stock — basic and diluted:	<u>\$ 0.48</u>	<u>\$ 0.30</u>	<u>\$ 0.41</u>
Weighted average number of shares of common stock used in computing loss per share of common stock, basic and diluted:	<u>67,187,329</u>	<u>75,890,633</u>	<u>76,942,840</u>

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



**PROTALIX BIOTHERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY**  
(U.S. dollars in thousands, except share data)

	<u>Common Stock Number of shares</u>	<u>Common Stock</u>	<u>Warrants</u>	<u>Additional paid-in Capital Amount</u>	<u>Accumulated deficit</u>	<u>Total</u>
<b>Balance at January 1, 2007</b>	<b>61,781,959</b>	<b>62</b>	<b>355</b>	<b>44,379</b>	<b>(20,512)</b>	<b>24,284</b>
<b>Changes during 2007:</b>						
Common Stock issued for cash (net of issuance costs of \$4,310) (see Note 5c)	10,000,000	10	—	45,680	—	45,690
Share-based compensation	—	—	—	20,437	—	20,437
Exercise of options granted to employees	110,064	*	—	14	—	14
Exercise of warrants	3,875,416	4	(355)	5,684	—	5,333
Restricted Common Stock issued for future services (1)	8,000	*	—	11	—	11
Net Loss	—	—	—	—	(32,084)	(32,084)
<b>Balance at December 31, 2007</b>	<b>75,775,439</b>	<b>76</b>	<b>—</b>	<b>116,205</b>	<b>(52,596)</b>	<b>63,685</b>
<b>Changes during 2008:</b>						
Restricted Common Stock issued for future services (1)	(5,333)	*	—	(3)	—	(3)
Share-based compensation			—	3,074	—	3,074
Exercise of options granted to employees (includes net exercise)	167,953	*	—	5	—	5
Net Loss	—	—	—	—	(22,414)	(22,414)
<b>Balance at December 31, 2008</b>	<b>75,938,059</b>	<b>76</b>	<b>—</b>	<b>119,281</b>	<b>(75,010)</b>	<b>44,347</b>
<b>Changes during 2009:</b>						
Share-based compensation			—	2,683	—	2,683
Exercise of options granted to employees and non-employees (includes net exercise)	4,903,178	5	—	288	—	293
Net Loss	—	—	—	—	(31,440)	(31,440)
<b>Balance at December 31, 2009</b>	<b>80,841,237</b>	<b>81</b>	<b>—</b>	<b>122,252</b>	<b>(106,450)</b>	<b>15,883</b>

\* Represents an amount less than \$1.

- (1) The Company issued a total of 8,000 shares of restricted Common Stock in consideration for services provided by, and to be provided by, a member of the Company's Scientific Advisory Board. Such services were terminated in October 2008 while the forfeiture provisions of the restricted stock were still in effect. Accordingly, 5,333 shares of the restricted Common Stock were forfeited. See Note 5d(2)(a)(1).

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

**PROTALIX BIOTHERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(U.S. dollars in thousands)

	Year ended December 31,		
	2007	2008	2009
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net Loss	\$ (32,084)	\$ (22,414)	\$ (31,440)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities:			
Share based compensation	20,448	3,071	2,683
Depreciation and impairment of fixed assets	759	1,301	1,990
Financial income net (mainly exchange differences)	(806)	(270)	(166)
Changes in accrued liability for employee rights upon retirement	254	247	265
Loss (Gain) on amounts funded in respect of employee rights upon retirement	(57)	39	(81)
Loss (Gain) on sale of fixed assets	(6)		29
Changes in operating assets and liabilities:			
Increase in deferred revenues (including non-current portion)			64,612
Decrease (increase) in accounts receivable	140	636	(1,224)
Increase in accounts payable and accruals	903	1,375	7,784
Net cash provided by (used in) operating activities	\$ (10,449)	\$ (16,015)	\$ 44,452
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	\$ (2,335)	\$ (3,371)	\$ (6,195)
Investment in restricted deposit	—	(175)	
Proceeds from sale of property and equipment	11	1	73
Amounts funded in respect of employee rights upon retirement, net	(114)	(156)	(52)
Net cash used in investing activities	\$ (2,438)	\$ (3,701)	\$ (6,174)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Issuance of shares and warrants, net of issuance cost	\$ 45,746	\$ (56)	
Exercise of options and warrants	12,924	5	\$ 293
Merger with a wholly-owned subsidiary of the Company, net of issuance cost	(104)		
Net cash provided by (used in) financing activities	\$ 58,566	\$ (51)	\$ 293
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH</b>	756	550	99
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	46,435	(19,217)	38,670
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR</b>	15,378	61,813	42,596
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<u>\$ 61,813</u>	<u>\$ 42,596</u>	<u>\$ 81,266</u>

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

**PROTALIX BIOTHERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(U.S. dollars in thousands)

(CONTINUED)

	Year ended December 31,		
	2007	2008	2009
<b>SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES</b>			
<b>NOT INVOLVING CASH FLOWS:</b>			
Purchase of property and equipment	\$ 666	\$ 932	\$ 4,525
Issuance cost not yet paid and accruals — other	\$ 61	\$ 5	\$ 5

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

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 1 — SIGNIFICANT ACCOUNTING POLICIES**

**a. General**

**1. Operation**

Protalix BioTherapeutics, Inc. and its wholly-owned subsidiary, Protalix Ltd. (the “Israeli Subsidiary” or “Protalix Ltd.,” and collectively with Protalix BioTherapeutics, Inc., the “Company”), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company’s proprietary ProCellEx™ protein expression system (“ProCellEx”). In September 2009, the Company formed another wholly-owned subsidiary under the laws of the Netherlands in connection with the EMEA application process in Europe. The Company’s lead product development candidate is taliglucerase alfa for the treatment of Gaucher disease (the brand name for which is UPLYSO™), which the Company is developing using its ProCellEx protein expression system.

In September 2009, the Company successfully completed its phase III pivotal trial of taliglucerase alfa. In December 2009, the Company filed a New Drug Application (“NDA”) submission with the U.S. Food and Drug Administration (“FDA”) for taliglucerase alfa for the treatment of Gaucher disease.

In addition to its phase III clinical trial, the Company initiated a clinical study in December 2008 to evaluate the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with taliglucerase alfa. This switchover-study is not a prerequisite for the marketing approval of taliglucerase alfa. In August 2009, the Company received Fast Track Designation for taliglucerase alfa, and in September 2009, the FDA’s Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status.

The Company has been in the development stage since its inception until November 2009 (see 2 below).

On November 30, 2009, Protalix Ltd. and Pfizer Inc. (“Pfizer”) entered into an Exclusive License and Supply Agreement (the “Pfizer Agreement”) pursuant to which Protalix Ltd. granted Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa, except in Israel. Under the terms and conditions of the Pfizer Agreement, Protalix Ltd. retained the right to commercialize taliglucerase alfa in Israel. See Note 9.

Successful completion of the Company’s development program and its transition to normal operations is dependent upon obtaining necessary regulatory approvals from the FDA prior to selling its products within the United States, and foreign regulatory approvals must be obtained to sell its products internationally. There can be no assurance that the Company will receive regulatory approval of any of its product candidates, and a substantial amount of time may pass before the Company achieves a level of sales adequate to support the Company’s operations, if at all. The Company will also incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during the developmental period. Obtaining marketing approval will be directly dependent on the Company’s ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. The Company cannot predict the outcome of these activities.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 1 — SIGNIFICANT ACCOUNTING POLICIES (continued):**

**2. The Merger**

On December 31, 2006, Protalix BioTherapeutics, Inc. (formerly Orthodontix, Inc.) consummated the acquisition of Protalix Ltd., a privately-held Israeli biotechnology company incorporated on December 27, 1993, by the merger (the “Merger”) of its wholly-owned subsidiary, Protalix Acquisition Co., Ltd., with Protalix Ltd. At and as of the Merger, the former shareholders of Protalix Ltd. received a number of shares of Common Stock equal to more than 99% of the outstanding shares of Common Stock. As a result, Protalix Ltd. is now the Company’s wholly-owned subsidiary. As of that date, for accounting purposes, the Merger was accounted for as a recapitalization of Protalix Ltd. Accordingly, the historical financial statements of the Company reflect the historical operations and financial statements of the Subsidiary before the Merger.

**3. Subsequent Events**

The Company has evaluated events through February 25, 2010, the date of issuance of the financial statements. See Note 10.

**b. Basis of presentation**

The Company’s financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”). Prior to December 2009, the Company was a development stage company as defined under the guidance for Development Stage Enterprises. Commencing November 2009, the Company ceased to consider itself a development stage company.

In June 2009, the Financial Accounting Standards Board (“FASB”) issued the FASB Accounting Standards Codification (“Codification” or “ASC”). The Codification became the single authoritative source for U.S. GAAP and changed the way in which the accounting literature is organized. The Codification does not change U.S. GAAP and accordingly its adoption did not have a material impact on the Company’s consolidated financial statements.

**c. Use of estimates in the preparation of financial statements**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

**d. Functional currency**

The dollar is the currency of the primary economic environment in which the operations of the Company and its Subsidiaries are conducted. The Company’s revenues are derived in dollars. Most of the Company’s expenses and capital expenditures are incurred in dollars, and the major source of the Company’s financing to date has been provided in dollars.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items (stated below) reflected in the statements of operations, the following exchange rates are used: (i) for transactions — exchange rates at the transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization, etc.) — historical exchange rates. Currency transaction gains or losses are carried to financial income or expenses, as appropriate.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 1 — SIGNIFICANT ACCOUNTING POLICIES (continued):**

**e. Cash equivalents**

The Company considers all short-term, highly liquid investments, which include short-term bank 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.

**f. Property and equipment**

1. Property and equipment are stated at cost, net of accumulated depreciation and amortization.
2. The Company's assets are depreciated by the straight-line method on the basis of their estimated useful lives as follows:

	years
Laboratory equipment	5
Furniture	10-15
Computer equipment	3

Leasehold improvements are amortized by the straight-line method over the expected lease term, which is shorter than the estimated useful life of the improvements.

**g. Impairment in value of long-lived assets:**

The Company tests long-lived assets for impairment if an indication of impairment exists. If the sum of expected future cash flows of definite life of long lived assets (undiscounted and without interest charges) is less than the carrying amount of such assets, the Company recognizes an impairment loss, and writes down the assets to their estimated fair values, calculated based on expected future discounted cash flows. See Note 2c.

**h. Income taxes**

**1. Deferred income taxes**

Deferred taxes are determined utilizing the assets and liabilities method based on the estimated future tax effects of the differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has provided a full valuation allowance with respect to its deferred tax assets.

The guidance prohibits the recognition of deferred tax liabilities or assets that arise from differences between the financial reporting and tax bases of assets and liabilities that are measured from the local currency into dollars using historical exchange rates, and that result from changes in exchange rates or indexing for tax purposes. Consequently, the above mentioned differences with respect to Protalix Ltd. were not reflected in the computation of deferred tax assets and liabilities.

**2. Uncertainty in income taxes**

As of January 1, 2007, the Company adopted accounting guidance with respect to accounting for uncertainty in income taxes.

Tax benefits recognized in the financial statements are at least more likely than not of being sustained, based on technical merits. The amount of benefits recorded for these tax benefits is measured as the largest benefit more likely than not to be sustained.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 1 — SIGNIFICANT ACCOUNTING POLICIES (continued):**

**i. Revenue Recognition**

The Company earns revenue under collaboration agreements with third parties to develop and produce drug candidates. The Company recognizes revenue and milestone payments in accordance with guidance regarding revenue recognition and accounting for revenue arrangements with multiple deliverables. Pursuant to this guidance, the Company determines whether an arrangement involves multiple revenue-generating deliverables that should be accounted for as a combined unit of accounting or separate units of accounting for revenue recognition purposes. If it is determined that there are multiple units of accounting, the consideration from the arrangement is allocated among the separate units based on a relative fair value allocation. If the arrangement represents a single unit of accounting, the revenue is recognized over the performance obligation period. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each collaboration agreement and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances.

**j. Research and development costs**

Research and development costs are expensed as incurred and consist primarily of personnel, subcontractors and consultants, facilities, equipment and supplies for research and development activities. Grants received by the Israeli Subsidiary from the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor (the "OCS") and other research foundations are recognized when the grant becomes receivable, provided there is reasonable assurance that the Company or the Subsidiary will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The grant is deducted from the related research and development expenses as the applicable costs are incurred. See Note 4(a).

In connection with purchases of assets, amounts assigned to intangible assets to be used in a particular research and development project that have no alternative future use are charged to research and development costs at the purchase date.

Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability.

**k. Comprehensive loss**

The Company has no other comprehensive loss components other than net loss for the reported periods.

**l. Concentration of credit risks**

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of bank deposits. The Company deposits these instruments with highly rated financial institutions, mainly in Israeli banks, and, as a matter of policy, limits the amounts of credit exposure to any one financial institution. The Company has not experienced any credit losses in these accounts and does not believe it is exposed to any significant credit risk on these instruments.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 1 — SIGNIFICANT ACCOUNTING POLICIES (continued):**

**m. Share-based compensation**

The Company accounts for employee's share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. The Company estimated forfeitures based on historical experience and anticipated future conditions.

The Company elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

**n. Net Loss per share**

Basic and diluted loss per share ("LPS") are computed by dividing net loss by the weighted average number of shares of Common Stock outstanding for each period.

Shares of restricted Common Stock and the shares of Common Stock underlying outstanding options of the Company were not included in the computation of diluted LPS because of the anti-dilutive effect of doing so.

Diluted LPS does not include options and restricted shares of Common Stock and warrants of the Company in the amount of 11,959,795, 11,037,356 and 10,660,447 shares of Common Stock for the years 2007, 2008 and 2009, respectively.

**o. Fair Value Measurement**

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

**p. Newly Issued and Recently Adopted Accounting Pronouncements**

1. In May 2009, the FASB issued ASC Topic 855 "Subsequent Events" (formerly SFAS No. 165, Subsequent Events). ASC 855 sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. ASC 855 is effective for interim or annual periods ending after June 15, 2009. The Company adopted the provisions of ASC 855 for the quarter ended June 30, 2009. The adoption of ASC 855 did not have a material impact on the Company's condensed financial statements.



**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 1 — SIGNIFICANT ACCOUNTING POLICIES (continued):**

2. In June 2009, the FASB issued Accounting Standards Update (“ASU”) No. 2009-1, “*Topic 105 — Generally Accepted Accounting Principles*” which amended ASC 105 “The “FASB Accounting Standards Codification” and the Hierarchy of Generally Accepted Accounting Principles (formerly SFAS No. 168 “The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles — A Replacement of FASB Statement No. 162”). ASU 2009-1 establishes the FASB Accounting Standards Codification™ (Codification) as the single source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the U.S. Securities and Exchange Commission (the “SEC”) under authority of federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. ASU 2009-1 and the Codification are effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification supersedes all existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. The FASB will no longer issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts. Instead, the FASB will issue Accounting Standards Updates, which will serve only to: (a) update the Codification; (b) provide background information about the guidance; and (c) provide the bases for conclusions on the change(s) in the Codification. The adoption of ASU 2009-1 did not have a material impact on the Company’s financial statements.

**3. Multiple Deliverable Revenue Arrangements**

In October 2009, the FASB issued an Accounting Standards Update to ASC 605, ASU No. 2009-13, “Multiple Deliverable Revenue Arrangements” (“ASU 2009-13”). ASU 2009-13 provides guidance on whether multiple deliverables in a revenue arrangement exist, how the arrangement should be separated, and how the consideration should be allocated. Pursuant to ASU 2009-13, when vendor specific objective evidence or third party evidence for deliverables in an arrangement cannot be determined, a best estimate of the selling price is required to separate deliverables and allocate arrangement consideration, using the relative selling price method. In addition, the residual method of allocating arrangement consideration is no longer permitted under ASU 2009-13.

ASU 2009-13 is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the potential impact of ASU 2009-13 on its consolidated financial position, results of operations and cash flows.

**NOTE 2 — PROPERTY AND EQUIPMENT**

- a. Composition of property and equipment grouped by major classifications, and changes, is as follows:

	December 31,	
	2008	2009
Laboratory equipment	\$ 5,898	\$ 10,008
Furniture and computer equipment	699	944
Leasehold improvements	3,058	5,665
Equipment under construction	97	2,615
	<u>\$ 9,752</u>	<u>\$ 19,232</u>
Less — accumulated depreciation and amortization	(2,911)	(4,695)
	<u>\$ 6,841</u>	<u>\$ 14,537</u>

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 2 — PROPERTY AND EQUIPMENT (continued):**

- b. Depreciation and amortization in respect of property and equipment totaled \$692, \$1,301 and \$1,990 for the years ended December 31, 2007, 2008 and 2009, respectively.
- c. The Company tested the carrying value of certain long lived assets. As a result, during the year ended December 31, 2007, the Company recorded a total impairment of \$67. See Notes 7c and 7d. The impaired long lived assets were mainly laboratory equipment and leasehold improvements.

**NOTE 3 — LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT**

The Israeli Subsidiary is required to make a severance payment upon dismissal of an employee, or upon termination of employment in certain circumstances. The severance pay liability to the employees (based upon length of service and the latest monthly salary — one month's salary for each year employed) is reflected by a balance sheet accrual under "Liability for employee rights upon retirement." The liability is recorded as if it were payable at each balance sheet date on an undiscounted basis.

The liability is funded in part by the purchase of insurance policies or pension funds and by the deposit of funds in dedicated deposits. The amounts funded are included in the balance sheets under "Funds in respect of employee rights upon retirement." These policies are the Company's assets. However, under labor agreements and subject to certain limitations, any policy may be transferred to the ownership of the individual employee for whose benefit the funds were deposited in the policy. In the years ended December 31, 2007, 2008 and 2009, the Company deposited \$128, \$161 and \$79, respectively, with the insurance companies in connection with its severance payment obligations.

In accordance with the current employment agreements with certain employees, the Company makes regular deposits with certain insurance companies for accounts controlled by each applicable employee in order to secure the employee's rights upon retirement. The Company is fully relieved from any severance pay liability with respect to each such employee after it makes the payments on behalf of the employee. The liability accrued in respect of these employees and the amounts funded, as of the respective agreement dates, are not reflected in the balance sheets, as the amounts funded are not under the control and management of the Company and the pension or severance pay risks have been irrevocably transferred to the applicable insurance companies (the "Contribution Plans").

The Company accounts for the severance pay obligations as contemplated by guidance regarding "determination of vested benefit obligation for a defined benefit pension plan" and, accordingly, records the obligations on a non-discounted basis as if they were payable at each balance sheet date.

The amounts of severance pay expenses were \$365, \$563 and \$488 for the years ended December 31, 2007, 2008 and 2009, respectively, of which \$140, \$319 and \$335 in the years ended December 31, 2007, 2008 and 2009, respectively, were in respect of a Contribution Plan. Gain (loss) on amounts funded in respect of employee rights upon retirement totaled \$57, \$(39) and \$81 for the years ended December 31, 2007, 2008 and 2009, respectively.

The Company expects to contribute approximately \$570 in 2010 to insurance companies in connection with its severance liabilities for its 2010 operations, \$420 of which will be contributed to one or more Contribution Plans.

During the 10-year period following December 31, 2009, the Company expects to pay future benefits to two employees upon their normal retirement age, which is anticipated to amount to \$64 and \$23 during the years 2010 and 2012, respectively. These amounts were determined based on each such employee's current salary rates and the number of years of employment that will be accumulated upon the retirement date of each such employee. This expectation does not include additional amounts that might be paid to employees that will cease working for the Company before their normal retirement age.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 4 — COMMITMENTS**

**a. Royalty commitments**

1. The Company is obligated to pay royalties to the OCS on proceeds from the sale of products developed from research and development activities that were funded, partially, by grants from the OCS. At the time the grants were received, successful development of the related projects was not assured.

In the case of failure of a project that was partly financed as described above, the Company is not obligated to pay any such royalties or repay funding received from the OCS.

Under the terms of the funding arrangements with the OCS, royalties of 3% to 6% are payable on the sale of products developed from projects funded by the OCS, which payments shall not exceed, in the aggregate, 100% of the amount of the grant received (dollar linked), plus, commencing upon January 1, 2001, interest at annual rate based on LIBOR. In addition, if the Company receives approval to manufacture the products developed with government grants outside the State 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 the State of Israel, and, possibly, an increased royalty rate.

The Company is obligated to pay the OCS royalties in respect of the amounts received from Pfizer under the Pfizer Agreement. Royalty expenses are included in the statement of operations as a component of royalties' expenses and were approximately \$1,950 in the aggregate during the year ended December 31, 2009.

At December 31, 2009, the maximum royalty amount payable by the Company under these funding arrangements is approximately \$13,941 (without interest, assuming 100% of the funds are payable).

2. The Company is a party to certain research and license agreements. Under the agreements, the Company is obligated to pay royalties at varying rates from its future revenues. As of December 31, 2009, royalty payments in the amount of \$1,625 have become payable under the agreements due to the execution of the Pfizer Agreement and are included in the statement of operations as a component of royalties' expenses.

Under each agreement, the Company is also obligated to pay milestone, licensing and other payments to the counterparties of the agreement. The payments under the agreements are for varying amounts and are subject to varying conditions. If all of the contingencies with respect to milestone payments under the research and license agreements are met, the aggregate milestone payments payable would be approximately \$1,050 and would be payable, if at all, as the Company's projects progress over the course of a number of years. A total of \$70 of milestone payments have become payable under the Company's agreements for the year ended December 31, 2009 in connection with the filing of the NDA for taliglucerase alfa with the FDA.

None of the agreements has a fixed termination date. Subject to earlier termination for other reasons, each agreement terminates after a certain number of years following the first commercial sale of any licensed product under the agreement or after a certain number of years without the initiation of commercial sales of any product under the agreement.

**b. Subcontracting Agreements**

The Company has entered into sub-contracting agreements with several clinical providers in Israel, the United States and certain other countries in connection with its primary product development process. As of December 31, 2009, total commitments under said agreements were approximately \$3,693.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 4 — COMMITMENTS (continued):**

**c. Lease Agreements**

The Company is a party to a number of lease agreements for its facilities, the latest of which expires in 2017. The Company has the option to extend certain of such agreements on three occasions for additional five-year periods, for a total of 15 additional years. Under the leases, the aggregate monthly rental payments are approximately \$63. As of December 31, 2008, the Company provided bank guarantees of approximately \$226, in the aggregate, to secure the fulfillment of its obligations under the lease agreements. The future minimum lease payments required in each of the next five years under the operating leases for such premises are approximately as follows: 2010 — \$791, 2011 - \$798, 2012 — \$798, 2013 — \$798 and 2014 — \$798. Lease expenses totaled \$197, \$220 and \$780 for the years ended December 31, 2007, 2008 and 2009, respectively.

**d. Vehicle Lease and Maintenance Agreements**

In July 2004, the Company entered into several three-year lease and maintenance agreements for vehicles which are regularly amended as new vehicles are leased. The current monthly lease fees aggregate approximately \$31. The expected lease payments for the years ending December 31, 2010, 2011 and 2012 are \$346, \$270 and \$173, respectively.

**e. Teva Agreement**

On September 14, 2006, the Company entered into agreement (the “Teva Agreement”) with Teva Pharmaceutical Industries Ltd. (“Teva”) under which the Company agreed to collaborate on the research and development of two proteins to be identified by Teva and the Company, using ProCellEx. The Teva Agreement also identifies additional matters for collaboration between Teva and the Company. The Company granted to Teva an exclusive license to commercialize any products developed under the collaboration in return for royalty and milestone payments payable upon the achievement of certain pre-defined goals. The Company 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. Subsequently, two proteins were identified to be researched and developed under the agreement but in 2009, both of the projects were terminated for commercial reasons. Eli Hurvitz, the Chairman of the Company’s Board of Directors, is the Chairman of Teva’s Board of Directors, and Phillip Frost M.D., a former director and a large, indirect shareholder of the Company, is the Vice Chairman of Teva’s Board of Directors.

**f. Yissum Agreement**

On August 8, 2007, the Company signed 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 acetylcholinesterase (AChE) and its molecular variants for the use in several therapeutic and prophylactic indications, including a biodefense program and organophosphate-based pesticide treatment. Pursuant to the agreement, the Company has received an exclusive worldwide right and license to certain technology, including patents and additional patent applications relating to AChE (the “Licensed Technology”), for all therapeutic and prophylactic indications. In consideration for the license, the Company is required to make certain milestone payments upon its achievement of clinical milestones and royalties from sales derived from any drugs developed by it with the Licensed Technology. The agreement does not terminate until either party to the agreement elect to terminate the agreement, subject to certain terms and conditions set forth therein.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 5 — SHARE CAPITAL**

**a. Rights of the Company's Stock**

**1. Common Stock**

Each share of Common Stock is entitled to one vote. The holders of Common Stock are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

**2. Preferred Shares**

The preferred shares were authorized in the Company's Restated Articles of Incorporation on April 16, 1998. The rights and privileges of the preferred stock may be established by the Company's Board of Directors. The directors have not designated any class of preferred stock and no shares of preferred stock have ever been issued.

**b.** On January 31, 2007, warrants that were issued in connection with a share purchase agreement dated August 2006, were exercised for 3,875,416 shares of Common Stock for an aggregate exercise price of \$5,333.

**c.** In October 2007, the Company issued and sold 10,000,000 shares of Common Stock in an underwritten public offering at a price equal to \$5.00 per share. The net proceeds to the Company were \$45,690 (net of underwriting commissions and issuance costs of \$4,310).

**d. Stock based compensation**

On December 14, 2006, the Board of Directors adopted the Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan (the "Plan"). The grant of options to Israeli employees under the Plan is subject to the terms stipulated by Sections 102 and 102A of the Israeli Income Tax Ordinance. Each option grant is subject to the track chosen by the Company, either Section 102 or Section 102A of the Israeli Income Tax Ordinance, and pursuant to the terms thereof, the Company is not allowed to claim, as an expense for tax purposes, the amounts credited to employees as a benefit, including amounts recorded as salary benefits in the Company's accounts, in respect of options granted to employees under the Plan, with the exception of the work-income benefit component, if any, determined on the grant date. For Israeli non-employees, the share option plan is subject to Section 3(i) of the Israeli Income Tax Ordinance.

Immediately prior to the closing of the Merger, options to purchase 88,001 ordinary shares of Protalix Ltd. were outstanding under the Plan. Pursuant to the terms of the Merger Agreement, the Company assumed all of the outstanding obligations under such plan and, accordingly, the Company issued options to purchase 5,375,174 shares of Common Stock, in the aggregate, in lieu of ordinary shares of Protalix Ltd., and has reserved an additional 4,366,481 shares of Common Stock under the Plan for future allocation under the Plan. As of December 31, 2009, 1,433,623 shares of Common Stock remain available for grant under the Plan.

For purposes of determining the fair value of the options and shares of restricted Common Stock granted to employees and non-employees, the Company's management uses the fair value of the Common Stock.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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**NOTE 5 — SHARE CAPITAL (continued):**

During the years ended December 31, 2001 through 2009, the Company granted options and shares of restricted Common Stock to certain employees and non-employees as follows:

**1. Options granted to employees:**

a) Below is a table summarizing all of the option grants to employees from inception through December 31, 2009:

<u>Year of Grant</u>	<u>No. of options granted</u>	<u>Exercise price range</u>	<u>Vesting period</u>	<u>Fair value at grant</u>	<u>Exercise Period</u>
2001	244,324	0.001	immediate	\$ 42	10 years
2003			Approximately 610,017 immediate and the remainder		
	1,243,977	0.12	in 4 years	\$ 389	10 years
2005	1,182,591	0.12-0.40	4 years	\$ 939	10 years
2006*	2,201,972	0.97	4 years	\$1,963	10 years
2007	204,351	4.33	4 years	\$5,790	10 years
2008	2,060,000	2.35-5.00	4 -5 years	\$2,914	10 years
2009**			Upon achievement of certain milestones		
	504,000	2.65		\$1,068	10 years
2009	120,400	2.65	4 years	\$ 212	10 years
	7,761,615				

\* Includes options granted outside of an option plan.

\*\* The milestone was achieved as of December 31, 2009 rendering the options fully vested.

Set forth below are grants made by the Company in 2009 and grants made by the Company prior to 2009 to certain related parties (such grants appear in the table above):

1. In May 2007, the Company's Board of Directors approved the grant of options to purchase 204,351 shares of Common Stock to a newly-hired officer of the Company, at an exercise price equal to \$4.33 per share. The options vest over a four-year period and are exercisable for a 10-year period commencing on the date of grant. In May 2008, the officer's employment by the Company was terminated. As a result, 127,719 of the options granted to the officer were forfeited.
2. In February 2008, the Company's Board of Directors approved the grant of options to purchase 1,900,000 shares of Common Stock to certain officers and employees of the Company with an exercise price equal to \$5.00 per share. The options vest variably over a period of up to five years. The options are exercisable over a 10-year period commencing on the date of grant.
3. In October 2008, the Company's Board of Directors approved the grant of options to purchase 160,000 shares of Common Stock to a new newly-hired officer of the Company of the Company with an exercise price equal to \$2.35 per share. The options vest over a four-year period. The options are exercisable over a 10-year period commencing on the date of grant.
4. In February 2008, the Company amended the stock option agreements of certain executive officers. As amended, such stock option agreements provide for the full acceleration of the vesting period of unvested options held by such officers immediately upon a change of control. The Company concluded that there was no incremental increase in the value of the awards and therefore no accounting charges need to be recorded in connection with such modification.

**PROTALIX BIOTHERAPEUTICS, INC.**  
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**NOTE 5 — SHARE CAPITAL (continued):**

5. In February, 2009, the Company's Board of Directors approved the grant of options to purchase 624,400 shares of Common Stock to certain officers and employees of the Company with an exercise price equal to \$2.65 per share. The options vest as follows:

(i) 504,000 of the options vest immediately upon the achievement of certain clinical and operational performance milestones, which milestones must be achieved within one year of the date of grant or the options will be forfeited. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately \$1,068, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 75.3%; risk-free interest rates of 2.95%; and expected life of 10 years. The vesting conditions of these options were satisfied prior to December 31, 2009. Accordingly, these options were fully vested at December 31, 2009 and the Company recognized all of the expenses for these options during 2009.

(ii) 120,400 of the options vest as follows: 25% within one year from the date of grant, with the remainder vesting in 12 equal quarterly tranches over 36 months. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately \$212, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 75.3%; risk-free interest rates of 1.84%; and expected life of six years. The Company's management assumed the simplified method to reflect the expected life regarding these options. The Company continued to use the simplified method in 2009 as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded.

- b) The fair value of options granted during the years ended December 31, 2007, 2008 and 2009 were \$5,790, \$2,914 and \$1,280, respectively. The fair value of each option granted is estimated on the date of grant using the Black-Scholes option-pricing model, with the following weighted average assumptions:

	2007	2008	2009
Dividend yield	0%	0%	0%
Expected volatility	53%	63%	75%
Risk-free interest rate	4.62%	2.99%	2.74%
Expected life — in years	6.0	6.0	9.2

The expected volatility is based on the historical volatility of the Common Stock and those of comparable companies. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock options granted in dollar terms. The Company's management uses the contractual term or its expectations, as applicable (through 2008 — using the simplified method), of each option as its expected life. The pre-vesting forfeiture rate of approximately 7% is estimated based on pre-vesting forfeiture experience.

The total unrecognized compensation cost of employee stock options at December 31, 2009 is \$782 (net of forfeiture rate), and it is expected to be recognized over a weighted average period of 0.9 years.

The total cash received from employees as a result of employee stock option exercises for the years ended December 31, 2007, 2008 and 2009 was \$14, \$5 and \$293, respectively. The Company did not realize any tax benefit in connection with these exercises.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 5 — SHARE CAPITAL (continued):**

During 2009, the Company issued 1,049,737 shares of Common Stock in connection with the exercise of 1,146,912 options by certain officers and employees of the Company. The Company received cash proceeds equal to \$293 in connection with such exercises as 642,050 of such options were exercised on a “net-exercise” basis.

**2. Options and shares of restricted Common Stock granted to consultants, directors, and other service providers:**

a) Set forth below is a table summarizing all of the option and restricted stock grants issued by the Company to consultants, directors and other service providers from its inception through December 31, 2009:

Year of Grant	No. of options granted	Exercise price range	Vesting period	Fair value at grant (\$)	Exercise Period
1999*	384,811	\$ 0.1	3 years	27	10 years
2000*	349,017	\$ 0.001	immediate	35	5.5 years
2001	837,727	\$ 0.17	mainly 2 years	51	7 years
2003	1,601,912	\$ 0.12	4 years	498	10 years
2005*	2,315,890	\$0.001-\$0.57	2-4 years	2,466	10 years
2006*	4,629,516	\$0.001-\$16.7	2.5 years	2,237	10 years
2007	16,000	\$ 0.001	4 years	246	10 years
2008	50,000	\$ 3.02	4 years	109	10 years
	10,184,873				

\* Includes options granted outside of an option plan.

Set forth below are grants made by the Company during the year ended December 31, 2009 and grants made by the Company prior to 2009 to certain related parties (such grants appear in the table above):

1. In May 2007, the Company’s Board of Directors approved the grant of 8,000 shares of restricted Common Stock to a new member of its Scientific Advisory Board. The shares vest as follows: 25% vest 12 months after the grant date and the remaining 75% of the shares vest over three years in 36 equal monthly installments. In October 2008, such services were terminated and 5,333 the 8,000 shares of restricted Common Stock were forfeited.
2. In February 2008, the Company’s Board of Directors approved the grant of options to purchase 50,000 shares of Common Stock to a new director of the Company with an exercise price equal to \$3.02 per share. The options vest over a four-year period and are exercisable over a 10-year period commencing on the date of grant.

b) The fair value of options and shares of restricted Common Stock granted to consultants and other non-employees during the years ended December 31, 2007, 2008 and 2009 were \$246, \$109 and \$0 respectively. The fair value of each option granted is estimated on the date of grant using the Black-Scholes option-pricing model, with the following weighted average assumptions:

	2008
Dividend yield	0%
Expected volatility	63%
Risk-free interest rate	2.99%
Expected life — in years	10



**PROTALIX BIOTHERAPEUTICS, INC.**  
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**NOTE 5 — SHARE CAPITAL (continued):**

The expected volatility is based on the historical volatility of the Company's stock and those of comparable companies. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock options granted in dollar terms. The Company's management used the contractual terms as the expected life in 2009.

The total unrecognized compensation cost as of December 31, 2009, is \$39, and it is expected to be recognized over a weighted average period of 0.9 years.

No cash was received from consultants as a result of consultant stock option exercises for the years ended December 31, 2007, 2008 and 2009. The Company did not realize any tax benefits in connection with these exercises.

During the year ended December 31, 2009, the Company issued 3,853,441 shares of Common Stock in connection with the exercise of 3,866,093 options by certain consultants, directors, and other service providers of the Company. The Company did not receive cash proceeds in connection with such exercises as all of such options were exercised on a "net-exercise" basis.

- e. A summary of share option plans, and related information, under all of the Company's equity incentive plans for the years ended December 31, 2007, 2008 and 2009 are as follows:

**1. Options granted to employees:**

	Year ended December 31,					
	2007		2008		2009	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	4,144,817	\$ 0.635	4,212,686	\$ 0.830	5,890,641	\$ 2.118
Changes during the year:						
Granted	204,351	4.330	2,060,000	4.794	624,400	2.650
Forfeited	25,197	0.120	177,237	4.405	1,400	2.650
Expired	1,221	0.970	—	—	—	—
Exercised (*)	110,064	0.131	204,808	0.565	1,146,912	0.733
Outstanding at end of year	4,212,686	\$ 0.830	5,890,641	\$ 2.118	5,366,729	\$ 2.476
Exercisable at end of year	2,503,399	\$ 0.365	3,267,607	\$ 0.995	3,680,382	\$ 1.785

(\*) The total intrinsic value of options exercised during the years ended December 31, 2007, 2008 and 2009, was \$907, \$450 and \$7,258, respectively.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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**NOTE 5 — SHARE CAPITAL (continued):**

**2. Options granted to consultants, directors, and other service providers:**

	2007		Year ended December 31, 2008		2009	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	7,572,035	\$ 5.996	5,254,785	\$ 1.250	5,304,785	\$ 1.285
Changes during the year:						
Granted	8,000	0.001	50,000	3.020		
Forfeited	2,325,250	16.700				
Exercised (*)					3,866,093	0.016
Outstanding at end of year	5,254,785	\$ 1.250	5,304,785	\$ 1.285	1,438,692	\$ 4.697
Exercisable at end of year	4,341,917	\$ 0.023	5,133,189	\$ 0.902	1,407,234	\$ 4.674

(\*) The total intrinsic value of options exercised during the years ended December 31, 2007, 2008 and 2009, was \$0, \$0 and \$41,281, respectively.

f. The following tables summarize information concerning outstanding and exercisable options as of December 31, 2009:

December 31, 2009				
Options outstanding			Options exercisable	
Exercise prices	Number of options outstanding at end of year	Weighted average remaining contractual life	Number of options exercisable at end of year	Weighted average remaining contractual life
\$0.001	919,207	4.09	915,875	4.08
\$0.120	1,107,926	4.32	1,107,926	4.32
\$0.399	47,569	5.35	47,569	5.35
\$0.972	1,666,365	6.51	1,312,287	6.49
\$2.350	160,000	8.82	40,000	8.82
\$2.650	623,000	9.15	504,000	9.15
\$3.020	50,000	8.10	21,875	8.10
\$5.000	1,843,812	8.10	750,542	8.10
\$16.700	387,542	7.00	387,542	7.00
	<u>6,805,421</u>		<u>5,087,616</u>	

The aggregate intrinsic value of the total outstanding and of total vested and exercisable options as of December 31, 2009, is \$29,317 and \$24,438, respectively.

g. The following table illustrates the effect of share-based compensation on the statement of operations:

	Year ended December 31,		
	2007	2008	2009
Research and development expenses	\$ 3,587	\$ 1,226	\$ 1,489
General and administrative expenses	16,861	1,845	1,194
	<u>\$ 20,448</u>	<u>\$ 3,071</u>	<u>\$ 2,683</u>

**PROTALIX BIOTHERAPEUTICS, INC.**  
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**NOTE 6 — TAXES ON INCOME**

**a. The Company**

Protalix BioTherapeutics, Inc. is taxed according to tax laws of the United States. The income of Protalix BioTherapeutics, Inc. is taxed in the United States at the rate of up to 39.4%.

**b. Protalix Ltd.**

The Israeli Subsidiary is taxed according to Israeli tax laws:

**1. Measurement of results for tax purposes under the Income Tax (Inflationary Adjustments) Law, 1985 (hereafter — the inflationary adjustments law)**

Pursuant to the Israel Income Tax Law (Adjustments for Inflation), 1985 (hereinafter — the Adjustments Law), the results for tax purposes have been measured through 2007 on a real basis, based on changes in the Israel consumer price index. The Subsidiary is taxed under this law.

Under the Israel Income Tax Law (Adjustments for Inflation) (Amendment No. 20), 2008 (the “amendment”), the provisions of the Adjustments Law will cease to apply to the Subsidiary in the 2008 tax year, and, therefore, commencing in 2008, the results of the Israeli Subsidiary have been measured for tax purposes in nominal terms. The amendment includes a number of transition provisions regarding the end of application of the Adjustments Law, which applied to the Israeli Subsidiary through the end of the 2007 tax year.

**2. Tax rates**

The income of the Israeli Subsidiary (other than income from “Approved Enterprises” see 3 below) is taxed in Israel at the regular rate. According to the provisions of the Law for Amending the Israel Income Tax Ordinance, 2005 (“Amendment 147”) of August 2005, corporate tax rates will be gradually lowered, resulting in the corporate following tax rates for 2007 and thereafter: 2007 — 29%, 2008 — 27%, 2009 — 26% and for 2010 and thereafter — 25%.

Capital gain for assets purchased since January 1, 2003 are subject to real capital gain tax at 25% and exempted from inflationary capital gains tax.

On July 23, 2009, the Israel Economic Efficiency Law (Legislation Amendments for Applying the Economic Plan for 2009 and 2010), 2009 (the “2009 Amendment”), became effective, stipulating, among other things, an additional gradual decrease in tax rates in 2011 and thereafter, as follows: 2011 — 24%, 2012 — 23%, 2013 — 22%, 2014 — 21%, 2015 — 20% and 2016 and thereafter — 18%.

In addition to the above decrease in corporate tax, the real capital gain tax was reduced to be in line with corporate tax in the year of selling the asset.

**3. The Law for the Encouragement of Capital Investments, 1959 (hereinafter, the “Law”)**

**a. Reduced tax rates**

The Israeli Subsidiary has been granted “Approved Enterprise” status under the Law for the Encouragement of Capital Investments, 1959. Income derived from the Approved Enterprise during a period of 10 years from the year in which the enterprise first realizes taxable income is tax exempt, provided that the maximum period to which it is restricted by the law has not elapsed.

The Israeli Subsidiary has an “Approved Enterprise” plan since 2004. The period of benefits in respect of the main enterprise of the Company, which has not yet commenced in 2009 expires in 2017.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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**NOTE 6 — TAXES ON INCOME (continued):**

If the Israeli Subsidiary subsequently pays a dividend out of income derived from the “Approved Enterprise” during the tax exemption period, it will be subject to tax on the amount distributed, including any company tax on these amounts, at the rate which would have been applicable had such income not been exempted.

In addition to the corporate taxes in Israel, the Company is subject to a withholding tax on the U.S. revenue source portion of the payments made to the Company for its share of Pfizer’s net profits under the Pfizer Agreement. The withholding tax rate is currently 15%.

**b. Accelerated depreciation**

The Israeli Subsidiary is entitled to claim accelerated depreciation as provided by Israeli law, commencing in the first year of operation of each asset, in respect of buildings, machinery and equipment used by the Approved Enterprise.

**c. Conditions for entitlement to the benefits**

The entitlement to the above benefits is conditional upon the Israeli Subsidiary fulfilling the conditions stipulated by the law, rules and regulations published thereunder, and the instruments of approval for the specific investment in an approved enterprise. In the event of any failure of the Israeli Subsidiary to comply with these conditions, the benefits may be cancelled and the Subsidiary may be required to refund the amount of the benefits, in whole or in part, with interest.

The Investment Center of Israeli Ministry of Industry, Trade and Labor (the “Investment Center”) is currently reviewing the Israeli Subsidiary’s final implementation report and, as a result, the Company has not yet received a final implementation approval with respect to its “Approved Enterprise” from the Investment Center. Additionally, given the Israeli Subsidiary’s significant amount of net operating losses and the limitation mentioned above to the benefit period, the Israeli Subsidiary cannot predict when it would be able to enjoy the tax benefits described above, if at all.

**5. The Law for the Encouragement of Industry (Taxation), 1969:**

The Israeli Subsidiary is an “industrial company”, as defined under the Law for the Encouragement of Industry (Taxation), 1969. As such, the Israeli Subsidiary is entitled to claim depreciation at increased rates for equipment used in industrial activity, as stipulated by regulations published under law, and has done so.

Under the provisions of the Income Tax Regulations “Accelerated Depreciation in respect of Equipment acquired during the Defined Period” (Temporary Orders), industrial companies whose operations are mostly “eligible operations” are entitled to claim accelerated depreciation at the rate of 50% on machinery and equipment acquired from June 1, 2008 to May 31, 2009. The accelerated depreciation is to be claimed over two years. For the year in which the equipment was acquired, depreciation is recorded at the regular rate. In the second year and thereafter, depreciation is recorded at a rate that would make the aggregate rate is 100%.

Under the regulations, the Company is entitled to accelerated depreciation in 2009 in respect of machines and equipment purchased in 2008 and 2009. The effect of the change in the rates of accelerated depreciation was included in deferred taxes described above.

**PROTALIX BIOTHERAPEUTICS, INC.**  
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**NOTE 6 — TAXES ON INCOME (continued):**

**c. Tax losses carried forward to future years**

As of December 31, 2009, the Company had aggregate net operating loss (NOL) carry-forwards equal to approximately \$14,690 that are available to reduce future taxable income as follows:

**1. The Company**

The NOL carry-forward of the Company equal to approximately \$5,911 may be restricted under Section 382 of the Internal Revenue Code ("IRC"). IRC Section 382 applies whenever a corporation with NOL experiences an ownership change. As a result of IRC Section 382, the taxable income for any post change year that may be offset by a pre-change NOL may not exceed the general IRC Section 382 limitation, which is the fair market value of the pre-change entity multiplied by the IRC long-term tax exempt rate.

**2. Protalix Ltd.**

At December 31, 2009, the Israeli Subsidiary had approximately \$8,779 of NOL carry-forwards that are available to reduce future taxable income with no limited period of use.

**d. Deferred income taxes:**

The components of the Company's net deferred tax asset at December 31, 2008 and 2009 were as follows:

	December 31,	
	2008	2009
In respect of:		
R&D expenses	\$ 2,728	
Property and equipment	7	\$ (161)
Holiday and recreation pay	162	200
Severance pay obligation	89	87
Deferred revenues	—	8,345
Net operating loss carry forwards	11,624	2,246
Valuation allowance	(14,610)	(10,717)
	<u>—</u>	<u>—</u>

**e. Reconciliation of the theoretical tax expense to actual tax expense**

The main reconciling items between the statutory tax rate of the Company and the effective rate is the tax exemptions in connections with the Approved Enterprise and the provision for full valuation allowance in respect of tax benefits from carry forward tax losses due to the uncertainty of the realization of such tax benefits (see above).

**f. Tax assessments**

In accordance with the Income Tax Ordinance, as of December 31, 2009, all of Protalix Ltd.'s tax assessments through tax year 2005 are considered final.

A summary of open tax years by major jurisdiction is presented below:

Jurisdiction:	Years:
Israel	2005-2009
United States (*)	2002-2009
Netherlands	2009

(\*) Includes federal, state and local (or similar provincial jurisdictions) tax positions.

**PROTALIX BIOTHERAPEUTICS, INC.**  
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**NOTE 7— SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (continued):**

**Balance sheets:**

	Year Ended December 31,	
	2008	2009
<b>a. Accounts receivable:</b>		
Institutions	\$ 223	\$ 740
State of Israel (see Note 4a )	166	832
Restricted deposit	211	213
Prepaid expenses	176	208
Sundry	17	151
	<u>\$ 793</u>	<u>\$ 2,144</u>

**b. Accounts payable and accruals — other:**

Payroll and related expenses	\$ 766	\$ 2,731
Provision for vacation and recreation pay	624	799
Accrued expenses	970	1,931
Royalties payable		3,575
Property and equipment supplier	932	4,525
	<u>\$ 3,292</u>	<u>\$ 13,561</u>

**Statement of operations:**

	Year ended December 31,		
	2007	2008	2009
<b>c. Research and development expenses — net:</b>			
Payroll and related expenses	\$ 7,510	\$ 9,296	\$ 10,479
Subcontractors and consultants	3,141	5,289	7,469
Materials and consumables	1,875	3,799	3,852
Rent, insurance and maintenance	905	1,592	2,238
Patent registration and licensing	331	182	387
Depreciation and impairment	689	1,171	1,799
Other	190	786	1,166
	<u>14,641</u>	<u>22,115</u>	<u>27,390</u>
Less — grants (see Note 4a)	1,071	4,714	5,752
	<u>\$ 13,570</u>	<u>\$ 17,401</u>	<u>\$ 21,638</u>
<b>d. General and administrative expense:</b>			
Payroll and related expenses	\$ 1,562	\$ 2,261	\$ 2,804
Management and consulting fees	16,407	1,335	681
Rent, insurance and maintenance	112	191	347
Professional fees	1,702	1,362	2,274
Travel	400	472	251
Depreciation	69	130	191
Other	342	1,019	596
	<u>\$ 20,594</u>	<u>\$ 6,770</u>	<u>\$ 7,144</u>

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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**NOTE 7— SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (continued):**

**e. Financial income:**

During the years 2007, 2008 and 2009 financial income includes transaction gain (loss) rate in the amount of \$50, (\$280) and \$67, respectively.

**NOTE 8 — RELATED PARTY TRANSACTIONS**

	Year ended December 31,		
	2007	2008	2009
<b>a. Management and consulting fees to the Chairman of the Board</b>	\$ 36	\$ 33	\$ 33
<b>b. Rent payments to a shareholder</b>	\$ 10		
<b>c. Compensation to the non-executive directors (except the Chairman of the Board)</b>		\$ 210	\$ 209

**d.** With respect to options granted to the Company's Chief Executive Officer and to a shareholder, see Notes 5(d)(1) and (2).

**e.** In March 2005, Protalix Ltd. entered into a management services agreement with Pontifax Management Company, Ltd. in connection with an investment in Protalix Ltd. by affiliates of Pontifax. The monthly management fees under the management services agreement are \$3. The management services agreement shall be in full force as long as Mr. Hurvitz serves as a member of the Company's Board of Directors. In 2009, the amount was set to \$33.

**NOTE 9 -LICENSE AND SUPPLY AGREEMENT**

On November 30, 2009, Protalix Ltd. and Pfizer Inc entered into the Pfizer Agreement pursuant to which Pfizer was granted an exclusive, worldwide license to develop and commercialize taliglucerase alfa, except Israel. Under the terms and conditions of the Pfizer Agreement, Protalix Ltd. retained the right to commercialize taliglucerase alfa in Israel. Under the Pfizer Agreement, Pfizer made an upfront payment to Protalix Ltd. of \$60,000 in connection with the execution of the agreement and shortly thereafter paid to Protalix Ltd. an additional \$5,000 upon the Company's filing of a proposed pediatric investigation plan to the Pediatric Committee of the European Medicines Agency (EMA). Protalix Ltd. is also eligible to receive additional potential milestone payments totaling up to \$50,000 for the successful achievement of other regulatory milestones. Protalix Ltd. is entitled to 40% of the profits earned on Pfizer's sales of taliglucerase alfa. Such profit will be calculated, among other things, while taking into account Protalix Ltd.'s cost of goods sold and Pfizer's commercial expenses with certain expenses capped or borne solely by one party.

The Company has determined that the initial, non-refundable upfront license fee payment of \$60,000 together with the first \$5,000 payment will be recognized on a straight line basis as revenue over the estimated relationship period. The Company has estimated that its relationship period will be approximately 14 years based on the Company's last significant patent to expire.

The Company's deliverables under this collaboration include an exclusive license to taliglucerase alfa as an enzyme replacement therapy for the treatment of Gaucher disease, certain research and development services as required under the Pfizer Agreement for taliglucerase alfa, manufacturing of taliglucerase alfa and optional participation in a joint steering committee.

In connection with the payments received under the Pfizer Agreement Protalix Ltd is obligated to pay certain royalties. See Note 4a.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands)

**NOTE 10 — SUBSEQUENT EVENTS**

- a.** On February 7, 2010, the Company's Board of Directors approved the grant of options to purchase 160,000 shares of Common Stock to a new executive officer of the Company with an exercise price equal to \$6.81 per share. The options vest over a four-year period, with the first 25% to vest on the first anniversary of the date of the grant and the remaining 75% in equal tranches on a quarterly basis for three years thereafter. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately \$740, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 76.02%; risk-free interest rates of 2.96%; and expected life of 6 years.
- b.** During January and February 2010, the Company issued a total of 14,000 shares of Common Stock in connection with the exercise of options to purchase 14,000 shares of Common Stock by certain employees of the Company. The Company received aggregate cash proceeds equal to approximately \$2.
- c.** In February 2010, the Company's Board of Directors approved the grant of options to purchase 1,043,623 shares of Common Stock, in the aggregate, to certain officers and employees of the Company with an exercise price equal to \$6.90 per share. The options vest quarterly over three years, commencing after the FDA's approval of taliglucerase alfa, if at all. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately \$5.8 million, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 75.74%; risk-free interest rates of 3.69%; and expected life of 10 years.



**Text omitted and submitted separately pursuant to confidential treatment request  
under 17 C.F.R. Sections 200.80(b)(4) and 230.406**

**EXCLUSIVE LICENSE AND SUPPLY AGREEMENT**

**by and between**

**PFIZER INC.**

**and**

**PROTALIX LTD.**

**November 30, 2009**

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- Appendix 7.4(a) — Protalix Account Information
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- Appendix 15.1(c) — Other Matters

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

## EXCLUSIVE LICENSE AND SUPPLY AGREEMENT

Exclusive License and Supply Agreement (this “Agreement”) dated as of November 30, 2009 between Protalix Ltd., a limited liability company incorporated under the laws of Israel with offices located at 2 Snunit Street, Science Park, P.O.B 455, Carmiel 20100, Israel (“Protalix”), and Pfizer Inc., a Delaware corporation with offices located at 235 East 42nd Street, New York, New York, 10017, U.S.A. (“Pfizer”).

WHEREAS, Protalix owns or otherwise controls certain patents, patent applications, technology, know-how and scientific and technical information relating to an enzyme replacement therapy for the treatment of Gaucher Disease;

WHEREAS, Pfizer has extensive experience and expertise in the development and commercialization of drug products, and desires to acquire an exclusive license in the Territory (as defined below) to such patents, patent applications, technology, know how and scientific and technical information, upon the terms and subject to the conditions set forth herein; and

WHEREAS, Protalix desires to grant such license to Pfizer;

NOW, THEREFORE, in consideration of the mutual covenants and agreements provided herein, Protalix and Pfizer hereby agree as follows:

### **Section 1. DEFINITIONS**

For purposes of this Agreement, the following definitions shall be applicable:

1.1 “Accumulated Net Loss” shall have the meaning assigned to it in Section 6.4(b)(ii).

1.2 “Actual Price” shall have the meaning assigned to it in Section 5.7(a)(iii).

1.3 “Additional Development Costs” has the meaning set forth in Section 6.3(h).

1.4 “Affiliate” means any entity directly or indirectly controlled by, controlling, or under common control with, a party to this Agreement, but only for so long as such control shall continue. For purposes of this definition, “control” (including, with correlative meanings, “controlled by”, “controlling” and “under common control with”) means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of at least 50% of the voting securities or other ownership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity, it being understood and agreed that for purposes of clause (a), neither ownership of voting securities or other ownership interests of an entity nor membership or representation on (if less than half of the members of) an entity’s board of directors shall, by themselves, be presumed to constitute the power to direct or cause direction of the management or policies of such entity; provided, further, that solely for purposes of Section 16.3 and 16.4, a Person (other than Protalix) who would otherwise be deemed to be an Affiliate of Protalix Parent solely by virtue of clause (a) of this definition shall be deemed to be a Third Party. With respect to the grant of license rights by Protalix to Pfizer under Section 3,

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“Affiliate” shall exclude any Third Party that becomes an Affiliate due to such Third Party’s acquisition of Protalix.

1.5 “Allocation Percentage” shall have the meaning set forth in Section 5.2(c).

1.6 “Allowable Expenses” shall have the meaning set forth in Exhibit E.

1.7 “Business Associates” shall have the meaning set forth in Appendix 10.1(t).

1.8 “Business Combination Transaction” shall have the meaning set forth in Section 16.1(d).

1.9 “Business Day” means a day other than a Saturday, Sunday, or bank or other public holiday in New York, New York.

1.10 “Capacity Cap” shall have the meaning set forth in Section 5.2(c).

1.11 “Commence” or “Commencement” when used with respect to a clinical trial, means the first dosing of the first patient for such trial.

1.12 “Commercialization” means any and all activities directed to and including marketing, promoting, distributing, offering for sale and selling a Licensed Product, importing a Licensed Product (to the extent applicable) and conducting [\*\*\*]. When used as a verb, “Commercialize” means to engage in Commercialization.

1.13 “Commercialization Plan” shall have the meaning set forth in Section 4.7(a).

1.14 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a party with respect to the objective that is the subject of such efforts, reasonable, good faith efforts and resources to accomplish such objective that such party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that with respect to the Development or Commercialization of the Licensed Product in the Territory by Pfizer, such efforts shall be similar to those efforts and resources consistent with the usual practice of Pfizer in pursuing the Development or Commercialization of drug products owned by it or to which it otherwise has rights that are of similar market potential as a Licensed Product in the Territory, taking into account all relevant factors, including the orphan drug status (if any) of the Licensed Product and other regulatory matters, safety and efficacy matters, product labeling or anticipated labeling, pricing, present and future market potential, past performance of the Licensed Product, past performance of Pfizer’s own drug products that are of similar market potential (taking into account that the Licensed Product is intended for the treatment of a rare disease), financial return [\*\*\*], medical and clinical considerations, present and future regulatory environment and competitive market conditions, all as measured by the facts and circumstances at the time such efforts are due. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time.

[\*\*\*] Redacted pursuant to a confidential treatment request.



1.15 “Competing Product” means [\*\*\*].

1.16 “Compound” means (a) prGCD and (b) any analogs, derivatives and variants thereof.

1.17 “Confidential Information” means the Protalix Confidential Information or the Pfizer Confidential Information, as applicable.

1.18 “Control” or “Controlled” means, with respect to any compound, material, information, or intellectual property right, that a party owns or has a license to use, commercialize, manufacture, market, distribute or sell, and has the ability to grant to the other party access and/or a license or a sublicense (as applicable under this Agreement) to such compound, material, information, or intellectual property right as provided for herein without violating (a) the terms of any agreement or other arrangements with any Third Party existing before or after the Effective Date or (b) any law or governmental regulation applicable to such license or sublicense.

1.19 “Cost of Goods Sold” or “COGS” shall have the meaning set forth in Exhibit E.

1.20 “Costs of Early Access Programs” means costs and expenses related to conducting Early Access Programs in the Territory, including the cost of (a) manufacturing, shipping and storing Licensed Product (or any intermediary) used in the Early Access Programs, (b) clinical laboratory testing, (c) patient visits to the relevant healthcare professional, (d) monitoring adverse events, and any other payments to a Third Party or contract research organization engaged to assist in the conduct of the Early Access Programs.

1.21 “Country” means any generally recognized sovereign entity.

1.22 “Court” shall have the meaning set forth in Section 17.2.

1.23 “Current Capacity Cap” shall have the meaning set forth in Section 5.2(a).

1.24 “Development” or “Develop” means conducting pre-clinical studies and clinical trials, collecting, validating and analyzing pre-clinical and clinical trial data, preparing and submitting regulatory filings, obtaining Regulatory Approvals, and regulatory affairs related to the foregoing. When used as a verb, “Develop” means to engage in Development. For clarity, Development does not include Phase 4 Trials or any of the foregoing in connection therewith.

1.25 “Development Costs” means all costs and expenses related to the Development of Licensed Product including (a) direct, out-of-pocket costs and expenses, including [\*\*\*], and (b) the conduct of clinical studies, including [\*\*\*].

1.26 “Development Plan” shall have the meaning assigned to it in Section 4.1.

[\*\*\*] Redacted pursuant to a confidential treatment request.

1.27 “Drug Substance” means the Compound component of a pharmaceutical drug product.

1.28 “Early Access Program” means any program to provide patients with the Licensed Product prior to Regulatory Approval and prior to Launch in any Country in the Territory. Early Access Programs include Treatment INDs / Protocols in the United States, Named Patient Programs in the EU and Compassionate Use programs in other Countries in the Territory.

1.29 “Effective Date” means the date of this Agreement.

1.30 “EMA” means the European Agency for the Evaluation of Medicinal Products or any successor agency thereto.

1.31 “Environmental Laws” means all applicable Laws relating to (a) safety (including occupational health and safety); conservation, preservation or protection of human health, drinking water, natural resources, biota and the environment; (b) the generation, use, storage, handling, treatment, transportation or disposal of Hazardous Materials or Waste, (c) Releases and threatened Releases of Hazardous Materials, or (d) chemical classification and labeling.

1.32 “Environmental Permits” shall have the meaning set forth in Section 10.3(a)(ii).

1.33 “Estimated Price” shall have the meaning set forth in Section 5.7(a)(i).

1.34 “European Union” or “EU” means the Countries that are members of the European Union as of the Effective Date or that become members of the European Union thereafter.

1.35 “Event Milestone” shall have the meaning set forth in Section 6.2(a).

1.36 “Event Milestone Payments” means the amounts set forth in Section 6.2(a) opposite the respective Event Milestones, subject to Section 6.2(d).

1.37 “Exchange Act” means the Securities Exchange Act of 1934, as amended and the rules of the Securities and Exchange Commission thereunder as in effect on the date hereof.

1.38 “Ex-US/EU Development Costs” has the meaning set forth in Section 6.3(f).

1.39 “Facility” means, as applicable, a party’s Manufacturing facility and such other facilities used by such party (or its Affiliates) in the Manufacture or storage of (a) Drug Substance, (b) Licensed Product or (c) materials utilized in the Manufacture of Drug Substance or Licensed Product.

1.40 “Failure to Supply” shall have the meaning assigned to it in Section 5.15.

1.41 “Field” means enzyme replacement therapy for the treatment of Gaucher Disease.

1.42 “FCPA” shall have the meaning set forth in Appendix 10.1(t).

1.43 “FDA” means the United States Food and Drug Administration or any successor

agency thereto.

1.44 “FDA Approval Date” means the date Protalix receives the first Regulatory Approval for the Licensed Product in the Field from the FDA.

1.45 “FDCA” means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder.

1.46 “Fill/Finish” means (a) formulating the Licensed Product using Drug Substance and other excipients, (b) filling the Licensed Product into vials, (c) lyophilization of the Drug Substance for incorporation into the Licensed Product, and (d) testing, including ongoing stability testing, and release of the Licensed Product. For the avoidance of doubt, Fill/Finish shall not include any activities included in the definition of Labeling and Packaging.

1.47 “Force Majeure Event” shall have the meaning assigned to it in Section 18.1.

1.48 “Forecast” shall have the meaning assigned to it in Section 5.6(a).

1.49 “Fully Absorbed Cost of Goods” shall have the meaning set forth in Exhibit E.

1.50 “GAAP” means United States generally accepted accounting principles consistently applied.

1.51 “GMP Audit” shall have the meaning set forth in Section 5.9(a).

1.52 “Good Manufacturing Practices” or “GMP” means all applicable Good Manufacturing Practices including, (i) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice, (ii) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601 and 610, (iii) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, (iv) the principles detailed in the ICH Q7A guidelines, and (v) the equivalent Laws in any relevant Country, each as may be amended and applicable from time to time.

1.53 “Governmental Authority” means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.54 “Government Official” shall have the meaning assigned to it in Section 10.1(r).

1.55 “Gross Sales” shall have the meaning set forth in the definition of Net Sales.

1.56 “Hazardous Materials” means any and all materials (including substances, chemicals compounds, mixtures, products, byproducts, biologic agents, living or genetically modified materials, wastes, pollutants and contaminants), that are (a) (i) listed, classified, characterized or regulated pursuant to Environmental Laws; (ii) identified or classified as “hazardous”, “dangerous”, “toxic”, “pollutant”, “contaminant”, “waste”, “irritant”, “corrosive”, “flammable”, “radioactive”, “reactive”, “carcinogenic”, “mutagenic”, “bioaccumulative”, or

“persistent” in the environment; or (iii) in quantity or concentration capable of causing harm or injury to human health, natural resources or the environment, if Released or resulting in human exposure; or (b) petroleum products and their derivatives, asbestos-containing material, lead-based paint, polychlorinated biphenyls, urea formaldehyde, or viral, bacterial or fungal material.

1.57 [\*\*\*]

1.58 “Hold Separate Transaction” means any “hold separate” transaction (whether through the establishment of a trust or otherwise) involving the proposed sale of a Competing Product pursuant to an agreement with any Governmental Authority responsible for antitrust laws.

1.59 “Improvement Notice” shall have the meaning assigned to it in Section 3.5(a).

1.60 “Increased Capacity Cap” shall have the meaning set forth in Section 5.2(b).

1.61 “Indemnified Party” shall have the meaning assigned to it in Section 15.3.

1.62 “Indemnifying Party” shall have the meaning assigned to it in Section 15.3.

1.63 “Initial Commercialization Plan” shall have the meaning assigned to it in Section 4.7(a).

1.64 “Initial Forecast” shall have the meaning assigned to it in Section 5.6(a).

1.65 [\*\*\*].

1.66 “Labeling and Packaging” means the final product labeling and packaging of the Licensed Product (whether in commercial or clinical packaging presentation), including materials to be inserted such as patient inserts, patient medication guides, professional inserts and any other written, printed or graphic materials accompanying the Licensed Product.

1.67 “Labeling and Packaging Costs” shall have the meaning set forth in Exhibit E.

1.68 “Launch” means the first shipment of a Licensed Product in commercial quantities for commercial sale by Pfizer, its Affiliates or its Sublicensees to a Third Party in a Country in the Territory after receipt by Pfizer of the first Regulatory Approval (and, in any Country in which Price Approval is necessary or relevant for a majority of the population to obtain access to drug products, Price Approval) for such Licensed Product in such Country.

[\*\*\*] Redacted pursuant to a confidential treatment request.

1.69 “Laws” means all laws, statutes, rules, regulations, codes, administrative or judicial orders, judgments, decrees, injunctions and/or ordinances of any Governmental Authority, and common law or other legal requirements of any kind, whether currently in existence or hereafter promulgated, enacted, adopted or amended.

1.70 “Licensed Product” means any finished dosage form of a drug product that contains Drug Substance (excluding any Oral Formulation) and either: (a) the manufacture, sale, offer for sale, importation, or use of such drug product (i) would, absent the license granted by Protalix to Pfizer herein, infringe at least one Valid Claim of a Protalix Patent Right, or (ii) embodies, incorporates or uses Protalix Technology; or (b) such drug product is supplied by Protalix to Pfizer under this Agreement (or is manufactured using Drug Substance supplied by Protalix to Pfizer under this Agreement) or is manufactured by Pfizer or a Third Party pursuant to Pfizer’s exercise of its rights under Section 5.17 (or is manufactured using Drug Substance manufactured by Pfizer or a Third Party pursuant to Pfizer’s exercise of its rights under Section 5.17).

1.71 “Long Range Forecast” shall have the meaning assigned to it in Section 5.6(a).

1.72 “Losses” shall have the meaning assigned to it in Section 15.2.

1.73 “Major EU Countries” means [\*\*\*].

1.74 “Major Market Country” means each of [\*\*\*].

1.75 “Manufacture” or “Manufacturing” means all activities related to the manufacturing of the Drug Substance or Licensed Product, and/or any ingredient thereof, including manufacturing for clinical use or commercial sale, in-process and finished product testing, Fill/Finish, Labeling and Packaging, release of product, quality assurance activities related to manufacturing and release of product and ongoing stability tests and regulatory activities related to any of the foregoing.

1.76 “Manufacturing Certificate of Analysis” shall have the meaning assigned to it in Section 5.10(a)(i).

1.77 “NDA” means a New Drug Application filed with the FDA in accordance with the FDCA with respect to a drug product or an analogous application or filing with any Regulatory Authority outside of the United States (including any supra-national agency such as the European Union) for the purpose of obtaining approval to market and sell a drug product in such jurisdiction.

1.78 “Net Profit or Loss” shall be calculated in accordance with Exhibit E.

[\*\*\*] Redacted pursuant to a confidential treatment request.

1.79 “Net Sales” means, with respect to a Licensed Product, the gross amount invoiced by Pfizer, its Affiliates and its Sublicensees of such Licensed Product to Third Parties (“Gross Sales”), less (a) bad debts related to such Licensed Product, (b) sales returns and allowances actually paid, granted or accrued, including, trade, quantity and cash discounts, any other adjustments, including, those granted on account of price adjustments, billing errors, rejected goods, damaged or defective goods, recalls, returns, rebates, chargeback rebates, reimbursement, fees or similar payments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, Governmental Authorities, or other institutions or health care organizations, (c) adjustments arising from consumer discount programs or other similar programs or arising in connection with any Pfizer Discount or Savings Program, (d) customs or excise duties, sales tax, consumption tax, value added tax, and other taxes (except income taxes) or duties relating to sales, any payment in respect of sales to the United States government, any state government or any foreign government, or to any other Governmental Authority, or with respect to any government-subsidized program or managed care organization, and (e) charges for freight and insurance (to the extent that Pfizer bears the cost of freight and insurance for a Licensed Product). Net Sales shall be determined from books and records maintained in accordance with GAAP, as consistently applied by Pfizer with respect to sales of all its drug products.

1.80 “Non-Conformance Period” shall have the meaning assigned to it in Section 5.10(b).

1.81 “Notice of Non-Conformance” shall have the meaning assigned to it in Section 5.10(a)(i).

1.82 “Ongoing Clinical Study” means each of the clinical studies of the Licensed Product identified as an ongoing clinical study and described in the Development Plan.

1.83 “Oral Formulation” means an oral formulation of a drug product for the treatment of Gaucher Disease which contains any Compound as the active pharmaceutical ingredient.

1.84 “Other Regulatory Commitments” means all [\*\*\*] as a condition of [\*\*\*].

1.85 “Outside of the Scope Product” shall have the meaning set forth in Section 8.2.

1.86 “Patent Application” means any application for a Patent.

1.87 “Patent Rights” means Patents and Patent Applications.

[\*\*\*] Redacted pursuant to a confidential treatment request.

1.88 “Patents” means issued patents, whether domestic or foreign, including all continuations, continuations-in-part, divisions, provisionals and renewals, and letters of patent granted with respect to any of the foregoing, patents of addition, supplementary protection certificates, registration or confirmation patents and all reissues, re-examination and extension thereof.

1.89 “[\*\*\*] Study” means the clinical study of the Licensed Product [\*\*\*] identified as such and described in [\*\*\*] with respect to [\*\*\*].

1.90 “[\*\*\*] Study Development Costs” has the meaning set forth in Section 6.3(c).

1.91 “Person” means an individual, corporation, partnership, company, joint venture, unincorporated organization, limited liability company or partnership, sole proprietorship, association, bank, trust company or trust, whether or not legal entities, or any Governmental Authority.

1.92 “Pfizer Chair” shall have the meaning assigned to it in Section 4.3(a).

1.93 “Pfizer Confidential Information” means all information relating to the Compound or Licensed Product, as well as any other information regarding the business and operations of Pfizer, that is or has been disclosed (whether orally or in writing) by Pfizer to Protalix or its Affiliates to the extent that such information is not: (a) as of the date of disclosure known to Protalix or its Affiliates; or (b) disclosed in published literature, or otherwise generally known to the public through no breach by or Protalix; of this Agreement or (c) obtained by Protalix or its Affiliates from a Third Party free from any obligation of confidentiality to Pfizer; or (d) independently developed by Protalix or its Affiliates without use of the Pfizer Confidential Information; or (e) in the good faith judgment of Protalix, after consultation with legal counsel, is required to be disclosed under Law; provided that, in the case of (e), Protalix provides Pfizer prior notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of Pfizer, with Pfizer’s efforts to preserve the confidentiality of such information.

1.94 “Pfizer Discount or Savings Program” means any discount, rebate or reimbursement program under which either party or its Affiliates provides to low income, uninsured or other patients the opportunity to purchase Licensed Product at discounted prices.

1.95 “Pfizer Quarter” means each of the four (4) thirteen (13) week periods (a) with respect to the United States, commencing on January 1 of any calendar year, and (b) with respect to any Country in the Territory other than the United States, commencing on December 1 of any calendar year.

[\*\*\*] Redacted pursuant to a confidential treatment request.

1.96 “Pfizer Third Party Fill/Finish Agreement” means any agreement between Pfizer and a Third Party entered into after the Effective Date with respect to Fill/Finish and/or Labeling and Packaging activities for the Licensed Product.

1.97 “Pfizer Year” means the twelve (12) month period (i) with respect to the United States, commencing on January 1 of any calendar year, and (ii) with respect to any Country in the Territory other than the United States, commencing on December 1 of any calendar year.

1.98 “Phase 4 Trial” means a clinical trial for the Licensed Product that is initiated in a Country after receipt of Regulatory Approval for the Licensed Product in such Country and is principally intended to support the marketing and Commercialization of the Licensed Product, including investigator initiated trials and clinical experience trials. [\*\*\*].

1.99 “prGCD” means a plant cell expressed recombinant human Glucocerebrosidase enzyme having the sequence set forth in Exhibit A to this Agreement.

1.100 “Price Approval” means, in any Country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, drug products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.101 “Price for Drug Substance” means the price per unit of Drug Substance, which equals the sum of (a) all direct costs actually accrued or incurred by Protalix to Manufacture Drug Substance, including [\*\*\*], and (b) all indirect costs (including [\*\*\*]) to the extent directly or indirectly related to the Manufacture of Drug Substance, allocated based upon the proportion of such costs and time directly attributable to the support of the applicable activity (such allocation to be consistent with the allocation percentages historically applied by Protalix prior to the Effective Date to the extent consistent with applicable accounting standards), including overhead variances and/or over or under absorption of costs. All such cost determinations shall be made in accordance with GAAP as consistently practiced by Protalix and used in Protalix’s accounting reports and shall be supported by appropriate documentation. [\*\*\*].

1.102 “Product Specifications” means those Manufacturing, performance, quality - control release, and Fill/Finish specifications for Drug Substance or Licensed Product in the Territory, which are initially as set forth in the applicable Regulatory Approval for a Licensed Product, as such specifications may be amended from time to time pursuant to the terms of this Agreement.

1.103 “Profit Sharing Term” means the period commencing on January 1, 2010 and ending on the date this Agreement is terminated pursuant to Section 14, subject to Section 14.4(c).

**[\*\*\*] Redacted pursuant to a confidential treatment request.**



1.104 “Protalix Chair” means one of the Protalix representatives on the Steering Committee designated by Protalix as Protalix’s chair for Steering Committee Meetings.

1.105 “Protalix Change of Control” means the occurrence of any of the following events:

(a) the acquisition by (i) any Person that is a Large Pharmaceutical Company or (ii) any Persons including a Large Pharmaceutical Company that together (x) are a group (within the meaning of Section 13(d)(3), Section 14(d)(2) of the Exchange Act, or any successor provision) or (y) are acting, for purposes of acquiring, holding or disposing of securities, as a group (within the meaning of Rule 13d-5(b)(1) of the Exchange Act, or any successor provision), in a single transaction or in a related series of transactions, by way of merger, consolidation or other business combination or purchase of beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act, or any successor provision), of securities representing fifty percent (50%) or more of the total voting power of (1) Protalix (or the surviving company of such merger, consolidation or other business combination transaction, as applicable) or (2) any one or more Persons who are direct or indirect parent holding companies of Protalix or Affiliates controlling Protalix (Protalix, together with the Persons described in clause (2), each hereinafter referred to individually as a “Protalix Group Company” and collectively as the “Protalix Group Companies”); or

(b) the sale or disposition, lease or transfer (other than by way of merger or consolidation), in one or a series of related transactions, of all or substantially all of the assets or business of a Protalix Group Company to any Person or group that is or contains a Large Pharmaceutical Company; or

(c) any Protalix Group Company enters into an agreement with any Person or group that is or contains a Large Pharmaceutical Company providing for the matters described in clauses (a) or (b) above.

For purposes of this definition of “Protalix Change of Control,” “Large Pharmaceutical Company” means (x) any pharmaceutical, biotechnology or biopharmaceutical company that (A) is either developing or commercializing a product for the treatment of Gaucher Disease or (B) has at least [\*\*\*] in annual aggregate net sales of drug products (based on data provided by IMS International, or, if such data is not available, such other reliable data source as reasonably determined by Pfizer and reasonably agreed to by Protalix), (y) any one or more Persons that are direct or indirect parent holding companies or subsidiaries of the pharmaceutical, biotechnology or biopharmaceutical company described in subclause (x) above or (z) any Affiliate of the pharmaceutical, biotechnology or biopharmaceutical company described in subclause (x) above.

1.106 “Protalix Confidential Information” means all information relating to the Protalix Technology, Compound or Licensed Product as well as any other information regarding the

[\*\*\*] Redacted pursuant to a confidential treatment request.

business, operations, research and Development activities of Protalix, that is or has been disclosed (whether orally or in writing) by Protalix to Pfizer or its Affiliates to the extent that such information is not: (a) as of the date of disclosure to Pfizer, known to Pfizer or its Affiliates; or (b) disclosed in published literature, or otherwise generally known to the public through no breach by Pfizer of this Agreement; or (c) obtained by Pfizer or its Affiliates from a Third Party free from any obligation of confidentiality to Protalix; or (d) independently developed by Pfizer or its Affiliates without use of the Protalix Confidential Information; or (e) in the good faith judgment of Pfizer, after consultation with legal counsel, is required to be disclosed under Law; provided that, in the case of (e), Pfizer provides Protalix prior notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of Protalix, with Protalix's efforts to preserve the confidentiality of such information.

1.107 "Protalix Improvement" means any necessary or useful improvement, change, or modification to the Drug Substance, Licensed Product or Protalix Technology which may be developed, created, or acquired by Protalix after the Effective Date and before termination of this Agreement, including new or improved methods of Manufacturing, means of delivery (other than an Oral Formulation), dosage, formulation (other than an Oral Formulation), and analysis. To the extent an improvement, change or modification to prGCD also constitutes an analog, derivative or variant of prGCD, such improvement, change or modification shall be deemed to be a Compound and not a Protalix Improvement.

1.108 "Protalix Patent Rights" means all Patent Rights owned or otherwise Controlled by Protalix or any of its Affiliates as of the Effective Date or at any time during the Term that claim the composition of matter, manufacture or use of the Compound, Drug Substance or a drug product that contains Drug Substance, including the Patent Rights listed in Exhibit B.

1.109 "Protalix System Patent Rights" means Protalix Patent Rights that relate primarily to the System.

1.110 "Protalix Technology," means any Technology owned or otherwise Controlled by Protalix or any of its Affiliates as of the Effective Date or at any time during the Term that is necessary or useful for the Development, Manufacture, use or Commercialization of Compound, Drug Substance or a drug product that contains Drug Substance, including the System.

1.111 [\*\*\*].

1.112 "Purchase Order" shall have the meaning assigned to it in Section 5.6(a).

1.113 "Quality Agreement" means the Quality Agreement(s) to be entered into between Protalix and Pfizer with respect to the Drug Substance [\*\*\*] being Manufactured by Protalix [\*\*\*] requirements in the Territory.

[\*\*\*] Redacted pursuant to a confidential treatment request.

1.114 “Redacted Agreement” shall have the meaning assigned to it in Section 9.5.

1.115 “Regulatory Approval” means any and all approvals, with respect to any Country, or authorizations (other than Price Approvals) of a Regulatory Authority, that are necessary for the commercial Manufacture, distribution, use, marketing or sale of a drug product in such Country.

1.116 “Regulatory Authority” means, in respect of a particular Country or jurisdiction, the Governmental Authority having responsibility for granting Regulatory Approvals in such Country or jurisdiction.

1.117 “Regulatory Exclusivity” means any rights or protections which are recognized, afforded or granted by a Regulatory Authority in any Country or region of the Territory, in association with the Regulatory Approval of a Licensed Product, providing such Licensed Product: (a) a period of marketing exclusivity, during which the Regulatory Authority recognizing, affording or granting such marketing exclusivity will refrain from either reviewing or approving a marketing authorization application or similar regulatory submission, submitted by a party other than Pfizer, its Affiliates or Sublicensees seeking to market a drug product in which the Drug Substance is the primary ingredient, or during which such an application or submission may be reviewed or approved by a Regulatory Authority, but the product may not be placed on the market or (b) a period of data exclusivity, during which a party, other than Pfizer, its Affiliates or Sublicensees, seeking to market a drug product in which the Drug Substance is the primary ingredient, is precluded from either referencing or relying upon a Licensed Product’s clinical dossier or relying on previous findings of safety or effectiveness with respect to a Licensed Product to support the submission, review or approval of a marketing authorization application or similar regulatory submission before the applicable Regulatory Authority. Regulatory Exclusivity shall include rights conferred in the United States pursuant to the Hatch-Waxman Act or the FDA Modernization Act of 1997 or in the European Union/European Economic Area pursuant to Section 10.1 of Directive 2001/EC/83 or section 14.11 of Regulation (EC) No. 726/2004.

1.118 “Release” means any release, spill, emission, leaking, pumping, injection, deposit, disposal, discharge, dispersal, leaching or migration into the indoor or outdoor environment, including the uncontrolled presence or the movement of Hazardous Materials through the ambient air, soil, subsurface water, groundwater, wetlands, lands or subsurface strata.

1.119 “Reporting Period” shall have the meaning assigned to it in Section 7.1(a).

1.120 “Required Studies” means all pre-clinical or clinical studies for a Licensed Product (other than [\*\*\*]) required by any Regulatory Authority in any Country in the European Union or the United States as a condition of obtaining Regulatory Approval for the Licensed Product in such Country, whether conducted prior to or after receipt of Regulatory Approval.

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

1.121 “Safety Stock” shall have the meaning assigned to it in Section 5.14(a).

1.122 “Sales and Marketing Expenses” shall have the meaning set forth in Exhibit E.

1.123 “Steering Committee” shall have the meaning assigned to it in Section 4.3(a).

1.124 “Steering Committee Meeting” shall have the meaning assigned to it in Section 4.3(b).

1.125 “Sublicense” means the grant by Pfizer of a sublicense under, or an agreement of Pfizer not to assert, any of the rights licensed by Protalix to Pfizer pursuant to Section 3.1.

1.126 “Sublicensee” means a Third Party to whom Pfizer has granted a Sublicense.

1.127 “Supply Failure” shall have the meaning assigned to it in Section 5.17(a).

1.128 “System” means Protalix’s proprietary protein expression system, ProCellEx™.

1.129 “Technology” means proprietary materials, technology, data, results and non-public technical, scientific and clinical information, in any tangible or intangible form, including know-how, expertise, trade secrets, practices, techniques, methods, processes, developments, specifications, formulations, formulae, including any intellectual property rights embodying any of the foregoing, but excluding any Patent Rights.

1.130 “Term” shall have the meaning assigned to it in Section 13.

1.131 “Territory” means the entire world, excluding Israel.

1.132 [\*\*\*].

1.133 “Third Party” means any Person other than Pfizer, Protalix, or any of their respective Affiliates.

1.134 “Third Party Claim” shall have the meaning assigned to it in Section 15.3.

1.135 “Third Party License” means each license agreement between Protalix and a Third Party pursuant to which or from which Protalix licenses Protalix Patent Rights or Protalix Technology, including the license agreements listed on Exhibit C.

1.136 [\*\*\*].

1.137 “Uncapped Expenses” shall have the meaning assigned to it in Exhibit E.

[\*\*\*] Redacted pursuant to a confidential treatment request.

1.138 “Uplyso Trademarks” means the trademark “UPLYSO™” in certain countries in the world, as set forth in the schedule attached to Exhibit H.

1.139 “Valid Claim” means (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination or disclaimer; or (b) a claim of a Patent Application, which claim has been pending less than five (5) years from the original priority date of such claim in a given jurisdiction, unless or until such claim thereafter issues as a claim of an issued Patent (from and after which time the same shall be deemed a Valid Claim subject to paragraph (a) above).

1.140 “[\*\*\*]” means [\*\*\*].

1.141 “[\*\*\*]License Agreement” means that License Agreement by and between Protalix and [\*\*\*] effective as of [\*\*\*], as amended from time to time.

1.142 “Waste” means all wastes which arise from the Manufacture, handling or storage of Drug Substance hereunder, or which is otherwise produced through the implementation of this Agreement, including Hazardous Materials.

Construction. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) “include”, “includes” and “including” are not limiting and mean include, includes and including, without limitation; (b) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (c) references to an agreement, statute or instrument mean such agreement, statute or instrument as from time to time amended, modified or supplemented; (d) references to a Person are also to its permitted successors and assigns; (e) references to an “Article”, “Section”, “Exhibit” or “Schedule” refer to an Article or Section of, or any Exhibit or Schedule to, this Agreement unless otherwise indicated; (f) the word “will” shall be construed to have the same meaning and effect as the word “shall”; and (g) the word “any” shall mean “any and all” unless otherwise indicated by context.

## **Section 2. [INTENTIONALLY OMITTED]**

## **Section 3. LICENSE**

3.1. Exclusive License. Subject to the terms of this Agreement, including Section 3.2, Protalix hereby grants to Pfizer and Pfizer hereby accepts an exclusive (including as to Protalix and its Affiliates, except as set forth in Section 3.2) license in the Territory and within the Field, including the right to Sublicense (subject to Section 3.4):

[\*\*\*] Redacted pursuant to a confidential treatment request.

(a) under the Protalix Patent Rights to (i) use, sell, offer for sale, supply, cause to be supplied, and import the Licensed Product, (ii) conduct the Fill/Finish activities and Labeling and Packaging activities, (iii) engage in Development activities with respect to the Licensed Product, and (iv) make and have made the Drug Substance solely for incorporation in the Licensed Product; and

(b) to use Protalix Technology and Protalix Confidential Information in connection with (i) the conduct of the Fill/Finish activities and Labeling and Packaging activities, (ii) preparing and submitting regulatory filings and communicating with Regulatory Authorities with respect to the Licensed Product, (iii) the use, sale, offer for sale, supply and importation of the Licensed Product, (iv) Development activities with respect to the Licensed Product, and (v) making and having made the Drug Substance solely for incorporation in the Licensed Product.

### 3.2. Other License Provisions.

(a) The licenses granted to Pfizer pursuant to Section 3.1 shall be co-exclusive with Protalix only to the extent it is necessary for Protalix to perform its obligations under this Agreement. In addition, in the event that Pfizer provides Protalix with a Section 14.2(c) Notice, during the Section 14.2(c) Termination Notice Period, the licenses granted to Pfizer pursuant to Section 3.1 shall be co-exclusive with Protalix to the extent reasonably necessary for Protalix to prepare for transition activities mutually agreed upon by the parties pursuant to Section 14.2(c) and Commercialization of the Licensed Product by Protalix upon the effective date of termination; provided that Protalix shall not be entitled to commence Commercialization prior to the effective date of termination. During the Term, and without limiting the scope of the licenses granted to Pfizer pursuant to Section 3.1, neither Protalix nor any of its Affiliates shall, directly or indirectly, alone or in collaboration with any Third Party, Commercialize the Compound (other than the Oral Formulation), a drug product containing the [\*\*\*]. The parties expressly acknowledge and agree that, subject to Section 12, the exclusivity grant in favor of Pfizer in Section 3.1 shall not be construed as limiting Protalix's right to Develop, Manufacture or Commercialize[\*\*\*].

(b) Notwithstanding the licenses granted to Pfizer pursuant to Section 3.1, Pfizer hereby covenants that it shall not exercise its rights to make and have made the Drug Substance unless and until there has been a Failure to Supply.

(c) For purposes of clarity, and without limiting the licenses granted under Section 3.1, Pfizer acknowledges that in the event Protalix does not have exclusive rights to Protalix Patent Rights licensed by Protalix from Third Parties [\*\*\*] vis à vis the Third Party licensor, Pfizer's rights to such Protalix Patent Rights under the sublicenses granted under Section 3.1 would not be exclusive vis à vis the Third Party licensor.

[\*\*\*] Redacted pursuant to a confidential treatment request.

### 3.3. Non-Assertion of Rights.

(a) During the Term, Pfizer shall not, and shall cause its Affiliates not to, assert any Patent Rights or Technology owned or Controlled by Pfizer and its Affiliates against Protalix, its Affiliates or permitted sublicensees for (i) exercising its rights and performing its obligations pursuant to this Agreement or (ii) using, making, having made, selling, offering for sale, supplying, causing to be supplied and importing the Drug Substance or Licensed Product outside the Territory. After the Term (except if this Agreement is terminated by Pfizer pursuant to Section 14.2(a)), Pfizer shall not, and shall cause its Affiliates not to, assert any Patent Rights that are owned or Controlled by Pfizer and its Affiliates on the effective date of termination against Protalix and its Affiliates for using, making, having made, selling, offering for sale, supplying, causing to be supplied and importing the Drug Substance or Licensed Product (as such Drug Substance or Licensed Product was constituted as of the effective date of termination) in the Field. For the purposes of this Section 3.3(a), the term “Technology” shall be limited to that which is necessary for Protalix and its Affiliates to use, make, have made, sell, offer for sale, supply, cause to be supplied, and import Drug Substance or Licensed Product (as such Drug Substance or Licensed Product was constituted as of the effective date of termination) in the Field.

(b) The covenant not to sue in Section 3.3(a) shall inure to the benefit of the respective successors and permitted assigns of Protalix and its Affiliates, and may be extended by Protalix and its Affiliates to a Third Party successor to all or substantially all of the assets of Protalix or its Affiliates, whether by merger, consolidation, sale of stock, or sale of all or substantially all of Protalix’s assets, so long as such Third Party agrees in writing to be bound by the terms of this Agreement.

### 3.4. Sublicensing and Subcontracting.

(a) Pfizer may not grant a Sublicense without the prior written consent of Protalix, such consent not to be unreasonably delayed or withheld, except that Pfizer may, without prior written consent of Protalix, grant Sublicenses to (i) its Affiliates, which Sublicense shall automatically terminate when such Affiliate ceases to be an Affiliate of Pfizer; and (ii) Third Parties, solely with respect to rights to use, import, offer to sell or sell the Licensed Product in any Country other than a Major Market Country. Any Sublicensee obligations required by the Third Party License to be included in a sublicense shall be deemed to be included in this Agreement as obligations of Pfizer.

(b) Each Sublicense granted by Pfizer pursuant to Section 3.4(a) shall be subject and subordinate to the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement, and shall not in any way diminish, reduce or eliminate any of Pfizer’s obligations under this Agreement. Without limiting the foregoing, each Sublicense agreement with permitted Sublicensees shall contain the following provisions: (i) a requirement that such Sublicensee submit applicable sales or other reports consistent with the requirements set forth in Section 7.1, (ii) a requirement to keep books and records, and permit Protalix to audit (either directly or through an independent auditor) such books and records, consistent with the requirement set forth in Section 7.5, (iii) a requirement that such Sublicensee comply with the confidentiality and non-use provisions of Section 9 with

respect to both parties' Confidential Information, (iv) a requirement to comply with all other applicable terms of this Agreement, and (v) a provision prohibiting such Sublicensee from further sublicensing. Pfizer shall provide Protalix with a copy of each such Sublicense agreement within thirty (30) days after the execution thereof, provided that Pfizer may redact confidential information from such Sublicense agreement that is not reasonably necessary to demonstrate Pfizer's compliance with the obligations set forth in clauses (i) through (v) of this Section 3.4(b).

(c) Right to Subcontract. Each party may, subject to Section 9, subcontract its obligations under this Agreement to an Affiliate or Third Party as it would in the normal course of its business without the prior written consent of the other party, except that, in the Major Market Countries:

(i) neither party may subcontract its obligations to a Third Party to create, oversee and manage the execution of the Development Plan without the prior written consent of the other party, such consent not to be unreasonably delayed or withheld; and

(ii) Pfizer may not subcontract to any Third Party (including sub-distributors and contract sales organizations), without the prior written consent of Protalix, such consent not to be unreasonably delayed or withheld, its obligations to:

(A) promote the Licensed Product, and all members of Pfizer's sales force shall be employees of Pfizer or its Affiliate; provided that Pfizer does not need Protalix's consent to use a subcontractor to act as a Medical Science Liaison for the Licensed Product in any Major Market Country; and

(B) prepare and submit regulatory filings and communicate with Regulatory Authorities with respect to the Licensed Product; provided that Pfizer does not need Protalix's consent to use Target Health to conduct such activities. Notwithstanding the foregoing, this Section 3.4(c)(ii) shall not obligate Pfizer to obtain Protalix's consent to use a Third Party subcontractor for Development activities in the Major Market Countries other than for preparing and submitting regulatory filings and communicating with Regulatory Authorities.

(d) Liability for Affiliates, Sublicensees and Subcontractors. Each party shall ensure that each of its Affiliates, permitted Sublicensees (in the case of Pfizer) and permitted subcontractors accepts and complies with all of the applicable terms and conditions of this Agreement as if such Affiliates or permitted Sublicensees or subcontractors were parties to this Agreement and each party shall remain fully responsible for its Affiliates' and permitted sublicensees' or subcontractors' performance under this Agreement.

### 3.5. Improvements.

(a) During the Term, Protalix shall give written notice (an "Improvement Notice") to Pfizer within thirty (30) days of any actual or constructive reduction to practice of any Protalix Improvement. The Improvement Notice shall set forth the nature and details of the Protalix Improvement and any data obtained or generated by Protalix. Where such Protalix Improvements are to an invention, Protalix shall state in the Improvement Notice whether it intends to prepare and file patent applications related thereto.



(b) Each Protalix Improvement shall be deemed to be included within the Protalix Technology licensed to Pfizer pursuant to Section 3.1 of this Agreement, without the payment of any additional fees, milestones, royalties, or adjustments to the profit sharing scheme set forth in Section 6.3. Any Patent Application directed to a Protalix Improvement shall be considered to be a Protalix Patent Right licensed pursuant to Section 3.1 of this Agreement, without the payment of any additional fees, milestones, royalties, or adjustments to the profit sharing scheme set forth in Section 6.4.

### 3.6. Patent Challenges.

(a) During the Term of this Agreement, including during any Section 14.2(c) Termination Notice Period, Pfizer and its Affiliates hereby covenant and agree not to, directly or indirectly, commence any legal proceeding that challenges the validity, enforceability or ownership of any Protalix Patent Right, including any Protalix System Patent Right, to the extent such Protalix Patent Right relates to the Compound or Licensed Product or the Development, Manufacture or Commercialization of the Compound or Licensed Product (a "Patent Challenge").

(b) If Pfizer, its Affiliate or Sublicensee directly or indirectly commences any Patent Challenge, Protalix shall have the right to immediately terminate this Agreement by written notice effective upon receipt by Pfizer. The foregoing right of Protalix to terminate this Agreement shall not apply to any such challenge that arises out of or is in connection with any legal action commenced by Protalix against Pfizer, in which Protalix asserts any Protalix Patent Rights or other Patent Rights against Pfizer, whether arising out of or in connection with this Agreement or otherwise.

3.7. No Implied License. Except for the licenses and other rights granted to Pfizer herein, all right, title and interest in and to the Protalix Patent Rights, Protalix Technology, Protalix Confidential Information and Protalix Improvements shall remain solely with Protalix and its Third Party licensors, as applicable. Except as expressly provided in this Section 3 or elsewhere in this Agreement, neither party will be deemed by this Agreement to have been granted any license or other rights to the other party's intellectual property rights, either expressly or by implication, estoppel or otherwise.

## **Section 4. DEVELOPMENT, REGULATORY APPROVALS AND MARKETING**

4.1. Development Plan. The Development of the Licensed Product in the United States and the Major EU Countries shall be governed by a Development Plan that describes (a) the proposed overall program of Development of the Licensed Product in the Field in the United States and the Major EU Countries, including [\*\*\*], (b) with respect to the [\*\*\*], the anticipated scope (including number of patients) and other material parameters that will determine the

[\*\*\*] Redacted pursuant to a confidential treatment request.

aggregate Development Cost for such [\*\*\*], and (c) the respective Development responsibilities of the parties with respect to such Development program (the “Development Plan”). The initial Development Plan is attached hereto as Exhibit D. All material amendments to the Development Plan shall be approved by the Steering Committee in accordance with Section 4.3(c)(ii). [\*\*\*].

4.2. Development Responsibilities. Pursuant to the Development Plan, and subject to the oversight of the Steering Committee (but without limitation of and subject to Sections 4.3(d)(i) and 4.3(d)(iii)), Protalix will be responsible for [\*\*\*]. Protalix will also be responsible for [\*\*\*]. Except as described in the foregoing sentences of this Section 4.2, Pfizer will be solely responsible for all Development of the Licensed Product in the United States and Major EU Countries in accordance with the Development Plan, as amended from time to time, and for all other Development of the Licensed Product in the Territory. Each party’s responsibility for paying the costs associated with such Development activities is set forth in Section 6.3.

#### 4.3. Steering Committee.

(a) Formation and Membership. The parties shall, within thirty (30) days after the Effective Date, form a steering committee (the “Steering Committee”). The Steering Committee shall consist of three (3) representatives appointed by Protalix and three (3) representatives appointed by Pfizer. The Steering Committee shall be chaired by one of the Pfizer representatives (the “Pfizer Chair”). From time to time, each party may substitute its representatives on the Steering Committee in its sole discretion, effective upon notice to the other party of such change. Additional representatives or consultants may from time to time, by mutual consent of the parties, be invited to attend Steering Committee Meetings, subject to such representatives’ and consultants’ written agreement to comply with the requirements of Section 9.

(b) Meetings. During the Term, the Steering Committee shall meet quarterly or as otherwise determined by the parties (each such meeting, a “Steering Committee Meeting”). Upon the request of the Steering Committee, each party will provide written materials relating to its activities under the Development Plan in advance of a Steering Committee Meeting. All Steering Committee Meetings may be conducted in person, by videoconference or by teleconference at such times and such Pfizer or Protalix locations as shall be determined by the Steering Committee. In-person meetings of the Steering Committee will alternate between appropriate offices of each party. The parties shall each bear all expenses of their respective representatives relating to their participation on the Steering Committee. The members of the Steering Committee also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate.

[\*\*\*] Redacted pursuant to a confidential treatment request.

(c) Responsibilities. The Steering Committee shall have the following roles and responsibilities:

(i) Discuss and approve the final design and conduct of [\*\*\*];

(ii) Review and approve any material amendments to the Development Plan, including material amendments that provide for pre-clinical or clinical studies in addition to [\*\*\*];

(iii) Provide updates, data and other information regarding each party's activities under the Development Plan;

(iv) Discuss the timing of [\*\*\*] with respect to the Compound or Licensed Product [\*\*\*];

(v) Act as a forum pursuant to which the parties will review and discuss plans and strategies relating to (w) the Development of the Licensed Product in the Field in the Territory, (x) regulatory matters with respect to the Licensed Product in the Field in the Territory, (y) Pfizer Discount or Savings Programs in the Territory, and (z) Commercialization of the Licensed Product in the Field in the Territory, including plans and strategies for, and the parties' responsibility for [\*\*\*];

(vi) Act as a forum pursuant to which the parties will review and discuss plans and strategies relating to (x) the Development of the Licensed Product in the Field outside the Territory, (y) regulatory matters with respect to the Licensed Product in the Field outside the Territory, and (z) Commercialization of the Licensed Product in the Field outside the Territory, in order to coordinate activities described in subsections (x), (y) and (z) of this Section 4.3(c)(vi), with respect to the Licensed Product outside the Territory with the plans and strategies for the Licensed Product in the Territory;

(vii) Oversee Early Access Programs for Licensed Product;

(viii) [\*\*\*];

(ix) Discuss the possibility, from time to time, of sharing promotional materials for the Licensed Product in the Field inside and outside the Territory;

(x) Discuss any request by Pfizer that Protalix build additional Manufacturing capacity in accordance with Section 5.2(b); and

(xi) Such other roles and responsibilities provided for in this Agreement or as may be assigned to the Steering Committee in writing by mutual agreement of the parties.

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

(d) Decision-Making by the Steering Committee. All decisions of the Steering Committee made pursuant to this Agreement shall be made by consensus with each party having one vote; provided, however, that in the event of a disagreement between Pfizer and Protalix with respect to any such proposed decision, the Pfizer Chair shall have the final decision-making authority; provided, further, however that:

- (i) the Protalix Chair shall have the final decision-making authority with respect to [\*\*\*];
- (ii) prior to the Pfizer Chair exercising final decision-making authority with respect to the matters discussed pursuant to Section 4.3[\*\*\*]
- (iii) with respect to [\*\*\*], the final decision-making authority of the Pfizer Chair shall not be exercisable if such decision would have [\*\*\*].

For the avoidance of doubt: (x) Pfizer will have [\*\*\*]; and (y) Protalix will have [\*\*\*].

(e) Minutes. The Pfizer Chair will appoint a secretary who will be responsible for preparing and distributing to all members of the Steering Committee minutes of each meeting reasonably promptly after a Steering Committee Meeting. Such minutes will report in reasonable detail actions taken by the Steering Committee during such meeting, issues requiring resolution and resolutions of previously reported issues. Such minutes will be reviewed and, if reasonably complete and accurate, signed by one Steering Committee member from each party. The secretary shall revise such minutes as necessary to obtain such signatures.

(f) [\*\*\*]. If Protalix (i) [\*\*\*] or (ii) [\*\*\*], Pfizer shall have the right to [\*\*\*] by submitting written notice to Protalix (x) in the case of [\*\*\*], no later than [\*\*\*], or (y) in the case Protalix [\*\*\*].

(g) Protalix Withdrawal from Steering Committee. At any time during the Term and for any reason, Protalix shall have the right to withdraw from participation on the Steering Committee upon written notice to Pfizer, which notice shall be effective immediately upon receipt ("Withdrawal Notice"). Following the issuance of a Withdrawal Notice and subject to this Section 4.3(g), Protalix's representatives on the Steering Committee shall not participate in any meetings of the Steering Committee, nor shall Protalix have any right to vote on decisions within the authority of the Steering Committee. If, at any time following the issuance of a Withdrawal Notice, Protalix wishes to resume participating on the Steering Committee, Protalix shall notify Pfizer in writing and, thereafter, Protalix representatives on the Steering Committee shall be entitled to attend any subsequent meeting of the Steering Committee and to participate in the activities of, and decision-making by, the Steering Committee as provided in this Section 4 as if a Withdrawal Notice had not been issued by Protalix pursuant to this Section 4.3(g). Following Protalix's issuance of a Withdrawal Notice pursuant to this Section 4.3(g), unless and

[\*\*\*] Redacted pursuant to a confidential treatment request.

until Protalix resumes participation in the Steering Committee in accordance with this Section 4.3(g): (i) all meetings of the Steering Committee shall be held at Pfizer's facilities; (ii) subject to Section 4.3(d), Pfizer shall have the right to make the final decision on all matters within the scope of authority of the Steering Committee; (iii) Protalix shall have the right to continue to receive all reports and materials provided to the Steering Committee hereunder as well as reasonable advance notice of any pending Steering Committee decisions, but shall not have the right to approve the minutes for any Steering Committee meeting held after Protalix's issuance of a Withdrawal Notice; and (iv) Protalix shall report to Pfizer in writing regarding the matters in Section 4.3(c)(vi) and Section 4.12 that would have otherwise been discussed by the Steering Committee. For clarity, the withdrawal by Protalix under this Section 4.3(g) shall only limit Protalix's rights under this Section 4 with respect to participation on the Steering Committee; notwithstanding any obligation to the contrary contained herein, Protalix's attendance at Steering Committee meetings shall be optional and Protalix's withdrawal or nonattendance at Steering Committee meetings shall have no impact on the consideration provided for or due to Protalix under this Agreement.

4.4. Records. During the Term, each party will prepare and maintain accurate records and books relating to the progress and status of its activities under the Development Plan and otherwise in relation to the development of the Drug Substance and Licensed Product.

4.5. Diligence. Each party will use Commercially Reasonable Efforts to carry out the Development activities contemplated by the Development Plan to be carried out by such party in order to Develop the Licensed Product in the Field in the Territory as soon as reasonably practicable. Pfizer will use Commercially Reasonable Efforts to seek as soon as reasonably practicable Regulatory Approval (and Price Approval and Governmental Authority or Third Party reimbursement approval where applicable) for the Licensed Product in the Field in the Territory. Pfizer will Launch and Commercialize the Licensed Product in the United States and each of the Major EU Countries promptly following Regulatory Approval (and Price Approval and Governmental Authority or Third Party reimbursement approval where applicable) of the Licensed Product in the Field in such Country, provided that (a) such Launch and Commercialization will not, in the good faith judgment of Pfizer, after consultation with legal counsel, [\*\*\*], and (b) Protalix has complied with and, at the time of Launch is complying with, Section 5.6 with respect to fulfilling Purchase Orders; provided, further, however that with respect to subclause (a), Pfizer will Launch and Commercialize in each such Country when (i) the Steering Committee determines in accordance with Section 8.7 that [\*\*\*] and (ii) Pfizer [\*\*\*] after using Commercially Reasonable Efforts to do so. Notwithstanding the foregoing, Pfizer shall not be in breach of its obligation to Launch and Commercialize the Licensed Product in the United States promptly following Regulatory Approval in the United States if Pfizer does not have a Launch supply because Pfizer has not issued Purchase Orders pursuant to Section 5.6(a) because the GMP Audit, mitigation plan (if any) and Quality Agreement(s) have not been completed pursuant to Section 5.9. Pfizer will use Commercially Reasonable Efforts to Launch and Commercialize as soon as reasonably practicable the Licensed Product in the Field in each

[\*\*\*] Redacted pursuant to a confidential treatment request.

Country in the Territory other than the United States and the Major EU Countries in which Regulatory Approval (and Price Approval and Governmental Authority or Third Party reimbursement approval where applicable) for the Licensed Product in the Field is obtained.

4.6. Regulatory Affairs.

(a) Copies of Regulatory Filings. Protalix shall provide to Pfizer, at Pfizer's expense, complete copies of any regulatory filings in the Territory relating to the Licensed Product, including INDs, filings with FDA or other Regulatory Authorities, supplements or amendments thereto, all written correspondence with FDA or other Regulatory Authorities regarding such regulatory filings, and all existing written minutes of meetings and memoranda of conversations between Protalix (including, to the extent practicable, Protalix's investigators) and FDA or other Regulatory Authorities in Protalix's possession (or in the possession of any of Protalix's agents and subcontractors, such as contract research organizations used by Protalix), to the extent Protalix has the right to access and provide to Pfizer such materials. To the extent available, Protalix shall provide such copies to Pfizer in electronic form.

(b) [\*\*\*].

(i) [\*\*\*].

(A) To the extent permitted by applicable Law, as of the [\*\*\*], Protalix shall [\*\*\*]. The parties shall take all actions necessary to accomplish the foregoing, including [\*\*\*].

(B) To the extent permitted by applicable Law, upon Pfizer's request, [\*\*\*].

(ii) [\*\*\*]. To the extent permitted by applicable Law, upon Pfizer's request, [\*\*\*].

(iii) Cooperation. The parties shall cooperate through the Steering Committee to ensure that [\*\*\*].

(c) Rights of Reference and Access to Data.

(i) [\*\*\*].

(ii) [\*\*\*].

[\*\*\*] Redacted pursuant to a confidential treatment request.

(iii) As the manufacturer and supplier of Drug Substance, Protalix shall provide to Pfizer original copies of any Certificate of Pharmaceutical Product (“CPP”) issued to Protalix as necessary to support Pfizer’s regulatory filings for the Licensed Product in the Field in the Territory. Protalix shall use Commercially Reasonable Efforts to apply for and obtain such CPP.

(d) Assignment of Contracts. Upon Pfizer’s reasonable request, Protalix shall assign to Pfizer any contract Protalix has entered into with a Third Party that solely relates to the Development of the Licensed Product in the Territory, to the extent Pfizer requests such contract to be assigned and such contract is assignable. If any such contract relates to the Development of the Licensed Product in the United States, Pfizer shall not request assignment of such contract until the FDA Approval Date.

(e) Responsibility. Subject to Sections 4.3(d)(i) and 4.3(d)(iii), Pfizer shall have the sole authority and exclusive right to determine all regulatory plans and strategies for the Licensed Product in the Field in the Territory; provided that Pfizer shall reasonably consider any comments on such plans and strategies that Protalix may communicate through the Steering Committee or otherwise. Without limiting the foregoing, subject to Section 4.6(b), Pfizer (or, in any Country in the Territory, one or more of its designated Affiliates) will own and be responsible for preparing, seeking, submitting and maintaining all regulatory filings and Regulatory Approvals for the Licensed Product in Field in the Territory, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval. Protalix shall provide such assistance as Pfizer reasonably requires to obtain Regulatory Approvals for the Licensed Product in the Field in the Territory. Pfizer shall have the sole right to apply for and secure exclusivity rights that may be available under the Law of Countries in the Territory, including any Regulatory Exclusivity. Protalix shall use Commercially Reasonable Efforts to cooperate with Pfizer and to take such reasonable actions to assist Pfizer, in obtaining such exclusivity rights in each Country, as Pfizer may reasonably request from time to time.

(f) Pharmacovigilance. After the Effective Date and prior [\*\*\*], the safety units of each of the parties shall meet and agree upon a written pharmacovigilance agreement that defines Pfizer’s pharmacovigilance responsibilities for the Licensed Product in the Territory and Protalix’s pharmacovigilance responsibilities for the Licensed Product outside the Territory and the process for exchanging adverse event reports and other safety information relating to a Licensed Product that will permit each party to comply with applicable Laws and requirements of Regulatory Authorities.

(g) Communications with Regulatory Authorities.

(i) For so long [\*\*\*], Protalix, and [\*\*\*], Pfizer, shall provide the other party with notice of all meetings, conferences, and discussions (including Advisory

[\*\*\*] Redacted pursuant to a confidential treatment request.

Committee meetings or any other meeting of experts convened by the FDA concerning any topic relevant to the Licensed Product) scheduled with the FDA concerning any regulatory matters relating to the Licensed Product promptly after the scheduling of such meeting, conference, or discussion. The party that [\*\*\*] shall be entitled to have one or more representatives present at all such meetings. Protalix and Pfizer shall use all reasonable efforts to agree in advance on the scheduling of such meetings, conferences and discussions and on the objectives to be accomplished at such meetings, conferences and discussions and the agenda for the meetings, conferences and discussions with the FDA, and with respect to Advisory Committee meetings, if any; provided that [\*\*\*].

(ii) For so long as [\*\*\*], shall provide the other party with copies, which copies may be in draft form, of all material submissions to the FDA relating to the Licensed Product. Such copies shall be provided sufficiently in advance of such planned submission to the FDA in order to allow such other party to provide comments regarding such submission. The party making the submission shall consider the other party's comments in good faith with respect to such submission; provided that [\*\*\*] with copies, which copies may be in draft form, of all material submissions to the EMEA relating to the Licensed Product. [\*\*\*] such copies sufficiently in advance of such planned submission to the EMEA [\*\*\*] will consider [\*\*\*] comments in good faith with respect to such submission; provided that [\*\*\*].

(iii) Each party shall provide to the other party, as soon as reasonably practicable but in no event more than three (3) Business Days after its receipt, copies of any material documents or other material correspondence received from the FDA or the EMEA pertaining to the Licensed Product.

(iv) Protalix shall use reasonable efforts to notify Pfizer in advance of material meetings with Regulatory Authorities outside the Territory with respect to the Licensed Product in the Field, and, upon request by Pfizer, Protalix shall not unreasonably withhold its consent for an appropriate representative of Pfizer to attend such meetings; provided that Protalix shall have final decision-making authority over such matters. Protalix shall provide Pfizer with copies, which copies may be in draft form, of all material submissions to the Regulatory Authority outside the Territory relating to the Licensed Product. Such copies shall be provided sufficiently in advance of such planned submission to such Regulatory Authority in order to allow Pfizer to provide comments regarding such submission. Protalix shall consider Pfizer's comments in good faith with respect to such submission; provided that Protalix shall have final decision-making authority over such matters.

(h) Regulatory Information. Each party agrees to provide the other with all reasonable assistance and take all actions reasonably requested by the other party that are necessary or desirable to enable the other party to comply with any Law applicable to the Licensed Product, including, but not limited to, Pfizer's meeting its reporting and other obligations to maintain and update any Regulatory Approval for the Licensed Product in the Territory.

[\*\*\*] Redacted pursuant to a confidential treatment request.



(i) Recalls or Other Corrective Action. Pfizer shall promptly notify Protalix of any material actions to be taken by Pfizer in the Territory with respect to any recall or market withdrawal or other corrective action related to the Licensed Product prior to such action, if reasonably practicable under the circumstances, to permit Protalix a reasonable opportunity to consult with Pfizer with respect thereto. All costs and expenses with respect to a recall, market withdrawal or other corrective action shall be borne by Pfizer; provided, however, that the out-of-pocket costs and expenses of any such recall shall be [\*\*\*] to the extent not resulting from or related to Pfizer's breach of its obligations under this Agreement or its negligence or intentional misconduct.

#### 4.7. Commercialization and Pricing.

(a) An initial Commercialization plan for the Licensed Product in the Field in the Territory prepared by Pfizer is attached hereto as Exhibit G (the "Initial Commercialization Plan"). Pfizer shall update such plan (any such updated plan, the "Commercialization Plan") at least once per calendar year in accordance with Pfizer's U.S. operating plan calendar for its other drug products. Each such subsequent Commercialization Plan shall be submitted to the Steering Committee for review and discussion no later than thirty (30) days prior to the beginning of the immediately succeeding calendar year. Protalix may, through its representatives on the Steering Committee, propose to Pfizer revisions to any such subsequent Commercialization Plan, and any proposed material updates or amendments to the Initial Commercialization Plan and any subsequent Commercialization Plan, that Protalix reasonably believes are appropriate, and Pfizer shall consider any such proposed revisions in good faith, but such Initial Commercialization Plan or Commercialization Plan, or any material amendments or updates thereto, shall not require approval of the Steering Committee.

(b) Pfizer shall have the sole authority and exclusive right to Commercialize, and shall be responsible for paying all costs and expenses associated with the Commercialization of, the Licensed Product in the Field in the Territory, including marketing, promoting, selling, distributing and [\*\*\*] of sale for the Licensed Product and obtaining any necessary Price Approvals, and such costs and expenses shall constitute [\*\*\*]. Protalix hereby agrees to refrain from selling Licensed Product outside the Territory to any Person if Protalix has knowledge or reason to believe that such Licensed Product is intended for transshipment or delivery by such Person in the Territory. Pfizer hereby agrees to refrain from selling the Licensed Product in the Territory to any Person if Pfizer has knowledge or reason to believe that such Licensed Product is intended for transshipment or delivery by such Person outside the Territory.

(c) At meetings of the Steering Committee, Pfizer will provide Protalix with periodic updates regarding the status and details of Price Approvals and Governmental and Third Party reimbursement approvals in each applicable Country in the Territory.

[\*\*\*] Redacted pursuant to a confidential treatment request.

4.8. Early Access Programs. The parties shall discuss at the Steering Committee the appropriate mechanism for transferring control of all Early Access Programs from Protalix to Pfizer with the goal of transferring such control as soon as reasonably practicable after the Effective Date.

4.9. Trademarks.

(a) Assignment. As of the Effective Date, Protalix hereby transfers and assigns to Pfizer all of its worldwide rights, title and interest to the Uplyso Trademarks, including any goodwill associated with the Uplyso Trademarks. In connection with and in furtherance of the transfer of the Uplyso Trademarks, the Parties on the Effective Date will execute a trademark assignment instrument in the form attached hereto as Exhibit H. Pfizer shall be responsible for paying all costs and expenses associated with recording the trademark assignment instrument with the appropriate governmental authorities throughout the world, and such costs and expenses shall constitute [\*\*\*].

(b) Choice of Trademarks. Pfizer may choose, in its sole discretion, to use the Uplyso Trademarks or any other trademarks to Commercialize the Licensed Product in the Field in the Territory and Pfizer shall own all such trademarks (the "Product Marks").

(c) License to Protalix. Pfizer hereby grants to Protalix an exclusive (except as to Pfizer) license, free of charge, to use the Product Marks outside the Territory solely in connection with the packaging, sale, marketing, promotion, advertising, disposition and distribution of the Licensed Product in the Field during the Term outside the Territory.

(d) Quality Control.

(i) The quality of the Licensed Product sold by Protalix outside the Territory under or in connection with the Product Marks must be of a sufficiently high quality to be generally comparable to the quality of the Licensed Product sold by Pfizer in the Territory under or in connection with the Product Marks.

(ii) Protalix shall comply with all applicable Laws pertaining to the proper use and designation of the Product Marks.

(iii) Protalix agrees to use the Product Marks only in the form and manner and with appropriate legends as prescribed from time to time during the Term by Pfizer.

(iv) Additionally, Protalix shall:

(A) display the proper form of trademark notice associated with the Product Marks;

[\*\*\*] Redacted pursuant to a confidential treatment request.

(B) on any item which bears a Product Mark, include where practicable a statement identifying Pfizer or its Affiliate, as applicable, as the owner of such Product Mark and where possible indicating that Protalix or its Affiliate, as applicable, is an authorized user of such Product Mark;

(C) not use any Product Mark as a corporate name, business name, or trade name;

(D) not use any Product Mark in a manner that would reasonably be expected to materially impair the validity, reputation, or distinctiveness of any Product Mark; and

(E) not use any Product Mark in a manner that would reasonably be expected to materially impair the reputation of Pfizer or any of its Affiliates.

(e) Prosecution and Maintenance of Product Marks.

(i) Pfizer shall have the sole right, but not the obligation, through counsel of its choosing, to prosecute and maintain the Product Marks in the Territory and the first right, but not the obligation, through counsel of its choosing, to prosecute and maintain the Product Marks outside the Territory. In the event Pfizer elects not to prosecute or maintain any Product Mark outside the Territory, Pfizer shall provide reasonable prior written notice to Protalix of its intention not to prosecute or maintain any such Product Mark outside the Territory, and Protalix shall have the right to do so on behalf of Pfizer. All costs and expenses incurred by Pfizer in the filing, prosecution and maintenance of Product Marks in the Territory shall be treated as [\*\*\*]. All costs and expenses incurred by either party in the filing, prosecution and maintenance of Product Marks outside the Territory as provided in this Section 4.8(e) shall be treated as [\*\*\*].

(ii) Notwithstanding anything to the contrary in Section 4.9(e)(i), if, after providing a Section 14.2(c) Notice to Protalix, Pfizer elects not to prosecute or maintain any Product Mark the Territory, Pfizer shall provide reasonable prior written notice to Protalix of its intention not to prosecute or maintain any such Product Mark in the Territory, and Protalix shall have the right to do so on behalf of Pfizer, and all costs and expenses incurred by Protalix in the prosecution and maintenance of Product Marks in the Territory shall be treated as [\*\*\*].

(f) Enforcement of Product Marks.

(i) Each party will promptly notify the other in the event of any actual, potential or suspected infringement of a Product Mark by any Third Party. Pfizer shall have the sole right, but not the obligation, to institute litigation or take other remedial measures in connection with Third Party infringement of Product Marks in the Territory and the first right, but not the obligation, to institute litigation or take other remedial measures in connection with

[\*\*\*] Redacted pursuant to a confidential treatment request.

Third Party infringement of Product Marks outside the Territory. If Pfizer fails to initiate litigation or take other remedial measures against a Third Party who is infringing a Product Mark outside the Territory within ninety (90) days after becoming aware of the basis for such litigation or action, then Protalix may, in its discretion, provide Pfizer with written notice of Protalix's intent to initiate a suit or take other appropriate action. If Protalix provides such notice and Pfizer fails to initiate litigation or take such other appropriate action within thirty (30) days after receipt of such notice from Protalix, then Protalix shall have the right to initiate litigation or take other appropriate action that it believes is reasonably required to protect its right to use the Product Mark outside the Territory. Upon request of Protalix, Pfizer agrees to timely join as party-plaintiff in any such litigation, and in any event to cooperate with Protalix in connection with such infringement action. All costs and expenses incurred by Pfizer in enforcing the Product Marks in the Territory shall be treated as [\*\*\*] and any recoveries resulting from such litigation or other appropriate action, in pursuing such litigation or other appropriate action, will be deemed Net Sales. All costs and expenses incurred by Protalix in enforcing the Product Mark outside the Territory shall be at Protalix's sole expense and Protalix shall reimburse Pfizer for any and all costs or expenses incurred by Pfizer in connection with such enforcement by Protalix outside the Territory. Protalix shall retain all recoveries received by Protalix as a result of its enforcement of Product Mark rights outside the Territory.

(ii) Notwithstanding anything to the contrary in Section 4.9(f)(i), if, after providing a Section 14.2(c) Notice to Protalix, Pfizer fails to initiate litigation or take other remedial measures against a Third Party who is infringing a Product Mark in the Territory within ninety (90) days after becoming aware of the basis for such litigation or action, then Protalix may, in its discretion, provide Pfizer with written notice of Protalix's intent to initiate a suit or take other appropriate action. If Protalix provides such notice and Pfizer fails to initiate litigation or take such other appropriate action within thirty (30) days after receipt of such notice from Protalix, then Protalix shall have the right to initiate litigation or take other appropriate action that it believes is reasonably required to protect its right to use the Product Mark in the Territory. Upon request of Protalix and at Protalix's expense, Pfizer agrees to timely join as party-plaintiff in any such litigation, and in any event to cooperate with Protalix in connection with such infringement action. Protalix shall be responsible for all costs and expenses incurred by Protalix in enforcing the Product Marks in the Territory and shall be entitled to retain all recoveries resulting from such litigation or other appropriate action.

#### 4.10. Use of Names.

(a) No right, expressed or implied, is granted by this Agreement to a party to use in any manner the name or any other trade name of the other party or its Affiliates in connection with this Agreement. Notwithstanding the foregoing:

(i) Protalix shall have the right to use the Pfizer corporate name, subject to Pfizer's trademark usage guidelines provided to Protalix from time to time during the Term, including at least sixty (60) days prior to the date of Protalix's first use of the Pfizer corporate name, on package inserts, packaging or trade packaging associated with the Licensed

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

Product outside the Territory solely as required by applicable Laws outside the Territory. Protalix will submit for Pfizer's approval (which approval shall not be unreasonably withheld or delayed) a sample of each such proposed use of the Pfizer corporate name within sixty (60) days before the first use permitted pursuant to this Section.

(ii) Pfizer agrees, during the Term, to display as prominently as reasonably practicable the Protalix corporate name on the trade packaging used for the Licensed Product in the Field in the Territory unless to do so would be prohibited under applicable Laws or is not in accordance with the request of a Regulatory Authority, subject to Protalix's trademark usage guidelines applicable to the Protalix corporate name provided from time to time during the Term, including at least sixty (60) days prior to the date of Pfizer's first use of the Protalix corporate name. Upon the written request of Protalix, Pfizer shall submit to Protalix a sample of each proposed use of the Protalix corporate name.

4.11. Access to Information. Within thirty (30) days after the Effective Date, and from time-to-time throughout the Term, and at any time during the Term at Pfizer's request, Protalix shall provide Pfizer, its designated Affiliate or its agents and representatives with reasonable access, during regular business hours to (a) information concerning the Drug Substance, Licensed Product, Protalix Patent Rights and/or Protalix Technology that may be reasonably necessary or useful for Pfizer to seek Regulatory Approval for, perform Fill/Finish activities on or Commercialize the Licensed Product in the Field in the Territory and (b) Protalix-designated employees who possess the information described in clause (a) of this Section 4.11.

4.12. Information Rights. At each Steering Committee Meeting (or on a quarterly basis if the Steering Committee meets less frequently than once per quarter), Protalix will provide to Pfizer written information regarding [\*\*\*]. Protalix will provide notice to Pfizer of [\*\*\*].

4.13. [\*\*\*]

4.14. Scope of Sections 4.12 and 4.13. For the avoidance of doubt, it is understood and agreed that Sections 4.12 and 4.13 do not apply with respect to any offer, proposal, due diligence, proposed term sheet or any other documents or actions in connection with a possible Business Combination Transaction or a possible investment in Protalix Parent.

## **Section 5. MANUFACTURE AND SUPPLY**

### **5.1. Supply Chain Committee**

(a) Formation and Membership. The parties shall, within thirty (30) days after the Effective Date, form a Supply Chain Committee (the "Supply Chain Committee"). The Supply Chain Committee shall consist of up to three (3) representatives appointed by each party. The Supply Chain Committee will provide a forum for the discussion of matters related to the Manufacture of and supply chain for the Drug Substance and Licensed Product.

[\*\*\*] Redacted pursuant to a confidential treatment request.

(b) Meetings. During the Term, the Supply Chain Committee shall meet monthly or as otherwise determined by the parties (each such meeting, a “Supply Chain Committee Meeting”). Upon the request of the Supply Chain Committee, each party will provide written materials relating to its Manufacturing and related activities in advance of a Supply Chain Committee Meeting. All Supply Chain Committee Meetings may be conducted in person, by videoconference or by teleconference at such times and such Pfizer or Protalix locations as shall be determined by the Supply Chain Committee. In-person meetings of the Supply Chain Committee will alternate between appropriate offices of each party. The parties shall each bear all expenses of their respective representatives relating to their participation on the Supply Chain Committee. The members of the Supply Chain Committee also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate.

(c) Responsibilities. The Supply Chain Committee will have the following roles and responsibilities:

(i) Discuss each party’s requirements for Drug Substance and Licensed Product for Development activities in accordance with Section 5.3;

(ii) Act as a forum pursuant to which the parties may discuss Manufacturing issues, Fill/Finish activities (including Pfizer’s timing for assuming responsibility for Fill/Finish activities in accordance with Section 5.5(b)), and any issues that may affect patient access to the Licensed Product in the Territory;

(iii) Receive monthly summaries of Safety Stock levels held in accordance with Section 5.14;

(iv) Be informed of requests for and results of regulatory inspections related to Drug Substance and Licensed Product and review steps to be taken by Protalix to address any deficiencies noted;

(v) Monitor logistical strategies, Protalix’s capacity for Manufacturing Drug Substance and inventory levels for Drug Substance and Licensed Product for consistency with the Forecasts and Long Range Forecasts;

(vi) Be informed of and discuss proposed changes in Manufacturing sites, testing sites, and responsibilities in the supply chain for Drug Substance and Licensed Product;

(vii) Be informed of any quality-related issues concerning the Drug Substance and Licensed Product;

(viii) Provide updates on the Supply Chain Committee’s activities and achievements to the Steering Committee, as applicable, no less frequently than once each quarter after the Effective Date;

(ix) Act as a forum pursuant to which (A) Protalix will update Pfizer regarding significant deviations reasonably expected by Protalix between the Estimated Price for a Pfizer Year and Protalix's reasonable estimate of the Actual Price for such Pfizer Year and (B) Protalix will provide a non-binding estimate of the aggregate deviation between the Estimated Price and Actual Price for such Pfizer Year no later than September 1 of such Pfizer Year.

(x) Such other roles and responsibilities provided for in this Agreement or as may be assigned to the Supply Chain Committee in writing by mutual agreement of the parties.

(d) Decision-Making. Except for a decision to create a Technical Subcommittee as described in Section 5.1(e), the Supply Chain Committee will have no decision-making authority, but instead will act in an advisory capacity to the Steering Committee and the parties, unless otherwise agreed by the parties in writing.

(e) Technical Subcommittee. The Supply Chain Committee may, from time to time, create a subcommittee (a "Technical Subcommittee") to analyze and advise the Supply Chain Committee and the parties on any technical issues relating to Manufacturing Drug Substance or Licensed Product, including issues relating to quality or process, identified by either party or by the Supply Chain Committee. Any Technical Subcommittee shall consist of representatives from each party with the appropriate technical expertise to analyze and provide advice with respect to any such technical issues, and such representatives may or may not also be representatives on the Supply Chain Committee. Each Technical Subcommittee will continue to operate until resolution of the identified problem, as determined by the Supply Chain Committee.

## 5.2. Capacity.

(a) On or before [\*\*\*], Protalix will [\*\*\*].

(b) At any time during the Term, Pfizer may make a written request that Protalix [\*\*\*] Along with such request, Pfizer shall submit to Protalix [\*\*\*] The Steering Committee shall consider and discuss Pfizer's request and supporting documentation, and determine whether or not [\*\*\*]. If the Steering Committee determines that [\*\*\*], Protalix shall [\*\*\*] Protalix shall notify Pfizer in writing[\*\*\*]. If this Agreement is terminated for any reason after Protalix has [\*\*\*], Pfizer shall reimburse Protalix for [\*\*\*].

(c) Protalix shall dedicate at least [\*\*\*] percent ([\*\*\*]%) of its Drug Substance Manufacturing capacity in order to Manufacture Drug Substance for Pfizer's clinical and commercial use in the Field in the Territory and may dedicate all remaining capacity to Manufacture Drug Substance for Protalix's clinical and commercial use in the Field outside the Territory (such allocation between the Territory and outside the Territory, the "Allocation Percentage"). Subject to the Current Capacity Cap or, after achieving the Increased Capacity Goal, the Increased Capacity Cap (collectively, the "Capacity Cap"), subject to the Allocation

[\*\*\*] Redacted pursuant to a confidential treatment request.

Percentage, and subject to and in accordance with the terms of this Section 5 and the Quality Agreement, Protalix shall supply all quantities of the Drug Substance ordered by Pfizer under this Agreement for clinical and commercial use in the Field in the Territory.

(d) In the event either party reasonably believes that capacity for the Manufacture of Drug Substance in excess of the Increased Capacity Cap is necessary to meet projected future clinical and commercial need for Licensed Product in the Territory, the parties shall discuss such matter in good faith, including the funding of any capital expenditures necessary to increase such Manufacturing capacity beyond the Increased Capacity Cap.

5.3. Development Supply of Drug Substance. Subject to the Capacity Cap and the Allocation Percentage, Protalix shall Manufacture and supply all requirements of the Drug Substance for incorporation into Licensed Product for activities to be performed by either party in accordance with the Development Plan, which supply shall be subject to and in accordance with the terms of this Section 5. The cost of Manufacturing Licensed Product (including Fill/Finish) for the [\*\*\*] and any other clinical studies referred to in Section 6.3 shall be borne by the parties and treated in the same manner as Development Costs for such studies are borne and treated pursuant to Section 6.3. For the avoidance of doubt, in no event shall Protalix be obligated to Manufacture or supply quantities of Drug Substance in excess of the Capacity Cap unless otherwise agreed by the parties.

5.4. Commercial Supply of Drug Substance. Subject to the Capacity Cap and the Allocation Percentage, Protalix shall Manufacture and supply Pfizer's requirements of the Drug Substance for incorporation into Licensed Product and commercial sale in the Field in the Territory pursuant to this Agreement, which supply shall be subject to and in accordance with the terms of this Section 5 and the Quality Agreement. For the avoidance of doubt, in no event shall Protalix be obligated to Manufacture or supply quantities of Drug Substance in excess of the Capacity Cap unless otherwise agreed by the parties.

5.5. Fill/Finish; Certain Other Manufacturing Activities.

- (a) [\*\*\*].
- (b) [\*\*\*].
- (c) [\*\*\*].
- (d) [\*\*\*].
- (e) [\*\*\*].

5.6. Forecasting and Ordering.

(a) Forecasts; Purchase Orders. [\*\*\*], Pfizer shall deliver to Protalix Pfizer's quarterly projection of the quantities of Drug Substance that Pfizer anticipates ordering from

[\*\*\*] Redacted pursuant to a confidential treatment request.



Protalix pursuant to this Agreement (including Drug Substance that will be used as Safety Stock in accordance with Section 5.14) for the four (4) calendar quarters commencing with the first quarter that includes the first requested delivery date (the “Initial Forecast”), together with a firm purchase order (a “Purchase Order”) for Drug Substance for the first calendar quarter covered by such Initial Forecast. The quantities of Drug Substance specified for the following quarter of such Initial Forecast shall be binding as provided in Section 5.6(d) and the remaining two (2) quarters of such Initial Forecast shall be non-binding. Thereafter, ninety (90) days prior to the first business day of each subsequent calendar quarter during the Term, Pfizer shall deliver to Protalix a rolling four (4) calendar quarter forecast updating the prior forecast (together with the Initial Forecast, each a “Forecast”), together with a Purchase Order for the first calendar quarter of such Forecast. The quantities of Drug Substance specified for the following quarter of such Forecast shall be binding as provided in Section 5.6(d) and the remaining two (2) quarters of such Forecast shall be non-binding. Unless agreed separately between the parties, each Purchase Order shall specify no more than three (3) delivery dates for the Drug Substance in each calendar quarter. Purchase Orders shall be in writing, and no verbal communications or e-mail shall be construed to mean a commitment to purchase or sell. Each Purchase Order delivered by Pfizer to Protalix pursuant to this Section 5.6(a) shall be binding on Protalix to the extent provided by Section 5.6(c). Protalix shall confirm receipt of any [\*\*\*]. [\*\*\*], Pfizer shall also submit Forecasts and Purchase Orders for Licensed Product and the provisions of this Section 5.6(a) shall apply to such Forecasts and Purchase Orders as they do for Forecasts and Purchase Orders for Drug Substance.

(b) Long Range Capacity Planning. Concurrent with the Initial Forecast, for the purposes of discussion and planning of Manufacturing capacity, Pfizer shall provide a non-binding forecast of its projected Drug Substance needs for the eight (8) calendar quarters following that specified in the Initial Forecast as described in Section 5.6(a) (a “Long Range Forecast”). Each Long Range Forecast shall be deemed to be revised by any subsequent Forecast. In the event Protalix anticipates that it will be unable to supply the quantities of Drug Substance reflected in a Long Range Forecast, Protalix shall promptly notify Pfizer and the Supply Chain Committee shall work to remedy the shortfall in accordance with and subject to the terms of this Section 5 in an effort to assure that the necessary capacity exists. Unless otherwise agreed to by the parties during the Term, the Long Range Forecast shall be updated by Pfizer annually by July 1 of each calendar year during the Term. During [\*\*\*], Pfizer’s Long Range Forecast shall also include[\*\*\*].

(c) Maximum Quantities. Unless otherwise agreed in writing by Protalix, in no event shall Protalix be obligated to deliver quantities of Drug Substance [\*\*\*] of the quantities specified by Pfizer for the same period in the Forecast delivered in the prior calendar quarter. The foregoing limitation shall be in addition to the Capacity Cap. Protalix shall, however, use Commercially Reasonable Efforts, but will be under no obligation, to supply Drug [\*\*\*] of such quantities specified in such Forecast.

[\*\*\*] Redacted pursuant to a confidential treatment request.

(d) Minimum Quantities. If the quantities of Drug Substance [\*\*\*] specified in a Purchase Order for a quarter are less than [\*\*\*] of the quantities specified by Pfizer for the same period in the Forecast delivered [\*\*\*], then, at the election of Pfizer set forth in a notice which Pfizer shall deliver to Protalix within [\*\*\*] (i) Protalix shall within [\*\*\*] or (ii) Pfizer shall [\*\*\*]

(e) Receipt and Acceptance. Subject to Sections 5.6(c) and 5.6(d), Pfizer shall purchase all Drug Substance [\*\*\*] ordered and specified in a Purchase Order. Purchase Orders may be delivered electronically or by other means to such location as Protalix shall designate. Nothing in any such Purchase Order or written acceptance shall supersede the terms and conditions of this Agreement or the Quality Agreement. All Purchase Orders, confirmations of receipt of Purchase Orders and other notices contemplated under this Section 5.6(e) shall be sent to the attention of such persons as each party may identify to the other in writing from time to time in accordance with Section 18.8.

5.7. Pricing, Invoicing and Supply Price Reconciliation.

(a) Supply Delivery Price; Invoices.

(i) On the Effective Date, or such later date that is at least sixty (60) days preceding the first requested delivery date for Drug Substance [\*\*\*], Protalix shall, based on the Initial Forecast and Long Range Forecast delivered concurrently with the Initial Forecast, estimate in good faith the Price for Drug Substance for the remainder of the Pfizer Year in which the first Launch occurs. Thereafter, Protalix shall, based on the then-current Forecast and Long Range Forecast, estimate in good faith the Price for Drug Substance for such successive Pfizer Year (such initial or revised estimated Price for Drug Substance, the "Estimated Price"), and shall notify Pfizer in writing prior to September 1 of each successive Pfizer Year of such Estimated Price with reasonable supporting documentation regarding the calculation of such Estimated Price.

(ii) Each delivery of Drug Substance [\*\*\*] under a Purchase Order hereunder shall be accompanied by an invoice. Protalix shall invoice Drug Substance at [\*\*\*]. Protalix shall include the following information, where applicable, on all invoices: the type, description, and quantity of the product delivered; the date of shipment; the prices; any applicable taxes, transportation charges or other charges provided for in the applicable Purchase Order; and the applicable Purchase Order number.

(iii) [\*\*\*] Any financial adjustments necessary because [\*\*\*] shall be reported and handled as part of the reconciliation pursuant to Section 7.1.

(b) Taxes. All sales and use taxes which Protalix is required by law to collect from Pfizer with respect to the Manufacture and supply of Drug Substance to Pfizer shall be separately stated in Protalix's invoice and shall be paid by Pfizer to Protalix unless Pfizer

[\*\*\*] Redacted pursuant to a confidential treatment request.

provides an exemption to Protalix. Protalix shall be solely responsible for the timely payment of all such taxes to the applicable taxing authority, and Protalix shall pay (without reimbursement by Pfizer), and shall hold Pfizer harmless against, any penalties, interest or additional taxes that may be levied or assessed as a result of the failure or delay of Protalix to pay any such taxes.

(c) Financial Records; Audits. Pfizer shall have the right to audit Protalix's [\*\*\*]. Such audit shall be carried out in the same manner as and limited to the same extent as the audit provisions of Section 7.5.

#### 5.8. Shipping and Delivery.

(a) Delivery. Subject to Section 5.6(c), Protalix shall deliver (or have delivered) to Pfizer in accordance with this Section 5.8 the quantities of the Drug Substance [\*\*\*], Licensed Product) specified for a given delivery date in each Purchase Order with, in the case of Drug Substance, no less than [\*\*\*] months remaining on the retest period and, during [\*\*\*], no less than [\*\*\*] months remaining on the shelf life, on the day it is delivered to Pfizer. All dates for delivery of Drug Substance [\*\*\*].

(b) Delivery Terms. The Drug Substance [\*\*\*] shall be supplied to Pfizer [\*\*\*]. The Drug Substance [\*\*\*] shall be shipped at [\*\*\*]. Pfizer shall be responsible for [\*\*\*], and for compliance with all applicable Laws and Regulatory Approvals for the Drug Substance and the Licensed Product in the Field in the Territory.

(c) Retention. Unless the parties agree otherwise, Protalix shall maintain analytical samples of each batch of Drug Substance in storage for a time period based upon Protalix's sample retention policy.

#### 5.9. Compliance; Quality Control Obligations.

(a) [\*\*\*]

(b) Within sixty (60) days after the completion of the GMP Audit, the parties shall enter into the Quality Agreement(s). The Quality Agreement(s) shall set forth the parties' compliance obligations with respect to the Drug Substance Manufactured by Protalix for clinical and commercial requirements in the Territory [\*\*\*], which compliance obligations with respect to [\*\*\*] shall not be inconsistent with [\*\*\*]. To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement(s) with respect to quality issues, the terms and conditions of the Quality Agreement(s) shall control.

#### 5.10. Certificate of Analysis; Acceptance and Returns.

(a) P&L Certificate of Analysis; Notice of Non-Conformance.

(i) Protalix shall supply to Pfizer the applicable batch number for the Drug Substance delivered, as well as such other information as the parties may set forth in the

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

Quality Agreement with respect to Manufacture (a “Manufacturing Certificate of Analysis”) for all Drug Substance [\*\*\*] shipped to Pfizer hereunder. Pfizer shall (within the time period specified in Section 5.10(b)) inspect, or cause to have inspected, each shipment of the Drug Substance [\*\*\*] for any damage, defect or shortage and give Protalix written notice of any such damaged, defective or short shipment (a “Notice of Non-Conformance”) within the time periods specified in Sections 5.10(a)(ii) and 5.10(b), as applicable.

(ii) Latent defects shall be communicated to Protalix, together with appropriate detail, within fifteen (15) Business Days of the date on which such latent defect was first discovered by Pfizer or was notified to Pfizer by the relevant party discovering the defect.

(b) Rejection. Pfizer shall have [\*\*\*] days following its receipt of each shipment of the Drug Substance [\*\*\*] (the “Non-Conformance Period”) to inspect such shipment. If Pfizer determines that any shipment of the Drug Substance [\*\*\*] does not conform to the Product Specifications (or is otherwise a short shipment), it shall promptly notify Protalix within [\*\*\*] Business Days following such determination in compliance with the procedures set forth in the Quality Agreement(s).

(c) Disputes. If Pfizer delivers a Notice of Non-Conformance in respect of all or any part of a shipment of the Drug Substance [\*\*\*], and Protalix does not agree with Pfizer’s determination that such shipment fails to meet the Product Specifications (or is otherwise a short shipment), the parties shall in good faith attempt to resolve such dispute at the Supply Chain Committee. Protalix and Pfizer shall have thirty (30) days, unless otherwise agreed in writing by the parties, from the date of Protalix’s receipt of a Notice of Non-Conformance to resolve such dispute regarding whether all or any part of such shipment was Manufactured in conformance with the Product Specifications (or was otherwise a short shipment). If the dispute regarding whether all or any part of a shipment rejected by Pfizer was Manufactured in conformance with the Product Specifications (or was otherwise a short shipment) is not resolved in such thirty (30) day period, then [\*\*\*].

(d) Remedies. In the event any shipment of Drug Substance [\*\*\*] is rejected pursuant to this Section 5.10 as a result of any act or omission of Protalix, then (i) Pfizer shall, at the direction of Protalix, either (x) destroy such rejected Drug Substance or Licensed Product at Protalix’s expense (in accordance with applicable Law) or (y) return such rejected Drug Substance or Licensed Product to Protalix, at a location designated by Protalix and at Protalix’s expense; provided that if Protalix requests the return of such rejected Drug Substance or Licensed Product, Protalix shall not use such Drug Substance or Licensed Product for any purpose, shall destroy such rejected Drug Substance or Licensed Product and certify to Pfizer that it has destroyed such rejected Drug Substance or Licensed Product, and (ii) Protalix, at no expense to Pfizer, shall (in its sole discretion) either (x) use its Commercially Reasonable Efforts to promptly replace such non-conforming Drug Substance [\*\*\*] (or short shipment) or (y) give Pfizer a credit in an amount equal to the amount paid or payable by Pfizer with respect to such rejected Drug Substance or Licensed Product (or short shipment).

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

5.11. Product Specification and Manufacturing Changes. Product Specification and Manufacturing changes, including those resulting from a request received by a party from a Governmental Authority, shall be dealt with pursuant to the Quality Agreement; provided that all applicable Regulatory Approvals shall be prepared and filed by the parties in accordance with the provisions of Section 4.

5.12. Master Cell Bank. During the Term, Protalix shall, as the supplier of Drug Substance, maintain half of the master cell bank relating to the Drug Substance in a location selected by Protalix and the other half of the master cell bank relating to the Drug Substance at a different location selected by Protalix and approved by Pfizer (such approval not to be unreasonably withheld or delayed), which may include the Facility where Pfizer performs Fill/Finish activities (provided that Pfizer obtains all required approvals from the applicable Regulatory Authority necessary to store the master cell bank in such Facility).

5.13. Shortages. In the event that the materials and/or Manufacturing capacity required to Manufacture and to deliver in a timely manner to Pfizer the Drug Substance ([\*\*\*]) required under outstanding Purchase Orders are in short supply, Protalix shall notify Pfizer of such shortage and the Supply Chain Committee shall promptly meet to discuss the shortage. Protalix shall provide to the Supply Chain Committee a written plan of action stating in reasonable detail the proposed measures to address such shortage and the date such shortage is expected to end. Protalix shall use its Commercially Reasonable Efforts to minimize the duration of any shortage, including using all capacity at its Facility to Manufacture Drug Substance and not other products for sales by Protalix or Third Parties. During any such shortage, Protalix shall allocate the materials and resources used in the supply of the Drug Substance [\*\*\*] such that Pfizer receives [\*\*\*] percent ([\*\*\*]%) for the Territory and Protalix receives [\*\*\*] percent ([\*\*\*]%) for outside the Territory.

5.14. Safety Stock Obligations.

(a) Build-Up. From and after the Effective Date, and subject to the limitations set forth in Section 5.14(c), unless otherwise agreed in writing by the parties, Protalix shall operate its Facility at maximum capacity in order to start building inventory of Drug Substance (the "Safety Stock") with the quantity of Drug Substance remaining after Protalix supplies the quantities of Drug Substance necessary to conduct clinical trials and Early Access Programs and, after the first Launch in the Territory, to meet commercial demand. Protalix shall operate its Facility at maximum capacity until there is a quantity of Safety Stock [\*\*\*]. Thereafter, subject to Section 5.14(b), Protalix shall operate its Facility as necessary to maintain [\*\*\*]. The Safety Stock may be used to fulfill Protalix's obligations to supply in the event there is a shortage as described in Section 5.13 or a Supply Failure.

[\*\*\*] Redacted pursuant to a confidential treatment request.

(b) Sharing of Responsibility and Cost.

(i) The parties shall share equally the responsibility and cost of building and maintaining the Safety Stock. Pfizer shall include in Purchase Orders placed in accordance with Section 5.6 an order for its [\*\*\*] percent ([\*\*\*]%) share of the Safety Stock, Pfizer shall pay for its share of the Safety Stock in accordance with Section 5.7, and Protalix shall deliver such Safety Stock to Pfizer in accordance with Section 5.8.

(ii) The Forecasts submitted by Pfizer pursuant to Section 5.6 shall make a distinction between the amounts of Drug Substance required by Pfizer for clinical and commercial needs in the Territory (the "Clinical and Commercial Forecast") and the amounts of Drug Substance needed for Safety Stock. Protalix will hold and keep its [\*\*\*] percent ([\*\*\*]%) share of the Safety Stock based on Pfizer's Clinical and Commercial Forecast.

(iii) Each party shall use its inventory of Safety Stock on a first-in first-out (FIFO) basis in order to ensure that the Safety Stock always has the maximum period of time remaining on the retest period. On a monthly basis, each party shall provide to the Supply Chain Committee updates as to the status of its share of the Safety Stock. Protalix shall, upon reasonable request and during regular business hours, allow Pfizer to audit the quantity of Safety Stock in Protalix's possession at least once in each calendar year.

(c) Limitations. Notwithstanding Sections 5.14(a) and 5.14(b), and unless otherwise agreed by the parties, neither party shall have any obligations with respect to the Safety Stock until [\*\*\*].

5.15. Certain Supply Chain Issues.

(a) If (i) prior to the time the parties have built-up [\*\*\*] (but following compliance with the limitations set forth in Section 5.14(c)), the output of Protalix's Facility falls to less than [\*\*\*] percent ([\*\*\*]%) of its maximum capacity output, or (ii) after the parties have built-up [\*\*\*], the aggregate Safety Stock maintained by the parties is less than [\*\*\*] (each, a "Significant Supply Chain Event"), then the Supply Chain Committee shall meet as soon as reasonably practicable to discuss the matter, identify the causes of the Significant Supply Chain Event and discuss possible solutions. If the Supply Chain Committee believes one cause of the Significant Supply Chain Event may be a technical issue relating to Manufacturing Drug Substance, including issues relating to quality or process, the Supply Chain Committee shall also form a Technical Subcommittee to address such issue. In addition, in the event of any Significant Supply Chain Event, the following shall apply until the cause of the Significant Supply Chain Event has been identified and resolved:

(A) Pfizer shall have the right to provide technical assistance and advice to Protalix on an ongoing basis, including in person at Protalix's Facility;

[\*\*\*] Redacted pursuant to a confidential treatment request.

(B) Pfizer may physically inspect Protalix's Facility, including being present during Manufacturing operations, quality control, quality assurance, pack out and shipping;

(C) Protalix will provide Pfizer with ongoing access to its Facility and all relevant Manufacturing records and personnel (wherever located) of Protalix and will use Commercially Reasonable Efforts to facilitate access to any Third Party suppliers of materials for the Drug Substance and Licensed Product; and

(D) Protalix will reasonably cooperate with Pfizer and its representatives in connection with the activities described above and, upon mutual agreement of the parties as to any deficiencies, Protalix will use its Commercially Reasonable Efforts to promptly correct any such deficiencies if and to the extent mutually agreed by the parties.

Pfizer and its representatives will carry out the activities described in this Section 5.15(a) during Protalix's regular business hours with as minimal disruption to Protalix's operations as reasonably practicable.

(b) Any costs incurred by Pfizer in providing technical assistance and advice to Protalix, inspecting Protalix's facility, or otherwise facilitating the resolution of the Significant Supply Chain Event, shall be paid for by Pfizer and treated as [\*\*\*].

5.16. Other Assistance by Pfizer. Protalix acknowledges that Pfizer has expertise with respect to manufacturing and pharmaceutical sciences and is able to provide assistance to Protalix in the following areas: (a) registering with the FDA and EMEA a manufacturing technology for commercial supply of Drug Substance, including the preparation of a complete, approvable chemistry, manufacturing, and controls section of an NDA and other regulatory filings packages, (b) the regulatory review process, (c) addressing regulatory review feedback or post-approval requirements by any Regulatory Authority, (d) bioprocess, analytical or formulation development, (e) validation, (f) characterization and stability studies, (g) preparing for and supporting pre-approval inspections; and (h) preparing Protalix's Facility to make it suitable for Regulatory Approval, including finalizing any required changes to the facility or equipment train, IQ/OQ/PQ, and equipment cleaning and cleaning validation (collectively, the "Advisory Services"). At any time during the Term, Pfizer shall have the right to provide Advisory Services to Protalix and upon reasonable notice from Pfizer, Protalix will reasonably consider in good faith the recommendations of Pfizer with respect to such Advisory Services. Pfizer shall be responsible for and bear [\*\*\*] percent ([\*\*\*]%) of the costs and expenses it incurs in providing Advisory Services to Protalix.

[\*\*\*] Redacted pursuant to a confidential treatment request.

5.17. Failure to Supply.

(a) “Failure to Supply,” shall occur in the event that Protalix does not supply according to the terms of this Agreement, including the Capacity Cap, the Allocation Percentage and Section 5.6(c), at least [\*\*\*] percent ([\*\*\*]%) of the quantities of Drug Substance[\*\*\*] specified by Pfizer on any Purchase Order for a particular calendar quarter, whether caused by a Force Majeure Event or otherwise (a “Supply Failure”), and (i) such Supply Failure is not cured in the following calendar quarter (whether by using Protalix’s share of Safety Stock or otherwise), (ii) such Supply Failure is cured in the following calendar quarter using Protalix’s share of Safety Stock and another Supply Failure occurs within [\*\*\*] months after the initial Supply Failure, or (iii) such Supply Failure is cured in the following calendar quarter without using Protalix’s share of Safety Stock, another Supply Failure occurs within [\*\*\*] months after the initial Supply Failure and the second Supply Failure is not cured in the following calendar quarter (whether by using Protalix’s share of Safety Stock or otherwise). In no event may Protalix use its share of Safety Stock to cure a Supply Failure more than once per [\*\*\*] month period. Notwithstanding the foregoing, the failure to supply at least [\*\*\*] percent ([\*\*\*]%) of the quantities of Licensed Product specified by Pfizer on any Purchase Order for a particular calendar quarter [\*\*\*]. For the sake of clarity, if Protalix uses its share of Safety Stock to cure a Supply Failure, that will be a Significant Supply Chain Event and the provisions of Section 5.15 shall apply. For the sake of this Section 5.17(a), “cure” means supplying [\*\*\*] percent ([\*\*\*]%) of the quantities of Drug Substance ([\*\*\*]) specified by Pfizer on a Purchase Order that is in compliance with the Capacity Cap, the Allocation Percentage and Section 5.6(c).

(b) [\*\*\*].

(c) Allocation of Costs.

(i) Capital Expenditure. Protalix shall be responsible for [\*\*\*].

(ii) Operating Costs. Notwithstanding Section 7.1(c)(iv), if the cost of making Drug Substance through the alternative source of supply pursuant to Section 5.17(b) exceeds Protalix’s Actual Price for making Drug Substance at the time of Failure to Supply, the parties will share such excess costs [\*\*\*].

(d) [\*\*\*].

5.18. Manufacturing Covenants.

(a) Protalix will, within sixty (60) days after the Effective Date, reasonably cooperate with Pfizer to allow Pfizer, at its sole cost and expense, to review Protalix’s supply chain security procedures and their implementation with a view to determining whether such procedures and Protalix’s implementation thereof meet the importer security criteria set forth by

[\*\*\*] Redacted pursuant to a confidential treatment request.



the Customs-Trade Partnership Against Terrorism (“C-TPAT”) program of the U.S. Bureau of Customs and Border Protection.

(b) Protalix acknowledges that Pfizer has advised Protalix that (i) Pfizer is a certified member of C-TPAT, (ii) importers that have joined C-TPAT are expected to have substantially fewer of their imports inspected and, hence, fewer supply chain delays (the “C-TPAT Benefits”) and (iii) as a C-TPAT member, Pfizer is required to make periodic assessment of its international supply chain based up C-TPAT security criteria. Protalix agrees that, after completion of the review referred to in [Section 5.18\(a\)](#), it will reasonably cooperate with Pfizer to allow Pfizer, at its sole cost and expense, to conduct an annual security audit at any Protalix Facility and will consider in good faith any corrective actions recommended by Pfizer as a result of such audit intended to ensure the continued eligibility of Pfizer to participate in C-TPAT. Pfizer agrees to share with Protalix the results of such annual audits, and Protalix agrees to advise Pfizer of any corrective actions taken in response thereto and to notify Pfizer if it becomes aware of an event that it knows jeopardizes Pfizer’s retention of its C-TPAT Benefits. Protalix agrees to use Commercially Reasonable Efforts to become a member of a supply chain security program administered by the customs administration in Israel if such a program exists and (a) Protalix determines in its good faith judgment that such a program will advance the parties’ mutual objective of securing each part of the supply chain or (b) Pfizer has determined in good faith that Protalix’s failure to become a member of such a program will jeopardize the continued eligibility of Pfizer to participate in C-TPAT and Pfizer has notified Protalix in writing reasonably setting forth the basis for such determination.

- 5.19. [\*\*\*].
- 5.20. [\*\*\*].

**Section 6. FINANCIAL PROVISIONS**

- 6.1. Effective Date Payment. Within fifteen (15) days after the Effective Date, Pfizer shall pay to Protalix the non-refundable, non-creditable amount of Sixty Million Dollars (US \$60,000,000).
- 6.2. Event Milestone Payments.

(a) Subject to the terms and conditions of this Agreement, Pfizer shall pay to Protalix the amount set forth in the table below opposite the corresponding event milestone (each an “Event Milestone”) within forty-five (45) days after the occurrence of such Event Milestone:

	Event Milestone	Event Milestone Payment
Commencement of [***] (“ <u>Event Milestone 1</u> ”)		\$[***]
Regulatory Approval of the first Licensed Product in the United States (“ <u>Event Milestone 2</u> ”)		\$[***]

[\*\*\*] Redacted pursuant to a confidential treatment request.

Regulatory Approval of the first Licensed Product in the European Union via the centralized approval procedure (“ <u>Event Milestone 3</u> ”)	\$[***]
Earlier of (a) [***] and (b) [***]	\$[***]
Submission of [***] for the Licensed Product to [***] (“ <u>Event Milestone 5</u> ”)	\$[***]

(b) If Protalix [\*\*\*].

(c) If the Steering Committee decides to [\*\*\*] payment shall become payable upon the [\*\*\*].

(d) Notwithstanding Section 6.2(a), if it is determined after the Effective Date that [\*\*\*].

(e) Notwithstanding any other provision of this Agreement, Pfizer shall not be entitled to exercise its final decision-making authority at the Steering Committee if such exercise would have the effect of delaying or preventing Protalix’s achievement of Event Milestone 5.

(f) For the avoidance of doubt: (i) each Event Milestone Payment shall be payable only on the first occurrence of the corresponding Event Milestone; (ii) none of the Event Milestone Payments shall be payable more than once; and (iii) should the first Licensed Product be replaced or succeeded by another Licensed Product, no additional Event Milestone Payments shall be due for Event Milestones already met with respect to any other Licensed Product.

(g) NOTWITHSTANDING THIS SECTION 6.2, PFIZER MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE THE LICENSED PRODUCT.

### 6.3. Development Costs.

(a) [\*\*\*]. Protalix shall be responsible [\*\*\*]; provided that after [\*\*\*], Protalix’s responsibility for such costs shall be limited to those necessary to conduct and complete [\*\*\*] activities described in the initial Development Plan attached hereto as Exhibit D and any excess costs shall be paid for by Pfizer and treated as [\*\*\*].

(b) [\*\*\*]. Protalix shall be responsible for paying [\*\*\*] percent ([\*\*\*]%) of the Development Costs incurred to conduct and complete [\*\*\*] activities set forth in the

[\*\*\*] Redacted pursuant to a confidential treatment request.

Development Plan (if [\*\*\*]). Pfizer shall be responsible for paying any Development Costs incurred to conduct and complete any [\*\*\*] activities not set forth in the Development Plan (“[\*\*\*] Development Costs”), and all [\*\*\*] Development Costs shall be treated as [\*\*\*].

(c) [\*\*\*]. Pfizer shall be responsible for paying [\*\*\*] percent ([\*\*\*]%) of the Development Costs incurred to conduct and complete [\*\*\*] set forth in the Development Plan (“[\*\*\*] Development Costs”), and all such [\*\*\*] Development Costs shall be treated as [\*\*\*].

(d) Combined [\*\*\*]. If the Steering Committee decides to combine [\*\*\*] and [\*\*\*], then the parties shall amend the Development Plan to reflect [\*\*\*] and Protalix shall be responsible for paying [\*\*\*] percent ([\*\*\*]%) of the Development Costs necessary to perform [\*\*\*] portion of [\*\*\*]; provided that such activities are set forth in the Development Plan, and any additional costs incurred in conducting and completing such combined study shall be paid for by Pfizer and treated as [\*\*\*].

(e) Combined [\*\*\*]. If the Steering Committee decides to combine [\*\*\*] and, then the parties shall amend the Development Plan to reflect [\*\*\*] and Protalix shall be responsible for paying [\*\*\*] percent ([\*\*\*]%) of the Development Costs necessary to perform [\*\*\*] portion of the combined study; provided that such activities are set forth in the Development Plan, and any additional costs incurred in conducting and completing such combined study shall be paid for by Pfizer and treated as [\*\*\*].

(f) [\*\*\*]. Pfizer shall be responsible for paying [\*\*\*] percent ([\*\*\*]%) of the Development Costs incurred to conduct and complete [\*\*\*], and all such Development Costs shall be treated as [\*\*\*].

(g) Development Costs Outside the United States and the European Union. Pfizer shall be responsible for paying [\*\*\*] percent ([\*\*\*]%) of the Development Costs incurred to conduct [\*\*\*] outside the United States and the European Union (“Ex-US/EU Development Costs”); provided that in the eight Reporting Periods following receipt of Regulatory Approval in such Country, Pfizer shall be entitled to deduct from the Net Profit payable to Protalix pursuant to Section 6.4(a) amounts which together total [\*\*\*] ([\*\*\*]%) of all Ex-US/EU Development Costs incurred to obtain Regulatory Approval for the Licensed Product in such Country through the date such Regulatory Approval is obtained, and provided further that Pfizer shall make such deductions in eight equal quarterly portions. If Pfizer is unable to offset [\*\*\*] percent ([\*\*\*]%) of all Ex-US/EU Development Costs after the eight Reporting Periods following receipt of Regulatory Approval in such Country, any such remaining amounts will be [\*\*\*].

(h) Other Development Costs. Pfizer shall be responsible for paying [\*\*\*] percent ([\*\*\*]%) of any Development Costs which are not referenced in Section 6.3(a) through Section 6.3(g) above (“Additional Development Costs”), and such Additional Development Costs shall be treated as [\*\*\*].

[\*\*\*] Redacted pursuant to a confidential treatment request.

(i) [\*\*\*]. For the avoidance of doubt, Pfizer shall be responsible for paying [\*\*\*]percent ([\*\*\*]%) of all costs and expenses for conducting and completing any [\*\*\*], and such costs and expenses shall be treated as [\*\*\*].

(j) Payments. If Protalix has incurred certain Development Costs but Pfizer is responsible for paying such Development Costs pursuant to this Section 6.3, then Protalix may, on a monthly basis, send an invoice to Pfizer with respect to such Development Costs, along with reasonable evidence that such Development Costs were payable and have been paid by Protalix, and Pfizer shall issue payment against such invoices within forty-five (45) days of the invoice date.

#### 6.4. Sharing of Net Profit and Net Loss.

(a) Sharing of Net Profits. For any Reporting Period during the Profit Sharing Term in which there is a Net Profit, the parties will share such Net Profit such that Pfizer receives sixty percent (60%) and Protalix receives forty percent (40%), subject to any adjustment pursuant to Section 5.7(a)(iii) (adjustment based on Actual Price of Drug Substance).

#### (b) Sharing of Net Loss.

(i) Subject to Section 6.4(b)(ii), for any Reporting Period during the Profit Sharing Term in which there is a Net Loss, the parties will share such Net Loss such that Pfizer bears sixty percent (60%) and Protalix bears forty percent (40%), subject to any adjustment pursuant to Section 5.7(a)(iii) (adjustment based on Actual Price of Drug Substance).

(ii) In the event a Net Loss occurs in any Reporting Period between the commencement of the Profit Sharing Term and [\*\*\*] (the aggregate of such Net Losses over such period, "Accumulated Net Loss"), Pfizer will be responsible for [\*\*\*] percent ([\*\*\*]%) of such Net Loss in each such Reporting Period; provided that the Accumulated Net Loss will be [\*\*\*].

### **Section 7. ACCOUNTING AND PROCEDURES FOR PAYMENT**

#### 7.1. Periodic Reporting and Reconciliation Payments.

#### (a) Quarterly Reports; Annual Reports.

(i) Within [\*\*\*] (a "Reporting Period"), Pfizer will submit to Protalix a written report setting forth in reasonable detail (A) Net Sales and number of units of Licensed Product sold in each Country in the Territory and in the aggregate during the Reporting Period, as well as the computation of such Net Sales amounts, (B) by category and in the aggregate, Allowable Expenses for the Reporting Period, as well as the computation thereof, (C)

[\*\*\*] Redacted pursuant to a confidential treatment request.

by category and in the aggregate, Uncapped Expenses for the Reporting Period, as well as the computation thereof, (D) the Fully Absorbed Cost of Goods, Labeling and Packaging Costs and COGS for the Reporting Period, as well as the computation thereof in accordance with Exhibit E, (E) Net Profit or Net Loss, as the case may be, for the Reporting Period, as well as the computation thereof in accordance with Exhibit E and (F) each party's share of the Net Profit or Net Loss pursuant to Section 6.4 (without giving effect to any adjustment pursuant to Section 5.7(a)(iii) (adjustment based on Actual Price of Drug Substance)).

(ii) In addition to the report described in Section 7.1(a)(i), within fifteen (15) days after the end of each Reporting Period, Pfizer will submit to Protalix a written report setting forth an estimate of the amounts described in clauses (A) through (F) of Section 7.1(a)(i). The report submitted by Pfizer under this Section 7.1(a)(ii) for a Reporting Period is for informational purposes only and will be superseded by the report submitted by Pfizer under Section 7.1(a)(i) for such Reporting Period.

(iii) For each Reporting Period during the Profit Sharing Term, Protalix will submit to Pfizer, within a reasonable period of time prior to the due date of Pfizer's report referred to above in Section 7.1(a)(i), a written report setting forth in reasonable detail [\*\*\*] in the applicable Reporting Period setting forth such costs in reasonable detail.

(iv) Within thirty (30) days after the end of each Pfizer Year during the Profit Sharing Term, Protalix will submit to Pfizer a written report setting forth in reasonable detail the Actual Price, together with a calculation of any adjustment required to be made to the parties' respective share of Net Profit (if any) or (subject to Section 6.4(b)(ii)) Net Loss (if any) for such Pfizer Year in accordance with Section 5.7(a)(iii) (adjustment based on Actual Price of Drug Substance).

(v) The reports required by this Section 7.1(a) shall be kept confidential by the recipient party and not disclosed to any Third Party, other than the recipient party's accountants who shall be obligated to keep such information confidential, and such information and reports shall only be used for purposes of this Agreement, unless otherwise required by Law.

(b) Quarterly Reconciliation Payment. Within fifteen (15) days following Pfizer's submission of each quarterly report due under Section 7.1(a)(i), (x) Pfizer shall pay Protalix's share of the Net Profit for the applicable Reporting Period, if any, to Protalix or (y) subject to Section 6.4(b)(ii), Protalix shall pay Protalix's share of the Net Loss, if any, to Pfizer.

(c) Annual Reconciliation Payment. Within thirty (30) days following Protalix's submission of each annual report due under Section 7.1(a)(iv) for any applicable Pfizer Year:

(i) if the Allowable Expenses deducted from Net Sales in such Pfizer Year exceed the greater of [\*\*\*] Dollars (US \$[\*\*\*]) or [\*\*\*] percent ([\*\*\*]%) of Net Sales for such Pfizer Year, Pfizer shall pay to Protalix the amount of the difference; provided that such payment shall be made, to the extent possible, by a deduction from Pfizer's share of the Net

[\*\*\*] Redacted pursuant to a confidential treatment request.

Profit (if any) (and corresponding increase in Protalix's share of the Net Profit), or (subject to Section 6.4(b)(ii)) by an addition to Pfizer's share of the Net Loss (if any) (and corresponding decrease in Protalix's share of the Net Loss), for the final Reporting Period during such Pfizer Year;

(ii) (x) if the Estimated Price exceeds the Actual Price, Protalix shall pay to Pfizer the amount of the difference, with respect to all Drug Substance purchased over such Pfizer Year; provided that such payment shall be made, to the extent possible, by a deduction from Protalix's share of the Net Profit (if any) (and corresponding increase in Pfizer's share of the Net Profit), or (subject to Section 6.4(b)(ii)) by an addition to Protalix's share of the Net Loss (if any) (and corresponding decrease in Pfizer's Share of the Net Loss), for the final Reporting Period during such Pfizer Year; and (y) if the Actual Price exceeds the Estimated Price, Pfizer shall pay to Protalix the amount of the difference, with respect to all Drug Substance purchased over such Pfizer Year; provided that such payment shall be made, to the extent possible, by a deduction from Pfizer's share of the Net Profit (if any) (and corresponding increase in Protalix's share of the Net Profit), or (subject to Section 6.4(b)(ii)) by an addition to Pfizer's share of the Net Loss (if any) (and corresponding decrease in Protalix's share of the Net Loss), for the final Reporting Period during such Pfizer Year;

(iii) **[\*\*\*]** of Net Sales for such Pfizer Year; provided that such payment shall be made, to the extent possible, by a deduction from Protalix's share of the Net Profit (if any) (and corresponding increase in Pfizer's share of the Net Profit), or (subject to Section 6.4(b)(ii)) by an addition to Protalix's share of the Net Loss (if any) (and corresponding decrease in Pfizer's Share of the Net Loss), for the final Reporting Period during such Pfizer Year;

(iv) for **[\*\*\*]**, if  $(X*Y) + (X*Z)$  is greater than **[\*\*\*]** percent (**[\*\*\*]**%) of Net Sales for such Pfizer Year, where "X" is the aggregate number of units of Licensed Product sold in each Country in the Territory in such Pfizer Year, "Y" is the Actual Price for such Pfizer Year, and "Z" is the sum of Fully Absorbed Cost of Goods and the Labeling and Packaging Costs per unit of Licensed Product for such Pfizer Year, then:

(A) if  $(X*Y)$  is greater than **[\*\*\*]** percent (**[\*\*\*]**%) of Net Sales for such Pfizer Year, and  $(X*Z)$  is greater than **[\*\*\*]** percent (**[\*\*\*]**%) of Net Sales for such Pfizer Year, then (1) Protalix shall pay to Pfizer the difference between  $(X*Y)$  and **[\*\*\*]** percent (**[\*\*\*]**%) of Net Sales for such Pfizer Year and (2) Pfizer shall pay to Protalix the difference between  $(X*Z)$  and **[\*\*\*]** percent (**[\*\*\*]**%) of Net Sales for such Pfizer Year; provided that such payments shall be made, to the extent possible, by adjustments to each party's share of Net Profit or, (subject to Section 6.4(b)(ii)) Net Loss for the final Reporting Period during such Pfizer Year;

(B) if  $(X*Y)$  is greater than **[\*\*\*]** percent (**[\*\*\*]**%) of Net Sales for such Pfizer Year and  $(X*Z)$  is less than or equal to **[\*\*\*]** percent (**[\*\*\*]**%) of Net Sales

**[\*\*\*]** Redacted pursuant to a confidential treatment request.

for such Pfizer Year, then Protalix shall pay to Pfizer the difference between [\*\*\*] percent ([\*\*\*]%) of Net Sales and the sum of (X\*Y) and (X\*Z); provided that such payment shall be made, to the extent possible, by a deduction from Protalix's share of the Net Profit (if any) (and corresponding increase in Pfizer's share of the Net Profit), or (subject to Section 6.4(b)(ii)) by an addition to Protalix's share of the Net Loss (if any) (and corresponding decrease in Pfizer's Share of the Net Loss), for the final Reporting Period during such Pfizer Year; and

(C) if (X\*Z) is greater than [\*\*\*] percent ([\*\*\*]%) of Net Sales for such Pfizer Year and (X\*Y) is less than or equal to [\*\*\*]percent ([\*\*\*]%) of Net Sales for such Pfizer Year, then Pfizer shall pay to Protalix the difference between [\*\*\*] percent ([\*\*\*]%) of Net Sales and the sum of (X\*Y) and (X\*Z); provided that such payment shall be made, to the extent possible, by a deduction from Pfizer's share of the Net Profit (if any) (and corresponding increase in Protalix's share of the Net Profit), or (subject to Section 6.4(b)(ii)) by an addition to Pfizer's share of the Net Loss (if any) (and corresponding decrease in Protalix's share of the Net Loss), for the final Reporting Period during such Pfizer Year.

(d) Reimbursement of Protalix Uncapped Expenses. If Protalix has incurred Uncapped Expenses not covered by Section 6.3(j), then Protalix may, on a monthly basis, send an invoice to Pfizer with respect to such Uncapped Expenses, along with reasonable evidence that such Uncapped Expenses were payable and have been paid by Protalix, and Pfizer shall issue payment against such invoices within forty-five (45) days of the invoice date.

(e) Disputes. In the event of a dispute regarding any amount reported by a party pursuant to Section 7.1(a) or any amount owed under Section 7.1(b), the parties will promptly meet and negotiate in good faith a resolution to such dispute. In the event that the parties are unable to resolve such dispute within sixty (60) days after notice by the disputing party, the parties will (i) use Commercially Reasonable Efforts to reach agreement on the appointment of one internationally-recognized independent accounting firm to determine the matter or (ii) if the parties cannot reach agreement on such accounting firm, then each party will appoint one internationally-recognized accounting firm and such firms will choose a third internationally-recognized independent accounting firm to make the final determination.

(f) Reconciliation After Termination. Notwithstanding the time periods set forth in Section 7.1(c), the parties shall make a final reconciliation in accordance with the provisions Section 7.1(c) within a reasonable period of time after the effective date of termination, including any inventory sell-off period described in Section 14.4, as applicable.

7.2. Inter-Company Sales. Sales of Licensed Product between or among Pfizer, its Affiliates or Sublicensees shall not be included in the calculation of Net Sales.

7.3. Currency. All payments to be made hereunder by one party to the other party shall be computed and paid in United States dollars. For the purposes of determining Net Sales, Allowable Expenses, Uncapped Expenses or COGs (including, separately, after the [\*\*\*] Period,

[\*\*\*] Redacted pursuant to a confidential treatment request.

the Fully Absorbed Cost of Goods and Labeling and Packaging Costs) in the Territory, the amount of Net Sales, Allowable Expenses, Uncapped Expenses or COGs (including, separately, after [\*\*\*], the Fully Absorbed Cost of Goods and Labeling and Packaging Costs) in any foreign currency shall be converted into United States dollars in a manner consistent with Pfizer's normal practices used to prepare its audited financial reports; provided that such practices use a widely accepted source of published exchange rates and are in accordance with GAAP. Pfizer shall, upon the request of Protalix, disclose to Protalix such practices for converting foreign currency into U.S. Dollars.

#### 7.4. Method of Payments.

(a) Each payment to be made hereunder by Pfizer to Protalix shall be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Protalix's election, to the account designated on Appendix 7.4(a). With respect to any payment invoiced by Protalix to Pfizer, Protalix may designate a different bank account on such invoice. With respect to any other payment, Protalix may designate a different bank account at least sixty (60) days before such payment is due.

(b) Each payment to be made hereunder by Protalix to Pfizer shall be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Pfizer's election, to the account designated on Appendix 7.4(b), or to such other bank account as Pfizer shall designate in a notice at least fifteen (15) Business Days before the payment is due.

7.5. Inspection of Records. Pfizer shall, and shall cause its Affiliates and Sublicensees to, keep accurate books and records setting forth gross sales of the Licensed Product, Net Sales, Allowable Expenses, Uncapped Expenses and COGs (including, separately, after [\*\*\*], the Fully Absorbed Cost of Goods and Labeling and Packaging Costs) sufficient to enable the calculation of amounts payable hereunder to be verified. Protalix shall, and shall cause its Affiliates and sublicensees to, keep accurate books and records setting forth Uncapped Expenses and the Price for Drug Substance for the Drug Substance purchased by Pfizer from Protalix hereunder, sufficient to enable the calculation of Actual Price to be verified. Each party will retain such books and records for five (5) years after the end of the calendar year in which they are generated in order to enable audit of such records as set forth below. Each party will retain such books and records during the Term and for three (3) years after final payment has been made under the Agreement. Each party will have the right to request that an independent certificate public accountant selected by it, and reasonably acceptable to the other party, examine the other party's books and records at any reasonable time, upon reasonable notice and at the facility(ies) where the other party's books and records are normally kept; provided that such examination shall be limited to the pertinent books and records for any calendar year ending not more five (5) years before the date of the request; provided further that after final payment is made, such examination shall be limited to the pertinent books and records for any calendar year ending not

[\*\*\*] Redacted pursuant to a confidential treatment request.



more than three (3) years after final payment has been made. The foregoing right of examination may be exercised only once during each twelve (12)-month period of the Term and only once during each twelve (12)-month period in the three (3) years after final payment has been made. The audited party may require such accountants to enter into a reasonably acceptable confidentiality agreement. The opinion of said independent accountants regarding such payments shall be binding on the parties, other than in the case of manifest error. Except as set forth below, the auditing party shall bear the cost of any such examination and review.

(a) If Protalix's review of Pfizer's records reveals that Pfizer failed to accurately report information pursuant to Section 7.1(a), then Pfizer shall promptly pay to Protalix the amount of any underpayment of Net Profit due pursuant to Section 6.4 and if the discrepancy is greater than five percent (5%) of the amount due, Pfizer shall promptly reimburse Protalix for all costs incurred in connection with such examination. Any overpayment of Net Profit to Protalix by Pfizer revealed by an examination shall be fully-creditable against Protalix's future share of Net Profit under Section 6.4(a).

(b) If Pfizer's review of Protalix's records reveals that Pfizer paid more than the Actual Price with respect to units of Drug Substance purchased from Protalix pursuant to Section 5, then any overpayment revealed by an examination shall be fully-creditable against Protalix's future share of Net Profit under Section 6.4(a) and if the discrepancy is greater than five percent (5%) of the amount due, Protalix shall promptly reimburse Pfizer for all costs incurred in connection with such examination.

#### 7.6. Tax Matters.

(a) VAT. It is understood and agreed between the parties that any payments made by Pfizer under this Agreement are inclusive of any value added or similar tax imposed upon such payments.

(b) Tax Cooperation. Subject to Sections 7.6(c)(c)(i) and (c)(ii), to the extent Pfizer is required to deduct and withhold taxes on any payments to Protalix, Pfizer shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Protalix an official tax certificate or other evidence of such withholding sufficient to enable Protalix to claim credits for such payments of taxes. Protalix shall provide to Pfizer any tax forms that may be reasonably necessary in order for Pfizer not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Protalix shall use reasonable efforts to provide any such tax forms to Pfizer at least thirty (30) days prior to the due date for any payments for which Protalix desires that Pfizer apply a reduced withholding rate. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax or VAT. Each party further agrees to provide reasonable cooperation to the other party, at the other party's expense, in connection with any official or unofficial tax audit or contest relating to payments made by Pfizer to Protalix under this Agreement.

(c) Withholding Tax Matters.

(i) Any amount payable by Pfizer to Protalix pursuant to Sections 6.1 or 6.2 shall be paid without any deduction for withholding taxes; [\*\*\*].

(ii) Pfizer shall deduct and withhold from any amount payable by Pfizer to Protalix pursuant to Section 6.4 with respect to Net Sales of Licensed Product in the United States at the rate of withholding applicable under the royalty article in the Income Tax Convention between the United States and Israel as in effect from time to time (the "Tax Treaty Rate"). [\*\*\*].

(iii) It is the understanding of the parties that, under current Laws, the payments to be made by Pfizer under this Agreement are not subject to withholding tax requirements in any jurisdiction outside of the United States and, accordingly, absent a change in such Laws requiring withholding, Pfizer will not withhold any amounts from such payments. In the event that, as a result of such a change in Law any of the payments made by Pfizer under this Agreement become subject to withholding taxes under the Laws of any jurisdiction outside of the United States, Pfizer shall deduct and withhold the amount of such taxes for the account of Protalix to the extent required by Law, and such payment to Protalix shall be reduced by the amount of taxes deducted and withheld. Any such withholding taxes required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, Protalix.

(iv) Notwithstanding anything in this Agreement to the contrary, if an action (a "Tax Action") by one party, including any assignment or sublicense by such party of its rights or obligations under this Agreement, or any failure on the part of such party or its Affiliates to comply with applicable Laws or filing or record retention requirements, leads to the imposition of withholding tax liability on the other party that would not have been imposed in the absence of such Tax Action, or in an increase in such liability above the liability that would have been imposed in the absence of such Tax Action, such party shall indemnify and hold harmless the other party from any such additional or increased tax liability. In the event of any such Tax Action, such party shall, or shall cause its assignee to, gross up any payments it makes to the other party to the extent necessary so that the net payment received by the other party after such additional or increased tax liability equals the amount due under this Agreement.

## **Section 8. PATENTS AND INFRINGEMENT**

8.1. Filing and Prosecution. Protalix shall have the exclusive right, subject to Sections 8.2 through 8.5, to:

(a) file Patent Applications on any invention included in the Protalix Patent Rights;

(b) take all reasonable steps to prosecute all pending and new Patent Applications included within the Protalix Patent Rights;

[\*\*\*] Redacted pursuant to a confidential treatment request.

(c) respond to oppositions, interferences, nullity actions, re-examinations, revocation actions and similar proceedings filed by Third Parties against the grant of Patents for such Patent Applications; and

(d) maintain in force any patents in the Territory included within the Protalix Patent Rights by duly filing all necessary papers and paying any fees required by the relevant patent laws and regulations of the particular Country in which the patent was granted.

(e) [\*\*\*] shall be responsible for bearing [\*\*\*] percent ([\*\*\*]%) of the expenses and costs incurred by [\*\*\*] in connection with the exercise of its rights under this Section 8.1.

8.2. Correspondence. [\*\*\*] will keep [\*\*\*] fully-informed of the status of the Protalix Patent Rights to the extent the Protalix Patent Rights [\*\*\*], and will provide [\*\*\*] with copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. With respect to any substantive submissions that [\*\*\*] is required to or otherwise intends to submit to a patent office regarding such Protalix Patent Rights, [\*\*\*] shall use Commercially Reasonable Efforts to provide a draft of such submission to [\*\*\*] at least thirty (30) days prior to the deadline or intended filing date, whichever is earlier, for submission of such documentation. [\*\*\*] shall have the right to review and comment upon any such submission by [\*\*\*] to a patent office that could affect the scope of coverage or validity of any claim of the Protalix Patent Rights to the extent covering [\*\*\*], and will provide such comments, if any, no later than ten (10) days prior to the applicable deadline or intended filing date. Notwithstanding the foregoing, when such substantive documentation submitted to or received from the patent offices is solely related to [\*\*\*], [\*\*\*] shall have the right, but no obligation, to fully inform [\*\*\*] of the status of these Protalix Patent Rights.

(a) Upon [\*\*\*] written request, provided that [\*\*\*] submits such written request reasonably in advance of any relevant filing deadline or intended filing date, [\*\*\*] will file Patent Applications directed to the rights licensed to [\*\*\*] under this Agreement [\*\*\*], including, for example, [\*\*\*].

(b) With respect to Protalix Patent Rights that are [\*\*\*] shall consider in good faith all comments provided by [\*\*\*] with respect to a Protalix Patent Right to the extent relating to [\*\*\*], and incorporate all such comments that [\*\*\*] deems reasonable and appropriate. If [\*\*\*] disagrees with any such comment provided by [\*\*\*] after giving such comments due consideration, [\*\*\*] shall provide [\*\*\*] with an explanation of the basis for such disagreement. If a failure to incorporate [\*\*\*] comment would reasonably be expected to [\*\*\*] shall have final-decision making authority with respect to filings and prosecution of such Protalix Patent Rights (other than the Protalix System Patent Rights). [\*\*\*] shall have final-decision making authority with respect to filings and prosecution of Protalix Patent Rights relating solely to [\*\*\*] and with respect to filings and prosecution of Protalix Patent Rights that [\*\*\*].

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

(c) Notwithstanding the foregoing, [\*\*\*] obligation to keep [\*\*\*] informed of the status of the Protalix System Patent Rights will be limited to situations where changes to the status of the Protalix System Patent Rights [\*\*\*]. With respect to the Protalix System Patent Rights, [\*\*\*] shall reasonably consider all comments provided by [\*\*\*], but [\*\*\*] shall have final-decision making authority with respect to filings and prosecution of the Protalix System Patent Rights.

8.3. Maintenance. Protalix will maintain for the full life thereof all Patent Rights under the Protalix Patent Rights where the abandonment for non-payment would [\*\*\*]. Protalix will notify Pfizer of any decision (a) not to file applications for, or (b) not to enter the national phase for a PCT patent application (or not to validate a patent in a particular Country) for, or (c) to cease prosecution and/or maintenance of, or (d) not to pursue, or (e) to cease to pay the expenses of prosecution or maintenance of, any Protalix Patent Rights in any Country in the Territory. Protalix will provide such notice upon the earlier of (i) its decision with respect to any of the foregoing, or (ii) ninety (90) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Protalix Patent Rights. In such event, Pfizer shall have the right to make the filing, or to continue the prosecution and maintenance of such Patent Rights (other than [\*\*\*]) in its own name and at its sole expense, and such Patent Rights shall be assigned to Pfizer and shall no longer be part of the Protalix Patent Rights. Notwithstanding the foregoing, Protalix shall have no obligation to provide such notice where the subject Protalix Patent Rights are directed solely to [\*\*\*] or otherwise where [\*\*\*].

8.4. Notices and Encumbrances. Protalix agrees that it will, and will cause its Affiliates to, (a) execute and file those notices and other filings as Pfizer shall request be made, from time to time with the United States Patent and Trademark Office (or any successor agency) or any analogous patent office in the Territory with respect to the rights granted under this Agreement and, (b) maintain (subject to Section 8.3) at all times during the Term sole ownership of the Patents and Patent Applications under the Protalix Patent Rights (other than Protalix Patent Rights directed solely to [\*\*\*]), free and clear of any and all mortgages, liens, pledges, security interests, charges or encumbrances. Protalix shall also keep the Protalix Technology (other than Protalix Technology directed solely to or solely embodied in [\*\*\*]), free and clear of any and all mortgages, liens, pledges, security interests, charges or encumbrances during the Term. For the sake of clarity, encumbrances as contemplated in this Section 8.4 specifically exclude licenses to Protalix Patent Rights and Protalix Technology, wherein such licenses are [\*\*\*].

8.5. Patent Term Extensions. Pfizer shall have the first right, but not the obligation, to seek, in Protalix's name if so required, patent term extensions, and supplemental protection certificates and the like available under Law, including 35 U.S.C. § 156 and applicable foreign counterparts, in any Country in the Territory in relation to the Protalix Patent Rights covering the Compound (other than Protalix Patent Rights directed solely to the Compound [\*\*\*]) or

[\*\*\*] Redacted pursuant to a confidential treatment request.

Licensed Products. In the event that Pfizer decides not to seek such patent term extension or supplemental patent protection in any Country in the Territory, Protalix shall have the right to seek such patent term extension or supplemental patent protection in any such Country. Protalix and Pfizer shall cooperate in connection with all such activities, and Pfizer, its agents and attorneys will give due consideration to all suggestions and comments of Protalix regarding any such activities, but in the event of a disagreement between the parties, as it relates to the Compound (other than [\*\*\*]) or Licensed Product, Pfizer will have the final decision-making authority. Any costs incurred by Pfizer in connection with this Section 8.5 shall constitute [\*\*\*]. Any costs incurred by Protalix in connection with this Section 8.5 shall be borne [\*\*\*].

8.6. Interpretation of Patent Judgments. If any claim relating to a patent under the Protalix Patent Rights becomes the subject of a judgment, decree or decision of a court, tribunal, or other authority of competent jurisdiction in any Country, which judgment, decree, or decision is or becomes final (there being no further right of review) and adjudicates the validity, enforceability, scope, or infringement of the same, the construction of such claim in such judgment, decree or decision shall be followed thereafter in such Country not only as to such claim but also as to all other claims in such Country to which such construction reasonably applies, in determining whether there are any Valid Claims in such Country. If at any time there are two or more conflicting final judgments, decrees, or decisions with respect to the same claim, the decision of the higher tribunal shall thereafter control, but if the tribunal be of equal rank, then the final judgment, decree, or decision more favorable to such claim shall control unless and until the majority of such tribunals of equal rank adopt or follow a less favorable final judgment, decree, or decision, in which event the latter shall control.

8.7. Third Party Royalty Obligations.

(a) Subject to Appendix 15.1(c), if Pfizer reasonably determines in good faith that in order to avoid infringement of any Patent Right not licensed hereunder, it is reasonably necessary to obtain a license from a Third Party in order to make, use, sell, offer for sale, supply, cause to be supplied, or import the Licensed Product in a Country in the Territory and to pay a royalty or other consideration under such license (including in connection with the settlement of a patent infringement claim), then the Steering Committee shall discuss the pertinent Third Party Patent Right and Pfizer's determination. If the Steering Committee decides that Pfizer should enter into such license, Pfizer shall use Commercially Reasonable Efforts to negotiate and enter into a license for such Third Party patent. [\*\*\*].

(b) If Pfizer is subject to a final court or other binding order or ruling requiring any payments, including the payment of a royalty to a Third Party patent holder in respect of sales of the Licensed Product in a Country in the Territory, then the amount of such payments made by Pfizer to the Third Party shall be treated as [\*\*\*].

[\*\*\*] Redacted pursuant to a confidential treatment request.

8.8. Third Party Infringement. Each party will promptly notify the other in the event of any actual, potential or suspected infringement of a Patent under the Protalix Patent Rights by any Third Party.

(a) Infringement of Protalix Patent Rights in the Field.

(i) Pfizer shall have the sole right, but not the obligation, to institute litigation or take other remedial measures in connection with Third Party infringement of the Protalix Patent Rights occurring in the Field within the Territory (other than Protalix Patent Rights directly solely to [\*\*\*]), where such Third Party infringement would reasonably be expected to [\*\*\*]. In order to establish standing, Protalix, upon request of Pfizer, agrees to timely commence or to join in any such litigation, at Pfizer's expense, and in any event to cooperate with Pfizer at Pfizer's expense. Any costs and expenses incurred by Pfizer with respect to any such litigation or remedial measures shall be treated as [\*\*\*] and any recoveries resulting from such litigation or measures relating to a claim of a Third Party infringement in pursuing such claim, will be deemed [\*\*\*].

(ii) Notwithstanding anything to the contrary in Section 8.8(a)(i), following receipt by Protalix of a Section 14.2(c) Notice, Protalix shall have the sole right during the Section 14.2(c) Termination Notice Period, but not the obligation, to institute litigation or take other remedial measures in connection with Third Party infringement of the Protalix Patent Rights occurring [\*\*\*]. In order to establish standing, Pfizer, upon request of Protalix, agrees to timely commence or to join in any such litigation, at Protalix's expense, and in any event to cooperate with Protalix at Protalix's expense. Any costs and expenses incurred by Protalix with respect to any such litigation or remedial measures shall be [\*\*\*]. Protalix shall retain [\*\*\*] received by Protalix as a result of its enforcement of Protalix Patent Rights under this Section 8.8(a)(ii).

(iii) Protalix shall have the sole right, but not the obligation, to institute litigation or take other remedial measures in connection with Third Party infringement of any Protalix Patent Rights occurring [\*\*\*] and with respect to Third Party infringement of any Protalix Patent Rights directed solely to [\*\*\*] any such litigation or remedial measures shall be [\*\*\*]. Protalix shall retain [\*\*\*] received by Protalix as a result of its enforcement of Protalix Patent Rights under this Section 8.8(a)(iii).

(b) Infringement of Protalix Patent Rights [\*\*\*]. Protalix shall have the sole right, but not the obligation, to institute litigation or take other remedial measures in connection with Third Party infringement occurring [\*\*\*] and any such litigation or remedial measures shall be [\*\*\*]. Protalix shall either (i) provide Pfizer with prior written notice of Protalix's intent to initiate a suit, take other appropriate action, or to not file suit or seek other redress or (ii) convene

[\*\*\*] Redacted pursuant to a confidential treatment request.

a meeting of the Steering Committee pursuant to Section 4.3(b) to discuss what would be in the parties' best interest with respect to the Third Party infringement occurring [\*\*\*]. Protalix shall retain [\*\*\*] received by Protalix as a result of its enforcement of Protalix Patent Rights under this Section 8.8(b).

#### 8.9. Paragraph IV Notices.

(a) If either party receives a notice under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) directed to a Compound (other than [\*\*\*]) or Licensed Product, concerning any Protalix Patent Right ("Paragraph IV Notice"), then it shall provide a copy of such notice to the other party promptly and in any event no later than two (2) Business Days after its receipt thereof. Pfizer shall have the exclusive right, but not the obligation, to initiate patent infringement litigation based on a Paragraph IV Notice directed to a Compound (other than [\*\*\*]) or Licensed Product, concerning a Protalix Patent Right, and any expenses incurred by Pfizer with respect to such infringement litigation shall constitute [\*\*\*]. Upon request of Pfizer, Protalix agrees to timely join as party-plaintiff in any such litigation, and in any event to cooperate with Pfizer in connection with such infringement action, including timely filing such action in Protalix's name if required. Pfizer shall promptly notify Protalix of its intention not to initiate patent infringement litigation based on such Paragraph IV Notice. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory will be deemed [\*\*\*].

(b) Notwithstanding anything to the contrary in Section 8.9(a), following receipt by Protalix of a Section 14.2(c) Notice, Protalix shall have the sole right during the remainder of the Section 14.2(c) Termination Notice Period, but not the obligation, to initiate patent infringement litigation based on a Paragraph IV Notice directed to a Compound or Licensed Product, concerning a Protalix Patent Right. Upon request of Protalix, Pfizer agrees to timely join as party-plaintiff in any such litigation, [\*\*\*], and in any event to cooperate with Protalix [\*\*\*] in connection with such infringement action, including timely filing such action in Pfizer's name if required. Protalix shall retain [\*\*\*] received by Protalix as a result of its enforcement of Protalix Patent Rights under this Section 8.9(b).

(c) [\*\*\*].

8.10. Other Actions by a Third Party. Each party shall promptly notify the other in the event of any (a) claims by a Third Party of alleged patent infringement by Pfizer or Protalix or any of their respective Affiliates with respect to [\*\*\*] of a Compound (other than [\*\*\*]) or Licensed Product or (b) legal or administrative action by any Third Party involving a Protalix Patent Right (other than Protalix Patent Rights directed solely to [\*\*\*]) of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. Pfizer shall have the first right, but no obligation, to defend against any such action involving such Protalix Patent Right in the Territory when the alleged patent infringement would reasonably be expected to [\*\*\*], and any such defense shall be at [\*\*\*]. Protalix, upon request

[\*\*\*] Redacted pursuant to a confidential treatment request.

of Pfizer, agrees to join in any such action [\*\*\*] and in any event to cooperate with Pfizer [\*\*\*]. If Pfizer fails to defend Protalix against any such action involving a Protalix Patent Right, then Protalix shall have the right to defend such action, and any such defense shall be [\*\*\*]. Pfizer, upon request of Protalix, shall reasonably cooperate with Protalix in any such action [\*\*\*]

8.11. Compensation [\*\*\*]

8.12. Patent Marking. Each party shall comply with the patent marking statutes in each Country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such party, its Affiliates and sublicensees.

8.13. In-Licensed Patents. With respect to Section 8, "Protalix Patent Rights" shall include Patent Rights that are Controlled by Protalix or any of its Affiliates pursuant to a Third Party License (*i.e.*, such Patent Rights are not owned by Protalix or any of its Affiliates) only if (a) [\*\*\*]; or (b) [\*\*\*].

**Section 9. CONFIDENTIALITY; PUBLICATION**

9.1. Confidential Information.

(a) Pfizer and Protalix each agree that during the Term and for five (5) years after the Term, it will keep confidential, and will cause its Affiliates to keep confidential, all of the other party's Confidential Information that is disclosed to it, or to any of its Affiliates. Pfizer and Protalix each agree to take such action, and to cause its Affiliates to take such action, to preserve the confidentiality of Protalix Confidential Information and Pfizer Confidential Information, respectively, as it would customarily take to preserve the confidentiality of its own similar types of confidential information.

(b) Each of Pfizer, Protalix and their respective Affiliates agree (i) to use Protalix Confidential Information and Pfizer Confidential Information, respectively, only as expressly permitted in this Agreement and (ii) not to disclose Protalix Confidential Information and Pfizer Confidential Information, respectively, to any Third Parties under any circumstance without the prior consent of the other party, except as expressly permitted in this Agreement.

9.2. Permitted Disclosure of Confidential Information.

(a) Disclosure of Protalix Confidential Information.

(i) Notwithstanding anything to the contrary in this Section 9, Pfizer may disclose Protalix Confidential Information: (A) to Governmental Authorities (x) to the extent desirable to obtain or maintain Regulatory Approvals for the Compound or Licensed Product within the Territory, and (y) in order to respond to inquiries, requests or investigations relating to this Agreement; (B) to outside consultants, contractors, advisory boards, managed care organizations, and non-clinical and clinical investigators, in each case to the extent desirable to develop, register or market the Compound or Licensed Product; provided that Pfizer shall

[\*\*\*] Redacted pursuant to a confidential treatment request.



obtain the same confidentiality obligations and degree of care from such Third Parties as it obtains with respect to its own similar types of confidential information; (C) in connection with filing or prosecuting Patent Rights or trademark rights as permitted by this Agreement; (D) in connection with prosecuting or defending litigation as permitted by this Agreement; (E) in connection with or included in scientific presentations and publications relating to the Compound or Licensed Product, including abstracts, posters, journal articles and the like, and posting results of and other information about clinical trials to clinicaltrials.gov or PhRMA websites; and (F) to the extent necessary or desirable in order to enforce its rights under this Agreement.

(ii) If Pfizer is required or requested to disclose Protalix Confidential Information (x) as required by Law or legal proceedings or (y) as required to be contained in Pfizer's financial statements prepared in accordance with GAAP, as applied on a consistent basis, Pfizer shall (1) with respect to disclosures described in clause (x), use Commercially Reasonable Efforts to obtain confidential treatment of financial and trade secret information, and (2) with respect to disclosures described in clauses (x) and (y), if reasonably practicable under the circumstances, give Protalix sufficient advance notice of the text so that Protalix will have the opportunity to seek, at its own cost, an appropriate protective order or other remedy or waive compliance with the provisions of this Agreement. If Protalix seeks a protective order, Pfizer will cooperate. If Protalix fails to obtain a protective order or waive compliance with the relevant portions of this Agreement, Pfizer will disclose only that portion of information concerning the Compound or Licensed Product which its legal counsel determines it is required to disclose.

**(b) Disclosure of Pfizer Confidential Information.**

(i) Notwithstanding anything to the contrary in this Section 9, Protalix may disclose Pfizer Confidential Information to: (x) Governmental Authorities in order to respond to inquiries, requests or investigations relating to this Agreement or to comply with applicable Laws and (y) to the extent necessary or desirable in order to enforce its rights under this Agreement.

(ii) If Protalix is required or requested to disclose Pfizer Confidential Information (x) as required by Law or legal proceedings or in connection with Section 9.2(b)(i) above or (y) as required to be contained in Protalix financial statements prepared in accordance with GAAP, as applied on a consistent basis, Protalix shall (1) with respect to disclosures described in clause (x), use Commercially Reasonable Efforts to obtain confidential treatment of financial and trade secret information, and (2) with respect to disclosures described in clauses (x) and (y), if reasonably practicable under the circumstances, give Pfizer sufficient advance notice of the text so that Pfizer will have the opportunity to seek, at its own cost, an appropriate protective order or other remedy or waive compliance with the provisions of this Agreement. If Pfizer seeks a protective order, Protalix will cooperate. If Pfizer fails to obtain a protective order or waive compliance with the relevant portions of this Agreement, Protalix will disclose only that portion of information concerning the Compound or Licensed Product which its legal counsel determines it is required to disclose.

(iii) If Protalix desires to disclose Pfizer Confidential Information that (x) has been announced previously in accordance with Section 9.4 (Publicity), or (y) has been announced previously by Pfizer, such disclosure is permitted so long as (1) it is consistent with

such previously announced statement and (2) Pfizer is permitted a review and comment period of no fewer than sixty (60) days prior to the planned disclosure to redact any Pfizer Confidential Information and ensure the disclosure is within the scope of previous disclosures as set forth in this Section 9.2(b)(iii).

### 9.3. Publication.

(a) Subject to Section 9.3(d), neither Pfizer nor any of its Affiliates or their respective employees, consultants, contractors and agents shall publish or present any information, including the results of any preclinical or clinical studies, with respect to the Compound or Licensed Product unless Pfizer has used Commercially Reasonable Efforts to provide Protalix with thirty (30) days' notice prior to any such publication or presentation.

(b) Subject to Section 9.3(c) and Section 9.3(d), neither Protalix nor any of its Affiliates or their respective employees, consultants, contractors and agents shall publish or present any information, including the results of any preclinical or clinical studies, with respect to the Compound [\*\*\*] or Licensed Product without the prior written approval of Pfizer [\*\*\*], except as may be required by Law or legal proceedings.

(c) Section 9.3(b) does not prohibit: (i) Protalix and its Affiliates (and their respective employees, consultants, contractors, licensees and agents) from publishing or presenting information relating to the development or use of the System that does not contain information with respect to the Compound (other than the Oral Formulation) or Licensed Product; (ii) Protalix and its Affiliates (and their respective employees, consultants, contractors, licensees and agents) from publishing or presenting information relating to the Oral Formulation; or (iii) Protalix and its Affiliates (and their respective employees, consultants, contractors, licensees and agents) from publishing or presenting information that has been either previously published or presented by Protalix in accordance with Section 9.3(b) or by Pfizer. Protalix will use Commercially Reasonable Efforts to provide Pfizer a copy of any such proposed publication or presentation described in clauses (i) or (ii) of this Section 9.3(c) at least thirty (30) days prior to any such publication or presentation.

(d) Nothing in this Section 9.3 shall be construed to (a) limit the rights of either party's Third Party clinical investigators to publish the results of their studies or (b) prevent either party from complying with applicable Law with respect to the disclosure of clinical study data and results or of any other material matter or information.

### 9.4. Publicity.

(a) The public announcement of the execution of this Agreement is set forth on Exhibit E attached hereto and shall be promptly disseminated as a press release following the execution of this Agreement by both parties.

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

(b) Except as set forth in Sections 9.3, 9.4(a) or 9.4(c), Protalix shall not make (and shall cause its Affiliates not to make) any public statement (written or oral), including in analyst meetings, concerning the terms of, or events related to, this Agreement or concerning the Licensed Product without the prior written approval of Pfizer (which may be withheld in its sole and final discretion) except where such statement: (i) is required by Law or legal proceedings (or to respond to a specific request of the securities exchange upon which Protalix's securities are listed); (ii) is required to be contained in Protalix financial statements prepared in accordance with GAAP; (iii) has been announced previously in accordance with this Section 9.4; or (iv) has been announced previously by Pfizer; so long as, in the case of (iii) or (iv), such public statement is consistent with such previously announced statement. In the case of any public statement (written or oral) that is required by Law or legal proceedings, Protalix shall (and shall cause its Affiliates to) (x) use Commercially Reasonable Efforts to obtain confidential treatment of financial and trade secret information (except in connection with press releases) and (y) if reasonably practicable under the circumstances, give Pfizer sufficient advance notice of the text so that Pfizer will have the opportunity to comment upon the statement, and give due consideration to any specific reasonable comments of Pfizer on such text timely received from Pfizer.

(c) Section 9.4(b) does not prohibit Protalix from making public announcements: (i) that any of the following has commenced or has been completed: any Ongoing Clinical Study; [\*\*\*]; provided that such public announcement complies with all applicable Laws; or (ii) reporting the aggregate worldwide (but not country-by-country or region-by-region) Net Sales amount of Licensed Product (expressed as a dollar amount, not in units of Licensed Product) for a particular quarter after Pfizer has filed with the SEC its quarterly earnings release for such quarter. Protalix will provide Pfizer a copy of any such proposed public announcement at least ten (10) Business Days prior to such announcement so that Pfizer will have the opportunity to comment upon the announcement, and give due consideration to any specific reasonable comments of Pfizer on such text timely received from Pfizer.

(d) Except as set forth in Sections 9.3 or 9.4(a), Pfizer shall, if reasonably practicable under the circumstances, give Protalix sufficient advance notice of the text of any public statement concerning the terms of, or events related to, this Agreement or concerning the Compound or Licensed Product so that Protalix will have the opportunity to comment upon such statement. Pfizer shall give due consideration to any specific reasonable comments of Protalix on such text timely received from Protalix.

9.5. Filing, Registration or Notification of the Agreement. The parties shall use reasonable efforts to agree upon a form of redacted copy of this Agreement (the "Redacted Agreement") as soon as reasonably practicable, but in no event later than fifteen (15) Business Days after the Effective Date. If a party determines that it is required by Law to publicly file, register or notify this Agreement with a Governmental Authority, such party shall (a) initially

[\*\*\*] Redacted pursuant to a confidential treatment request.

file the Redacted Agreement, (b) request, and use Commercially Reasonable Efforts to obtain, confidential treatment of all terms redacted from this Agreement, as reflected in the Redacted Agreement, for a period of at least ten (10) years, (c) permit the other party to review and approve such request for confidential treatment and any subsequent correspondence with respect thereto at least five (5) Business Days prior to its submission to such Governmental Authority, (d) promptly deliver to the other party any written correspondence received by it or its representatives from such Governmental Authority with respect to such confidential treatment request and promptly advise the other party of any other communications between it or its representatives with such Governmental Authority with respect to such confidential treatment request, (e) upon the written request of the other party, request an appropriate extension of the term of the confidential treatment period, and (vi) if such Governmental Authority requests any changes to the redactions set forth in the Redacted Agreement, use Commercially Reasonable Efforts to support the redactions in the Redacted Agreement as originally filed and shall not agree to any changes to the Redacted Agreement without first discussing such changes with the other party and taking the other party's comments into consideration when deciding whether to agree to such changes. Each party shall be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

#### **Section 10. REPRESENTATIONS, WARRANTIES AND COVENANTS**

10.1. Protalix Representations, Warranties and Covenants. Protalix hereby represents and warrants as of the Effective Date and covenants to Pfizer as follows:

(a) Protalix has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by Protalix have been duly and validly authorized and approved by proper corporate action on the part of Protalix, and Protalix has taken all other action required by Law, its certificate of incorporation, by-laws or other organizational documents or any agreement to which it is a party or to which it may be subject, required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of Pfizer, this Agreement constitutes a legal, valid and binding obligation of Protalix, enforceable against Protalix in accordance with its terms.

(b) The execution and delivery of this Agreement by Protalix and the performance by Protalix contemplated hereunder does not and will not violate any Laws (as in effect on the Effective Date), except for such violations that would not have an adverse effect on the ability of Protalix to perform its obligations under this Agreement, or any order of any court or Governmental Authority in effect on the Effective Date.

(c) To the knowledge of Protalix, the Protalix Patent Rights owned by Protalix or its Affiliates are valid and enforceable and no Third Party (i) is infringing any such Protalix Patent Rights or (ii) has challenged the validity or enforceability of the Protalix Patent Rights owned by Protalix or its Affiliates (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign entity).

(d) To the knowledge of Protalix, neither (i) the Manufacture, use or Development (including the use or provision of Licensed Product in Early Access Programs) by Protalix (or its Affiliates) of the Drug Substance or Licensed Product on or prior to the Effective

Date has infringed nor (ii) the Manufacture, use, Development, sale, offer for sale, supply or importation by Protalix or Pfizer (or their respective Affiliates) of the Drug Substance or Licensed Product (as currently constituted) as contemplated by this Agreement would infringe any issued Patent of any Third Party that exists on the Effective Date or, if and when issued, any valid claim within any Third Party Patent Application published before the Effective Date

(e) Exhibit B contains a complete and correct list as of the Effective Date of all Patents and Patent Applications owned by or otherwise Controlled by Protalix (and indicating which entity owns or controls each Patent and Patent Application and which are owned and which are Controlled) covering the Compound, any Licensed Product and the System.

(f) Protalix is the sole and exclusive owner of all the Protalix Patent Rights and Protalix Technology (other than Patent Rights licensed to Protalix as described in Exhibit B), free of any lien, encumbrance, charge, security interest, mortgage or other similar restriction, and no Person (including any Affiliate of Protalix) has any right, interest or claim in or to, and neither Protalix nor any of its Affiliates has entered into any agreement granting any right, interest or claim in or to any Protalix Patent Rights owned by Protalix or its Affiliates or Protalix Technology to any Third Party, including any academic organization or agency.

(g) Protalix has complied in all material respects with all applicable Laws, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Protalix Patent Rights (other than Patent Rights licensed to Protalix) in the Territory.

(h) Prior to the Effective Date, the Compound, Drug Substance and Licensed Product have been Developed, Manufactured, stored, labeled, distributed and tested by Protalix and its Affiliates and, to the knowledge of Protalix, by any Third Parties acting on behalf of Protalix, in compliance in all material respects with all applicable Laws.

(i) Other than Patent Rights licensed to Protalix as described in Exhibit B, none of the rights of Protalix or its Affiliates under the Protalix Patent Rights were developed with federal funding from the United States government or any other Governmental Authority, other than grants received by Protalix from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor.

(j) Protalix has obtained assignments from the inventors of all inventorship rights relating to the Protalix Patent Rights (other than Patent Rights licensed to Protalix), and all such assignments of inventorship rights covering the Protalix Patent Rights (other than Patent Rights licensed to Protalix) are valid and enforceable.

(k) Each Third Party License as heretofore delivered by Protalix to Pfizer represents the complete agreement and understanding between the Third Party licensor(s) under such Third Party License and Protalix relating to the Protalix Patent Rights and Protalix Technology which are the subject of such Third Party License. No Third Party License has been modified, supplemented or amended, other than by amendments thereto provided to Pfizer prior to the Effective Date. Except for the Third Party Licenses listed on Exhibit C, there are no agreements to which Protalix or any of its Affiliates is a party pursuant to which Protalix or any of its Affiliates has a license, or an option to obtain a license, or holds an immunity from suit, with respect to patents which (i) are pending, applied for, granted or registered, and (ii) but for

Protalix's rights under such agreements, could be asserted by Third Parties to be infringed by the Manufacture, distribution, use, marketing or sale of the Drug Substance or Licensed Product. Each Third Party License is in full force and effect, all payments to date required to be made thereunder by Protalix have been made, and Protalix is in compliance in all respects with its respective obligations thereunder.

(l) Protalix has previously delivered to Pfizer all of its material agreements with any Third Parties regarding the Development, supply and Manufacture of all goods and services relating to the Drug Substance and Licensed Product to the extent requested by Pfizer, none of which have been modified, supplemented or amended in any material respect, other than by amendments thereto provided to Pfizer prior to the Effective Date. Each such agreement is in full force and effect, all payments to date required to be made thereunder by Protalix have been made, and Protalix is in compliance in all respects with its respective obligations thereunder.

(m) Protalix has heretofore disclosed to Pfizer all material scientific and technical information and all material information relating to safety and efficacy known to it or its Affiliates with respect to the Drug Substance and Licensed Product.

(n) Protalix has heretofore disclosed to Pfizer all material correspondence and contact information between Protalix and the FDA and any other Governmental Authorities regarding the Drug Substance or Licensed Product.

(o) Neither the execution and delivery of this Agreement nor the performance hereof by Protalix requires Protalix to obtain any permits, authorizations or consents from any Governmental Authority or from any other Person, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination, rescission, renegotiation or acceleration under, or trigger any other rights under, any agreement or contract to which Protalix is a party or to which it may be subject that relates to the Protalix Patent Rights, Protalix Technology, Drug Substance or Licensed Product.

(p) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Protalix, threatened against Protalix, any of its Affiliates or any Third Party, in each case in connection with the Protalix Patent Rights owned by Protalix, Protalix Technology owned by Protalix, Drug Substance, Licensed Product or System or relating to the transactions contemplated by this Agreement.

(q) To the knowledge of Protalix, information provided by Protalix in response to any of Pfizer's due diligence requests prior to the Effective Date was in all material respects complete, truthful and accurate.

(r) Protalix has not and will not directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value or improperly seek to influence any Government Official in connection with this Agreement. For purposes of this Section, a "Government Official" is defined as and includes: (i) any elected or appointed government official (e.g., a member of a ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party, officer, employee, or person acting for or on behalf of a political party or candidate for public office; (iv) an employee or person acting for or on behalf

of a public international organization; or (v) any person otherwise categorized as a Government Official under local law where “Government” includes all levels and subdivisions of non-U.S. governments (i.e., local, regional, or national and administrative, legislative, or executive).

(s) To the knowledge of Protalix, all information provided by Protalix or its Affiliate to Pfizer in the Third Party Entity Due Diligence Questionnaire is in all material respects complete, truthful and accurate. Further, Protalix undertakes to promptly update this representation and warranty if (during the Term) Protalix, or any of its employees, or individuals, or subcontractors who will be primarily responsible for performing under this Agreement, or a relative of such an employee or individual or subcontractor, becomes a Government Official or, if a government or Government Official becomes an owner of ten percent (10%) or more of Protalix.

(t) Protalix will comply in all material respects with Pfizer’s Anti-Bribery and Anti-Corruption Principles set forth on Appendix 10.1(t).

(u) Protalix agrees to provide to Pfizer upon request an executed copy of the compliance certification attached hereto as Exhibit I.

10.2. Manufacturing Representations, Warranties and Covenants. Each party hereby represents and warrants as of the Effective Date and covenants to the other party as follows:

(a) All Drug Substance and Licensed Product Manufactured and supplied hereunder by, or under authority of, such party shall be Manufactured and supplied such that:

(i) Any Facility and all equipment, tooling and molds utilized in the Manufacture and supply of Drug Substance and Licensed Product hereunder by such party shall, during the Term, be maintained in good operating condition and shall be maintained and operated in accordance with all applicable Laws. The Manufacturing and storage operations, procedures and processes utilized by such party in Manufacture and supply of Drug Substance and Licensed Product hereunder (including any Facility) shall be in full compliance with all applicable Laws, including GMP and health and safety Laws.

(ii) Such party shall perform all of its Manufacturing and supply obligations under this Agreement in full compliance with all applicable Laws. Such party shall hold during the Term all licenses, permits and similar authorizations required by any Governmental Authority for such party to perform its Manufacturing and supply obligations under this Agreement.

(b) The Drug Substance and Licensed Product, as applicable, furnished by such party [\*\*\*]:

(i) shall be Manufactured, packaged, labeled, handled, stored and shipped in accordance with, shall be of the quality specified in, and shall conform to, the Product Specifications;

(ii) shall be Manufactured, packaged, labeled, handled, stored and shipped in compliance with all applicable Laws including GMP, and in accordance with the Quality Agreement (with respect to Drug Substance and/or Licensed Product furnished by Protalix to Pfizer under this Agreement) and any other quality assurance requirements provided in writing to such party by the other party, and this Agreement;

(iii) shall not contain any material that has not been used, handled or stored in accordance with the Product Specifications, all applicable Laws, the Quality Agreement (with respect to Drug Substance and/or Licensed Product furnished by Protalix to Pfizer under this Agreement) and any other quality assurance requirements of the other party or the supplier of such material, and this Agreement;

(iv) shall not contain any material that would cause the Drug Substance or Licensed Product to be adulterated or misbranded within the meaning of any Laws;

(v) shall be free from defects in material and workmanship; and

(vi) shall, at the time delivered, have a remaining shelf-life as specified in the Quality Agreement (with respect to Drug Substance and/or Licensed Product furnished by Protalix to Pfizer under this Agreement) and Section 5.8(a).

(c) Such party does not currently employ and will not employ during the Term, and such party does not use as a subcontractor and will not use during the Term, and such party's subcontractors do not currently employ and will not employ or engage during the Term, any Person that has been debarred or is subject to debarment or has otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the FDA or any other Governmental Authority or Regulatory Authority or professional body with respect to the performance of scientific or clinical investigations; any other Person who by virtue of any Laws is or may be disqualified, restricted or prevented in any way from performing the services to be provided under this Agreement; or any Person convicted of a criminal offense in relation to:

[\*\*\*] Redacted pursuant to a confidential treatment request.



(i) In respect of a company, partnership or association, the development or approval, including the process for development or approval of an abbreviated drug application;

(ii) In respect of an individual:

(A) the development or approval of any drug product or otherwise relating to the regulation of any drug product; or

(B) bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records or interference with, obstruction of an investigation into a prosecution of any criminal offense.

(d) Notwithstanding the foregoing in this Section 10.2: (i) Pfizer shall not be responsible for any failure to conform to the representations and warranties under Sections 10.2(a) and 10.2(b), and shall have no liability to Protalix under this Agreement where Pfizer's failure to conform to such representations and warranties is as a result of an act or omission of Protalix, Protalix's Affiliates or their respective agents, consultants or contractors in respect of the Manufacture of Drug Substance; and (ii) to the extent the terms of the [\*\*\*] as in effect on the Effective Date are not consistent with the representations, warranties and covenants set forth above in this Section 10.2, Protalix shall not be deemed to be in breach of this Section 10.2 on the basis of such inconsistency; provided, however, that in the event the [\*\*\*]

10.3. Environmental Representations, Warranties and Covenants. Each party hereby represents and warrants as of the Effective Date and covenants to the other party as follows:

(a) Compliance With Environmental Laws.

(i) To the knowledge of such party, there is no pending or threatened governmental enforcement action or private claim against such party pursuant to applicable Environmental Law, no Release or threatened Release of Hazardous Materials, nor any other existing environmental conditions, events or circumstances that are reasonably likely to limit, impede or otherwise jeopardize such party's ability to meet its Manufacturing obligations under this Agreement.

(ii) Such party shall perform all of the Manufacturing services to be provided by it hereunder in compliance with all Environmental Laws and all licenses, registrations, notifications, certificates, approvals, authorizations or permits required under applicable Environmental Laws ("Environmental Permits"), except where such non-compliance would not be reasonably likely to limit, impede or otherwise jeopardize such party's ability to meet its Manufacturing obligations under this Agreement. Such party shall abate any condition

[\*\*\*] Redacted pursuant to a confidential treatment request.

or practice, regardless of whether such condition or practice constitutes non-compliance with Environmental Laws, with respect to its usage, handling, storage or disposal of Hazardous Materials, that would be reasonably likely to limit, impede or otherwise jeopardize such party's ability to fulfill its Manufacturing obligations under this Agreement.

(b) Notice to Other Party. Such party shall provide the other party with reasonably prompt notice in the event of any significant event, occurrence or circumstance, including any governmental or private action in connection with such party's compliance with applicable Environmental Laws or with respect to such party's usage, handling, storage or disposal of Hazardous Materials, which would be reasonably likely to limit, impede or otherwise jeopardize such party's ability to fulfill its Manufacturing obligations under this Agreement. These could include, but are not limited to: (i) material revocation or modification of any of such party's Environmental Permits, (ii) any action by Governmental Authorities that may reasonably lead to the material revocation or modification of such party's Environmental Permits, (iii) any Third Party claim against the management or ownership of any Facility pursuant to applicable Environmental Law that could reasonably and materially impact such party's obligations under this Agreement, (iv) any fire, explosion, significant accident (one causing serious injury or fatality), or catastrophic Release of Hazardous Materials, (v) any significant non-compliance with Environmental Laws, and (vi) any environmental condition or operating practice that may reasonably be believed to present a significant threat to human health, safety or the environment.

(c) Equipment. Such party shall be solely responsible for the safe operation and maintenance of all equipment used to fulfill its Manufacturing obligations under this Agreement, and all associated employee training, regardless of whether the equipment is owned by such party, the other party or a Third Party.

(d) Environmental, Health and Safety Reviews. Each party shall permit the other party reasonable access to conduct periodic reviews during regular business hours of the environmental and health and safety practices and performance of the Facility(ies) where such party's performance is occurring. In connection with such audit or evaluation, such party shall assist in the other party's completion of an Environmental Health & Safety survey of such party or the scheduling of an Environmental Health & Safety audit of any Facility, as applicable. Such party will provide copies of all Environmental Permits to the other party upon request in connection with such review. The other party shall share its findings with such party as soon as practicable and such party shall correct, at no expense to the other party, such deficiencies in its environmental and health and safety management practices that materially jeopardize its ability to fulfill its Manufacturing obligations under this Agreement. Such party acknowledges that such reviews and evaluations conducted by the other party are for the benefit of the other party only; they are not a substitute for such party's own environmental and health and safety management obligations under this Agreement and accordingly, such party may not rely upon them.

10.4. Pfizer Representations, Warranties and Covenants. Pfizer hereby represents and warrants as of the Effective Date and covenants to Protalix as follows:

(a) Pfizer has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by Pfizer have been duly and validly authorized and approved by

proper corporate action on the part of Pfizer, and Pfizer has taken all other action required by Law, its certificate of incorporation or by-laws, or any agreement to which it is a party or to which it may be subject, required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of Protalix, this Agreement constitutes a legal, valid and binding obligation of Pfizer, enforceable against Pfizer in accordance with its terms.

(b) The execution and delivery of this Agreement by Pfizer and the performance by Pfizer contemplated hereunder does not and will not violate any Laws, except for such violations that would not have an adverse effect on the ability of Pfizer to perform its obligation under this Agreement, or any order of any court or Governmental Authority.

(c) Neither the execution and delivery of this Agreement nor the performance hereof by Pfizer requires Pfizer to obtain any permits, authorizations or consents from any Governmental Authority (other than any Regulatory Approvals relating to the Manufacture, use, importation or sale of the Compound or Licensed Product) or from any other Person, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination under any agreement or contract to which Pfizer is a party or to which it may be subject, except for those breaches or rights that would not adversely affect the ability of Pfizer to perform its obligations under this Agreement.

(d) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Pfizer, threatened against Pfizer or any of its Affiliates or any Third Party relating to the transactions contemplated by this Agreement.

(e) To the actual knowledge of Pfizer, without any investigation other than the inquiries expressly described in the next sentence, neither Pfizer nor any of its Affiliates (i) [\*\*\*] on the Effective Date nor (ii) has in effect on the Effective Date [\*\*\*]. The representations and warranties in the prior sentence are based solely on inquiries of other Pfizer employees made by phone and e-mail by the following Pfizer employees: [\*\*\*].

**10.5. Disclaimer of Warranty.** EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO THE COMPOUND, DRUG SUBSTANCE, ANY LICENSED PRODUCT, PROTALIX IMPROVEMENT, PROTALIX PATENT RIGHTS, PROTALIX TECHNOLOGY OR CONFIDENTIAL INFORMATION. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

## Section 11. ADDITIONAL COVENANTS

11.1. Restrictions on Transfers and Liens. During the Term, Protalix shall not (and shall cause its Affiliates not to) sell, assign or otherwise transfer to any Person any Protalix Patent Rights or any Protalix Technology (or agree to do any of the foregoing), except to the extent permitted by, and in compliance with, Section 18.5. In addition, Protalix hereby covenants and agrees that, during the Term, Protalix shall not incur or permit to exist (and shall cause each of its Affiliates not to incur or permit to exist), with respect to any Protalix Patent Rights owned by Protalix and/or Protalix Technology owned by Protalix, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties in the Field in the Territory or other restriction (including in connection with any indebtedness). For purposes of clarity, this Section 11.1 is not intended to prohibit Protalix from licensing to an Affiliate of Protalix or a Third Party rights under any Protalix Patent Rights or any Protalix Technology to the extent such rights have not been licensed to Pfizer pursuant to this Agreement and to the extent such license by Protalix does not otherwise conflict with the terms of this Agreement.

11.2. Third Party Licenses and Agreements. Protalix (a) shall not execute or otherwise permit, and shall cause its Affiliates to refrain from executing or otherwise permitting, any amendment, modification or waiver to any of the Third Party Licenses or the [\*\*\*] without the prior written consent of Pfizer, (b) shall not make any election or exercise any right or option (or omit to take any action) which would, and shall cause its Affiliates to refrain from making any election or exercising any right or option (or omitting to take any action) which would, terminate or relinquish in whole or in part any right under a Third Party License or the [\*\*\*], (c) shall comply, and shall cause its Affiliates to comply in all respects, with all of its, and its Affiliates', obligations under the Third Party Licenses and the [\*\*\*], (d) shall take, and shall cause its Affiliates to take, such actions as shall be necessary to keep in full force and effect the Third Party Licenses and the [\*\*\*], and (e) shall give prompt notice to Pfizer, together with a detailed summary of outstanding issues if Pfizer so requests, of any notice received from the Third Party, of any actual or alleged defaults, breaches, violations, proposed amendments or proposed modifications of, or any proposed waivers under, any of the Third Party Licenses or the [\*\*\*] by any of the parties thereto. Protalix shall not assign or otherwise transfer any Third Party License or the [\*\*\*] or any of its rights or obligations thereunder to any Person (or agree to do any of the foregoing) except to the extent permitted by, and in compliance with, Section 18.5.

11.3. [\*\*\*] Letter Agreement. Protalix shall use Commercially Reasonable Efforts to obtain a letter agreement with [\*\*\*] in substantially the form set forth in Exhibit J into which the parties and [\*\*\*] will enter and, upon entering such letter agreement, the provisions of Section 11.2 shall apply to such letter agreement to the same extent that they apply to a Third Party License or the [\*\*\*].

[\*\*\*] Redacted pursuant to a confidential treatment request.

11.4. Compliance with Laws. Each of Protalix and Pfizer shall conduct, and shall use reasonable efforts to cause its Affiliates to conduct, all its activities contemplated under this Agreement in accordance with all applicable Laws of the Country in which such activities are conducted.

11.5. Coordination outside the Territory. Protalix and its Affiliates shall not, unless required by applicable Law, (a) conduct, or consent to or support any activities by a Third Party, with respect to the Licensed Product in the Field outside the Territory (including investigator-initiated research) if, in the good faith and reasonable judgment of Protalix, such activities could impact the market for the Licensed Product in the Field in the Territory or (b) make any revisions to the labeling for the Licensed Product in the Field outside the Territory without first discussing such activities with Pfizer at the Steering Committee.

11.6. Operational Plan. The parties hereby agree to comply with the provisions of Appendix 11.6 hereto.

## **Section 12. NON-COMPETITION**

12.1. Pfizer Non-Compete. From the Effective Date until the earlier of (a) (i) the effective date of termination of this Agreement, unless such termination is by Pfizer pursuant to Section 14.2(c) or (ii) the first anniversary of such effective date if such termination is by Pfizer pursuant to Section 14.2(c) or (b) the [\*\*\*] anniversary of the Effective Date, neither Pfizer nor any of its Affiliates shall, directly or indirectly, alone or in collaboration with any Third Party, Commercialize in any Country in the Territory any Competing Product, subject to the provisions of Section 12.3.

12.2. Protalix Non-Compete. From the Effective Date until the earlier of (a) the effective date of termination of this Agreement or (b) the [\*\*\*] anniversary of the Effective Date, neither Protalix nor any of its Affiliates shall, directly or indirectly, alone or in collaboration with any Third Party, Commercialize in any Country in the Territory any Competing Product.

12.3. Acquisition of Competing Product. Pfizer will not be deemed to be in breach of the restrictions set forth in Section 12.1 if Pfizer or any of its Affiliates acquires a Competing Product through an acquisition of or a merger with the whole or substantially the whole of the business or assets of another entity, so long as Pfizer (or its Affiliate) (a) enters into a definitive agreement with a Third Party to divest such Competing Product (other than as part of any Hold Separate Transaction) within [\*\*\*] after the closing of such acquisition or merger, or, if such divestiture is subject to the terms of a Hold Separate Transaction, within twelve (12) months after the closing of the acquisition or merger, or (b) discontinues sales of the Competing Product no later than [\*\*\*] after the closing of such acquisition or merger.

[\*\*\*] Redacted pursuant to a confidential treatment request.

### **Section 13. TERM**

This Agreement shall be effective as of the Effective Date and shall remain in effect until it is terminated pursuant to Section 14 (the “Term”).

### **Section 14. TERMINATION**

#### **14.1. [INTENTIONALLY OMITTED]**

14.2. Termination Rights. This Agreement may be terminated as follows:

(a) If either Pfizer or Protalix materially breaches or materially defaults in the performance or observance of any of its respective obligations under this Agreement, and such breach or default is not cured within ninety (90) days after the giving of written notice by the other party specifying such breach or default, then such other party shall have the right to terminate this Agreement by providing the breaching party written notice within ten (10) days following the expiration of such ninety (90)-day period (such termination to be effective upon receipt of such termination notice). Notwithstanding the foregoing or any other term or provision of this Agreement, with respect to any particular Failure to Supply, if Pfizer is entitled and elects to exercise the rights provided for in Section 5.17(b), and Protalix complies in all material respects with its obligations under such Section, Pfizer shall have no right to terminate this Agreement pursuant to this Section 14.2(a) based on such Failure to Supply.

(b) Pfizer may terminate this Agreement in its entirety, or with respect to a particular Country or Countries, effective as provided below in this Section 14.2(b), if Pfizer reasonably determines, based on information from credible sources, that payments in violation of applicable Laws are being or have been made to Government Officials by Protalix either with respect to services performed on behalf of Pfizer or in connection with Protalix’s provision of services to any Third Party. In order to terminate pursuant to this Section 14.2(b) Pfizer must give written notice of termination to Protalix within fifteen (15) Business Days after Pfizer’s termination right pursuant to this Section 14.2(b) first arises, stating in reasonable detail the factual basis for such termination and specifying whether such termination is with respect to this Agreement in its entirety or only as to a particular Country or particular Countries. Termination pursuant to this Section 14.2(b) shall be effective ten (10) Business Days after such written notice of termination is given in accordance with this Section 14.2(b), provided such notice is not rescinded within such ten (10) day period.

(c) At any time (subject to the proviso in this sentence) and for any reason, Pfizer, upon [\*\*\*] prior written notice to Protalix (a “Section 14.2(c) Notice”), shall have the right, at Pfizer’s sole discretion, to terminate this Agreement, such termination to be effective upon the expiration of such [\*\*\*] period (such [\*\*\*] period, the “Section 14.2(c) Termination”).

[\*\*\*] Redacted pursuant to a confidential treatment request.

Notice Period”); provided, however, that a Section 14.2(c) Notice may not be given prior to [\*\*\*]. In order to ensure the smooth transition of the Development, Manufacture (to the extent being performed by Pfizer or a Third Party on Pfizer’s behalf at the time notice of termination is given), including Fill/Finish, and/or Commercialization of the Drug Substance or Licensed Product from Pfizer to Protalix or a Third Party designated by Protalix, promptly after receipt by Protalix of such written notice, Pfizer and Protalix will develop a transition plan with respect to all then-current as well as planned activities relating to the Development, Manufacture (to the extent being performed by Pfizer or a Third Party on Pfizer’s behalf at the time notice of termination is given), including Fill/Finish, and/or Commercialization of the Drug Substance or the Licensed Product so as to minimize disruption to the continued Development, Manufacture (including Fill/Finish) and Commercialization of the Licensed Product. The transition plan shall include a mutually agreed-upon schedule for transition activities. The parties shall conduct transition activities pursuant to such transition plan and Section 14.4(a).

(d) Protalix may terminate this Agreement as provided in and in accordance with Section 3.6(b).

14.3. Continuing and Accrued Obligations and Surviving Provisions. After notice of termination is given and, subject to the further provisions of this Section 14.3, prior to the effective date of termination, this Agreement, including all payment obligations hereunder, shall continue in full force and effect, and the parties shall continue to carry out and perform their respective Development, Manufacturing and Commercialization activities in accordance with this Agreement through the effective date of termination. Without limitation of the foregoing, termination of this Agreement for any reason (i) shall be without prejudice to and shall not impair or limit in any manner (A) Protalix’s right to receive payment from Pfizer of Protalix’s share of Net Profit under Section 6.4(a) in respect of sales of Licensed Product in the Territory occurring prior to the effective date of such termination, whether or not the due date for such payment is after such effective date of termination, as well as Protalix’s share of Net Profit with respect to sales of Licensed Product contemplated by Section 14.4(c), (B) Protalix’s right to receive the applicable Event Milestone Payment in respect of any Event Milestone which occurs prior to the effective date of termination, whether or not the due date for such payment is after such effective date of termination, (C) Protalix’s right to receive payment from Pfizer in accordance with this Agreement for any Drug Substance ordered by Pfizer pursuant to this Agreement prior to the effective date of such termination, whether or not the due date for such payment is after such effective date of termination, and (D) any remedies that either party may have and (ii) shall not release a party hereto from any indebtedness, liability, payment or other obligation incurred hereunder (including liability for breach of this Agreement) by such party prior to the effective date of termination, including Protalix’s obligation to pay its share of Net Loss accrued under Section 6.4(b), as well as its share of any Net Loss with respect to sales of Licensed Product in the Territory contemplated by Section 14.4(c).

[\*\*\*] Redacted pursuant to a confidential treatment request.

14.4. Effects of Termination. Upon the effective date of termination of this Agreement in accordance with this Section 14, except as otherwise provided in Section 14.3, this Section 14.4 and Section 18.5, all licenses and rights provided for herein, and all obligations of the parties hereunder, shall terminate and this Agreement shall cease to be of further force or effect.

(a) Upon termination of this Agreement for any reason in accordance with Section 14.2, then except as otherwise provided in Section 14.4(b):

(i) Pfizer shall, promptly after such termination, provide to Protalix or its designee the following materials, provided that such materials shall be provided in the form and format in which such materials are maintained by Pfizer in the ordinary course of business (provided that Pfizer shall use Commercially Reasonable Efforts to provide such materials in a form and format useable by Protalix), and Pfizer shall not be required to prepare any new data, reports or information solely for purposes of transfer to Protalix:

(A) all regulatory filings, Regulatory Approvals, Price Approvals and Governmental and Third Party reimbursement approvals to the extent related to the Drug Substance or Licensed Product, including to the extent related to the Fill/Finish step in the Manufacture of the Licensed Product;

(B) all pre-clinical and clinical data, reports and information (including drug master files) in Pfizer's possession or control to the extent relating to a Licensed Product or Drug Substance;

(C) all reports, records, regulatory correspondence and other materials in Pfizer's possession or control to the extent relating to the pre-clinical and clinical development of the Drug Substance or Licensed Product, including the Fill/Finish step in the manufacture of the Licensed Product, and also including, if applicable, any information contained in the global safety database established and maintained by Pfizer for the Licensed Product; and

(D) all Product Marks actually used in commerce by Pfizer or its Affiliates for the Licensed Product, excluding the corporate or trade name or logo of Pfizer or its Affiliates.

(ii) Effective upon such termination:

(A) Pfizer assigns to Protalix, or a Protalix Affiliate identified by Protalix, all of Pfizer's right, title and interest in and to the materials transferred or delivered or deliverable by Pfizer pursuant to Section 14.4(a)(i), including the goodwill attendant to any Product Marks, to the extent Pfizer Controls such materials; with respect to the Product Marks, Pfizer shall execute an assignment of such Product Marks in favor of Protalix and Protalix shall be responsible for recording such assignment with the appropriate governmental trademark authorities. Protalix shall bear all costs associated with such recordation, unless this Agreement is terminated by Protalix pursuant to Section 14.2(a) or by Pfizer pursuant to Section 14.2(c), in which event Pfizer shall bear all such recordation costs. Pfizer shall cooperate in facilitating such assignment and recordation by timely executing all necessary documents



provided to it by Protalix;

(B) If such termination is by Protalix pursuant to Section 14.2(a) or (d), or by Pfizer pursuant to Section 14.2(c), then the license granted by Pfizer to Protalix pursuant to Section 4.10(a)(i) shall survive such termination solely to the extent, if any, necessary for Protalix to sell outside the Territory its inventory of Licensed Product in existence as of the effective date of termination and shall automatically terminate upon the earlier of the date of the sale of the last Licensed Product in such inventory or 180 days after such effective date of termination; and

(C) Pfizer assigns to Protalix any applicable sublicenses to the extent related to the Licensed Product and/or Third Party agreements, with respect to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Licensed Product in the Field, unless Protalix has advised Pfizer that it will not require such assignment.

(iii) If such termination is by Protalix pursuant to Section 14.2(a) or Section 14.2(d), then to the extent at the effective date of such termination Pfizer or its Affiliate is performing the Fill/Finish and Labeling and Packaging for, or any other aspect of the Manufacture of, the Licensed Product: (A) Pfizer (or its Affiliate) will continue to do so and will supply Protalix, at the same price, and on such other terms and conditions on which Pfizer was supplying, or in the absence of termination would have been required to supply, through the first anniversary of the effective date of termination of this Agreement or such shorter period if Protalix notifies Pfizer that Protalix is able to perform or have performed the Fill/Finish and Labeling and Packaging for, or such other aspect(s) of the Manufacture of, the Licensed Product on comparable financial terms; and (B) Protalix will use Commercially Reasonable Efforts to be able to perform or have performed the Fill/Finish and Labeling and Packaging for, or such other aspect(s) of the Manufacture of, the Licensed Product as soon as is reasonably possible after the effective date of termination of this Agreement (including by taking assignment of any then-existing subcontract for Fill/Finish of the Licensed Product to the extent assignable).

(iv) If such termination is by Pfizer pursuant to Section 14.2(b) solely with respect to a particular Country or Countries, such termination shall have the applicable effects set forth in Section 14.4(a) solely with respect to such Country or Countries.

(v) Without limitation of the generality of the foregoing, the parties shall use diligent efforts to complete the transition of the Development (if applicable), Manufacture, and Commercialization of the Licensed Product in the Field in the Territory hereunder to Protalix (or its sublicensee or Third Party designee) as soon as is reasonably possible.

(b) (i) In the event that (x) Pfizer advises Protalix that it has determined that it is not advisable for Pfizer or Protalix to continue Development or Commercialization of the Licensed Product as a result of a serious safety issue, or potential serious safety issue, regarding the use of the Licensed Product, (y) thereafter, at a meeting of the Steering Committee, representatives of Pfizer present in reasonable detail the basis for such determination and representatives of Protalix are afforded an opportunity to consider and discuss such presentation and Pfizer's determination and (z) following such meeting of the Steering Committee, Pfizer delivers a Section 14.2(c) Notice, then if Protalix agrees with Pfizer that it is not advisable to

continue Development or Commercialization of the Licensed Product, (A) the parties will promptly wind-down and terminate all Development and Commercialization of the Licensed Product (including, to the extent permitted by Law, the wind-down and cessation of any then ongoing clinical trials and Post-Approval Commitments) and all costs of such wind-down and termination will be borne [\*\*\*]% by Pfizer and [\*\*\*]% by Protalix, (B) this Agreement shall, effective immediately upon Pfizer's delivery of the Section 14.2(c) Notice, terminate without the requirement of a Section 14.2(c) Termination Notice Period and for purposes of Section 14.4(a) shall be treated as a termination by Pfizer pursuant to Section 14.2(c), except that paragraphs (ii)(B), (ii)(C), (iii) and (v) of Section 14.4(a) shall not be applicable and (C) Protalix agrees not to conduct future Development or Commercialization of the Licensed Product.

(ii) If, after the parties have complied with the procedures set forth in clauses (x), (y) and (z) of paragraph (b)(i) immediately above, Protalix does not agree with Pfizer that it is not advisable to continue Development or Commercialization of the Licensed Product as contemplated by Section 14.4(c)(i) and Protalix so notifies Pfizer in writing, then this Agreement shall be deemed to have terminated, effective upon Pfizer's delivery of the Section 14.2(c) Notice without the requirement of a Section 14.2(c) Termination Notice Period, and for purposes of Section 14.4(a) such termination shall be treated as a termination by Pfizer pursuant to Section 14.2(c), except that paragraphs (ii)(B) and (iii) of Section 14.4(a) shall not be applicable.

(c) Following termination of this Agreement, other than termination by Protalix pursuant to Section 14.2(a) or (d), notwithstanding the termination of the licenses and rights granted by Protalix to Pfizer hereunder, Pfizer and its Affiliates shall have the right to continue to sell their existing inventories of the Licensed Product for a period not to exceed one hundred eighty (180) days after the effective date of such termination and Protalix shall continue to receive its share of the Net Profit and bear its share of any Net Loss with respect to such sales. Following any termination of this Agreement by Protalix pursuant to Section 14.2(a), Pfizer shall promptly return to Protalix or destroy all inventory of Licensed Products in its possession as of the effective date of termination.

(d) Following any termination of this Agreement, each of Pfizer and Protalix shall, upon request of the other party, return or destroy all Protalix Confidential Information and Pfizer Confidential Information, respectively, disclosed to it pursuant to this Agreement, including all copies and extracts of documents, as promptly as practicable following receipt of such request, except (i) that one (1) copy may be kept for the purpose of complying with continuing obligations under this Agreement and (ii) to the extent and for so long as necessary to perform its obligations or exercise its rights under this Section 14.4.

14.5. Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Protalix are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S.

[\*\*\*] Redacted pursuant to a confidential treatment request.

Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The parties agree that Pfizer, as the licensee of intellectual property under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The parties further agree that, in the event of a rejection of this Agreement by Protalix in any bankruptcy proceeding by or against Protalix under the U.S. Bankruptcy Code, (a) Pfizer shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the possession of the licensee, shall be promptly delivered to it upon Pfizer’s written request therefor, and (b) Protalix shall not interfere with Pfizer’s rights to intellectual property and all embodiments of intellectual property, and shall assist and not interfere with Pfizer in obtaining intellectual property and all embodiments of intellectual property from another entity. The term “embodiments” of intellectual property includes all tangible, intangible, electronic or other embodiments of rights and licenses hereunder, including all compounds and products embodying intellectual property, Licensed Products, regulatory filings, clinical studies and related rights, and Technology.

## **Section 15. INDEMNIFICATION AND INSURANCE**

### **15.1. Indemnification.**

(a) Protalix will indemnify, defend and hold Pfizer and Pfizer’s Affiliates, and their respective directors, officers and employees harmless from and against all Third Party Claims (defined in Section 15.3 below) and associated Losses, in each case to the extent arising out of:

(i) the breach of any covenant, warranty or representation made by Protalix under this Agreement;

(ii) the negligence, recklessness, or willful misconduct of, or violation of law by, Protalix or any of its Affiliates; or

(iii) any acts or omissions of Protalix or any of its Affiliates, agents, consultants or contractors (A) in connection with the research, Development, Manufacture (including Fill/Finish) or Commercialization of the Drug Substance or Licensed Product prior to the Effective Date, (B) in connection with the research, Development or Commercialization of the Drug Substance or Licensed Product outside the Territory or the Manufacture (including Fill/Finish) of the Drug Substance or Licensed Product for sale outside the Territory, or (C) in connection with the research, Development, Manufacture (including Fill/Finish) or Commercialization of the Drug Substance or Licensed Product after termination of this Agreement and the reversion of the applicable rights hereunder to Protalix in accordance with Section 14.4 (including pursuant to Section 14.4(b)(ii)).

Protalix shall be obligated to so indemnify, defend and hold Pfizer harmless only to the extent that such Losses (i) do not arise from the negligence, recklessness or willful misconduct of Pfizer and (ii) are not Losses as to which Protalix is entitled to indemnification pursuant to Section 15.1(b).

(b) Pfizer will indemnify, defend and hold Protalix, its Affiliates, and their respective directors, officers and employees harmless from and against all Third Party Claims

and associated Losses, to the extent arising out of:

- (i) the breach of any covenant, warranty or representation made by Pfizer under this Agreement; or
- (ii) the negligence, recklessness, or willful misconduct of, or violation of law by, Pfizer or any of its Affiliates.

Pfizer shall be obligated to so indemnify, defend and hold Protalix harmless only to the extent that such Losses (i) do not arise from the negligence, recklessness or willful misconduct of Protalix and (ii) are not Losses as to which Pfizer is entitled to indemnification pursuant to Section 15.1(a) or Section 15.1(c).

(c) In addition to Section 15.1(a), Protalix will indemnify, defend and hold Pfizer and Pfizer's Affiliates, and their respective directors, officers and employees harmless as described in Appendix 15.1(c).

15.2. Losses. For purposes of this Agreement, "Losses" means any and all damages (including all incidental, consequential, statutory and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses and expenses incurred by or awarded to Third Parties with respect to a Third Party Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into, and all other documented costs and expenses incurred in investigating, preparing or defending any Third Party Claim litigation or proceeding, commenced or threatened, or in complying with any judgments, orders, decrees, stipulations and injunctions (including court costs, interest and reasonable fees of attorneys, accountants and other experts).

15.3. Defense Procedures; Procedures for Third Party Claims.

(a) For purposes of this Agreement, "Third Party Claim" means a claim asserted by a Third Party (in no event to include any Affiliate of either party) against a party or any of its Affiliates, or any of their respective directors, officers and employees. In the event a Third Party Claim is asserted with respect to any matter for which a party or any of its Affiliates, or any of their respective directors, officers and employees (the "Indemnified Party") is entitled to indemnification hereunder, then the Indemnified Party shall promptly notify in writing the party obligated to indemnify the Indemnified Party (the "Indemnifying Party") thereof; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

(b) The Indemnifying Party shall assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. The Indemnified Party shall have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the Indemnifying Party is defending as provided in this Agreement. Notwithstanding anything to the contrary contained herein, an Indemnified Party shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnified Party, upon

written notice to the Indemnifying Party, in which case the Indemnifying Party shall be relieved of liability under Section 15.1, as applicable, solely for such Third Party Claim and related Losses.

(c) Neither party will enter into any settlement of any suit involving Licensed Products that materially affects the other party's rights or obligations with respect to the Licensed Product without the other party's prior written consent. Without limiting the foregoing, the Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld), effect any settlement of any pending or threatened litigation in which the Indemnified Party has sought indemnification hereunder by the Indemnifying Party, unless such settlement involves solely monetary damages and includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such litigation.

#### 15.4. Certain Other Losses.

(a) Any Losses incurred by either party or any of its Affiliates with respect to any Product Liability Claim (other than a Third Party Claim for which Protalix is obligated to indemnify Pfizer under Section 15.1(a) or Section 15.1(c) or Pfizer is obligated to indemnify Protalix under Section 15.1(b)) shall be treated as [\*\*\*]. Solely for the purposes of coordinating the defense of any litigation relating to such Product Liability Claims, such Product Liability Claims will be treated as if they were Third Party Claims covered by Section 15.3 and Pfizer shall be deemed to be the "Indemnifying Party" under Section 15.3 for such Product Liability Claims. For purposes of this Agreement, "Product Liability Claim" means any Third Party Claim concerning any Licensed Product sold in the Territory in the Field during the Term pursuant to this Agreement (or sold during the period described in Section 14.4(c)) that is a product liability claim, including claims involving the death of or bodily injury to any individual (or allegations thereof) relating to use of the Licensed Product.

(b) Any Losses incurred by either party or any of its Affiliates with respect to any Third Party Infringement Claim (other than a Third Party Claim for which Protalix is obligated to indemnify Pfizer under Section 15.1(a) or Section 15.1(c) or Pfizer is obligated to indemnify Protalix under Section 15.1(b)) shall be treated as [\*\*\*]. Solely for the purposes of coordinating the defense of any litigation relating to such Third Party Infringement Claims, such Third Party Infringement Claims will be treated as if they were Third Party Claims covered by Section 15.3 and Pfizer shall be deemed to be the "Indemnifying Party" under Section 15.3 for such Third Party Infringement Claims. For purposes of this Agreement, "Third Party Infringement Claim" means a Third Party Claim that the (i) Development, Manufacture, use, distribution, marketing or sale of a Licensed Product in the Field in the Territory during the Term or (ii) Manufacture of Drug Substance or Licensed Product outside the Territory for sale in the Territory pursuant to this Agreement infringes or misappropriates such Third Party's intellectual property or other proprietary rights.

[\*\*\*] Redacted pursuant to a confidential treatment request.

(c) Any Losses with respect to any Third Party Claim arising out of or relating to the Development, Manufacture, use, distribution, marketing or sale of a Licensed Product in the Field in the Territory during the Term pursuant to this Agreement (other than (i) a Third Party Claim for which Protalix is obligated to indemnify Pfizer under Section 15.1(a) or Section 15.1(c) or Pfizer is obligated to indemnify Protalix under Section 15.1(b), (ii) a Product Liability Claim and (iii) a Third Party Infringement Claim) shall be treated as follows: (x) any such Losses incurred by Pfizer or its Affiliates shall be treated as [\*\*\*] and (y) any such Losses incurred by Protalix or its Affiliates shall be treated as [\*\*\*].

(d) In the event a party or any of its Affiliates incurs any Losses described in this Section 15.4 after the Term and after the final reconciliation of Net Profits and Net Losses pursuant to Section 7.1(c), Pfizer shall be responsible for [\*\*\*]% of such Losses and Protalix shall be responsible for [\*\*\*]% of such Losses. Each party will promptly pay the other party its share of such Losses after receipt of detailed supporting documentation evidencing such Losses.

15.5. Disclaimer of Liability for Consequential Damages. IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE, SUFFERED BY PFIZER, PROTALIX OR ANY OF THEIR RESPECTIVE AFFILIATES. THE FOREGOING SENTENCE SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 15 OR LIABILITIES RESULTING FROM A BREACH OF THE CONFIDENTIALITY OBLIGATIONS UNDER SECTION 9 ABOVE AND PROVIDED THAT THIS SECTION 15.5 SHALL NOT RELIEVE EITHER PARTY FROM ITS PAYMENT OBLIGATIONS UNDER THIS AGREEMENT.

15.6. Sole Remedy. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT AND EXCEPT FOR ANY EQUITABLE REMEDIES THAT MAY BE AVAILABLE TO A PARTY, INDEMNIFICATION PURSUANT TO SECTION 15 SHALL BE THE SOLE AND EXCLUSIVE REMEDY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY) AVAILABLE TO PROTALIX OR PFIZER FOR THE MATTERS COVERED THEREIN.

15.7. Insurance Requirements. As of the Effective Date, Protalix shall provide and maintain such insurance coverage, in minimum types and amounts as described in subsection (b) below. As of the Effective Date, Pfizer shall self insure or provide and maintain such insurance coverage, in minimum types and amounts as described in subsection (d) below.

(a) Protalix Insurance Generally.

[\*\*\*] Redacted pursuant to a confidential treatment request.

(i) Any and all deductibles for Protalix's insurance policies (the "Protalix Insurance Policies") shall be assumed by, for the account of, and at Protalix's sole risk. All deductibles and self-insured retention amounts shall be assumed by Protalix.

(ii) Such Protalix Insurance Policies shall be primary and non-contributing with respect to any other similar insurance policies available to Pfizer or its Affiliates. Except for employers' liability and property insurance policies, Protalix will add Pfizer and its Affiliates on all such Protalix Insurance Policies as additional insureds with respect to liability incurred by Pfizer or its Affiliates arising from any acts or omissions of Protalix, and Protalix will require that the property insurance policy included in the Protalix Insurance Policies include a waiver of subrogation in favor of Pfizer and its Affiliates.

(iii) Prior to the Effective Date, Protalix has provided Pfizer with original certificates and additional insurance endorsements evidencing the specified insurance coverage, and at each renewal thereof or expiration of any one coverage, whichever occurs first, Protalix shall furnish to Pfizer original certificates and additional insurance endorsements evidencing the specified insurance coverage. Such certificates shall provide that not less than thirty (30) days prior written notice of any policy cancellation or detrimental change shall be given to Pfizer. The certificate(s) of insurance shall be signed by a person authorized by the insurer(s) to bind coverage on its (their) behalf. Protalix shall provide, pay for, and maintain in effect, the Protalix Insurance Policies with a minimum "A-" A.M. Bests rating or S&P minimum of BBB or their substantial equivalent (in the case of such policies in Israel, to the extent such ratings or substantial equivalents are available).

(b) Protalix Insurance Requirements. The insurance required under subsection (a) shall be written for not less than any limits of liability specified herein or as required by law, whichever is greater; Protalix has the right to provide the total limits required by any combination of primary and excess/umbrella coverage; said Protalix insurance to include, without limitation, the following:

(i) Insurance for liability applicable with respect to persons performing the work hereunder and employer's liability insurance covering all claims by or in respect to the employees of Protalix and all subcontractors, providing:

(ii) Employer's liability insurance with a limit of the greater of the equivalent of \$[\*\*\*] for each occurrence and in the aggregate in the Protalix Insurance Policies.

(iii) Commercial General/Public Liability insurance with the following limits and forms/endorsements:

[\*\*\*] Redacted pursuant to a confidential treatment request.

(A) Each occurrence and in the aggregate: \$[\*\*\*].

(B) Clinical Trials Coverage or Products & Completed Operations Aggregate once products are marketed: \$[\*\*\*].

(C) Pfizer and its Affiliates as additional insureds with respect to any legal liability of Pfizer or its Affiliates, arising out of Protalix's performance hereunder.

If Protalix has care, custody or control of Pfizer property or inventory, Protalix shall be responsible for any loss or damage to it, and provide all risk property coverage included within the Protalix Insurance Policies at full replacement cost for same.

(c) Pfizer Insurance Generally.

(i) Any and all deductibles for Pfizer's insurance policies (the "Pfizer Insurance Policies") shall be assumed by, for the account of, and at Pfizer's sole risk.

(ii) To the extent of its negligence, such Pfizer Insurance Policies shall be primary and non-contributing with respect to any other similar insurance policies available to Protalix or its Affiliates. Except for workers compensation/employers' liability, Pfizer will add Protalix and its Affiliates, as additional insureds, and Pfizer will require that the Pfizer Insurance Policies provide a waiver of subrogation in favor of Protalix and its Affiliates.

(iii) Prior to the Effective Date of the Agreement and, at Protalix's request, at each renewal thereof or expiration of any one coverage, whichever occurs first, Pfizer shall furnish to Protalix original certificates evidencing the specified insurance coverage. Such certificates shall provide that not less than thirty (30) days prior written notice of any policy cancellation or detrimental change shall be given to Protalix. The certificate(s) of insurance shall be signed by a person authorized by the insurer(s) to bind coverage on its (their) behalf. Pfizer shall provide, pay for, and maintain in effect the Pfizer Insurance Policies with minimum "A-" A.M. Bests rated insurance carriers.

(d) Pfizer Insurance Requirements. The insurance required under subsection (c) shall be written for not less than any limits of liability specified herein or as required by law, whichever is greater; Pfizer has the right to provide the total limits required by any combination of self insurance, primary and excess/umbrella coverage; said Pfizer Insurance to include, without limitation, the following:

(i) Insurance for liability under the workers' compensation or occupational disease laws of any state or other jurisdiction in which Pfizer performs activities

**[\*\*\*] Redacted pursuant to a confidential treatment request.**



pursuant to this Agreement (or be a qualified self-insurer in those states and jurisdictions) or otherwise applicable with respect to persons performing hereunder and employer's liability insurance covering all claims by or in respect to the employees of Pfizer, providing:

Employer's liability insurance with a limit of \$[\*\*\*]

(ii) Commercial General Liability insurance with the following limits and forms/endorsements:

(A) Each occurrence: \$[\*\*\*]

(B) Products & Completed Operations Aggregate: \$[\*\*\*]

(C) Protalix and its Affiliates as additional insureds with respect to any legal liability of Protalix or its Affiliates, arising out of Pfizer's performance hereunder.

(iii) Umbrella (Excess) Liability Coverage (follow form) in an amount not less than \$[\*\*\*] per occurrence.

## **Section 16. STANDSTILL**

16.1. Standstill Provisions. Upon the Effective Date, and for a period during the Term lasting until the [\*\*\*] anniversary of the first Launch of the Licensed Product, except as otherwise permitted herein, Pfizer and its Affiliates will not (and will not assist or encourage others to) directly or indirectly in any manner, absent a request by Protalix Parent:

(a) acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule 13d—3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of or interest in any securities of Protalix Parent entitled to vote on the election of directors ("Voting Securities"), or any direct or indirect rights, warrants or options to acquire, or any securities convertible into or exchangeable for, any Voting Securities of Protalix Parent, except for such beneficial ownership not exceeding [\*\*\*] percent ([\*\*\*]%) of all then outstanding Voting Securities;

(b) make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the Securities and Exchange Commission (the "SEC") promulgated pursuant to Section 14 of the Exchange Act);

(c) form, join or in any way participate in a "group" within the meaning of Section 13(d)(3) of the Exchange Act with respect to any Voting Securities of Protalix Parent;

[\*\*\*] Redacted pursuant to a confidential treatment request.

(d) alone, or in concert with others: make any tender or exchange offer to Protalix Parent's stockholders, or make any other offer or proposal to Protalix Parent or its stockholders for any merger, consolidation, restructuring, recapitalization or similar transaction with or involving Protalix Parent (a "Business Combination Transaction"), or otherwise seek to control, change or influence the management, board of directors or policies of Protalix Parent, seek to have called any meeting of the stockholders of Protalix Parent, propose or nominate any person as a director of Protalix Parent who is not nominated by the then incumbent directors, or propose any matter to be voted upon by the stockholders of Protalix Parent, provided that actions taken by Pfizer to exercise its rights or comply with its obligations under this Agreement shall not be deemed to violate the foregoing; or

(e) enter into any arrangement or understanding with others to do any of the actions restricted or prohibited under Sections 16.1(a) through 16.1(d).

16.2. Exceptions. The foregoing standstill provisions set forth in Sections 16.1(a) through 16.1(e) inclusive (the "Standstill Provisions") shall not prohibit Pfizer or its Affiliates from (a) any investment in any Voting Securities of Protalix Parent by or on behalf of any pension or employee benefit plan or trust, provided that such investment is directed by independent trustees, administrators or employees, including (i) any direct or indirect interests in portfolio securities held by an investment company registered under the Investment Company Act of 1940, as amended, or (ii) interests in securities comprising part of a mutual fund or broad based, publicly traded market basket or index of stocks approved for such a plan or trust in which such plan or trust invests; (b) acquiring Voting Securities of Protalix Parent held by an entity (other than an entity the sole or principal asset of which is Voting Securities of Protalix Parent) acquired by Pfizer on the date such entity first entered into an agreement to be acquired by Pfizer or acquired after such entity was acquired by Pfizer pursuant to an agreement requiring (but only to the extent requiring) such entity to acquire such Voting Securities, which agreement was in effect on the date such entity first entered into an agreement to be acquired by Pfizer; (c) acquiring any securities of Protalix Parent, as debtor, in a transaction subject to the approval of the United States Bankruptcy Court pursuant to proceedings under the United States Bankruptcy Code; or (d) selling Voting Securities to any Third Party as part of an Acquisition Proposal or Business Combination or voting against any such Acquisition Proposal or Business Combination.

Notwithstanding the foregoing, Pfizer shall not play an active role directly or indirectly or otherwise influence any of the decisions or actions described in, or related to, clause (a) or (b) of this Section 16.2.

16.3. Termination of Standstill Provisions. Upon the occurrence of a Trigger Event (defined below) with respect to Protalix Parent, Section 16.1 shall automatically terminate and be of no further force or effect, provided that such termination shall not relieve Pfizer from liability for breach of Section 16.1 prior to such termination. For purposes of this Agreement, (a) a "Trigger Event" shall occur with respect to Protalix Parent if (i) Protalix Parent shall have publicly announced that it has entered into, or that it is in discussions or negotiations with respect to, an agreement or agreement in principle with a Third Party (including a Third Party acting in concert with others) with respect to an Acquisition (defined below) or (ii) it shall have been

publicly disclosed that any Person or group (defined in Section 13(d)(3) of the Exchange Act), other than Pfizer or its Affiliates, has (A) acquired or agreed to acquire, or (B) commenced or intends to commence a tender offer or an exchange offer to acquire, beneficial ownership (as defined in Rule 13d-3 under the Exchange Act) of [\*\*\*] percent ([\*\*\*]%) or more of the outstanding Voting Securities of Protalix Parent or any rights or options to acquire such beneficial ownership, including from a Third Party; or (iii) it shall have been publicly disclosed that any Person or group, other than Pfizer or its Affiliates, has made an offer or proposal which if effected would result in an Acquisition of Protalix Parent, or is in negotiations or discussions with respect to a transaction which if effected would result in an Acquisition of Protalix Parent, which offer or proposal is not rejected or otherwise recommended against, or in the case of reported negotiations or discussions, not publicly rebutted, by Protalix Parent by the earlier of (a) the relevant time period under applicable Law or (b) ten (10) Business Days, in each case after such offer or proposal becomes public; and (b) “Acquisition” means, with respect to Protalix Parent (i) a Business Combination Transaction, unless, immediately following such Business Combination Transaction all or substantially all of the individuals and entities who were the beneficial owners of the outstanding Voting Securities of Protalix Parent immediately prior to such Business Combination Transaction beneficially own, directly or indirectly (including through one more holding companies or subsidiaries) at least [\*\*\*] percent ([\*\*\*]%) of the then-outstanding voting securities entitled to vote generally in the election of directors of the corporation or other entity resulting from such Business Combination Transaction (including a corporation or other entity that as a result of such transaction owns Protalix Parent or all or substantially all of a Protalix Parent’s assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership, immediately prior to such Business Combination Transaction, of the outstanding Voting Securities of Protalix Parent; (ii) the acquisition, directly or indirectly, by any Person or group (other than Pfizer or its Affiliates) of beneficial ownership of [\*\*\*] percent ([\*\*\*]%) or more of the outstanding Voting Securities of Protalix Parent or any rights or options to acquire such beneficial ownership, including from a Third Party, or (iii) the acquisition by a Third Party of all or substantially all of the assets of Protalix or Protalix Parent.

For the purposes of clarity, but without impairment or limitation of Pfizer’s obligations under, and liability for breach of, this Section 16, Pfizer’s possession, and consideration in connection with an Acquisition, of Protalix Confidential Information obtained under this Agreement shall not, by itself, be deemed a breach of Section 9 of this Agreement.

16.4. Sales Process. Notwithstanding anything to the contrary contained in this Section 16, Protalix Parent agrees that, in the event during the Term it or its authorized representatives is engaged in an auction or other sale process, whether formal or informal, authorized by Protalix Parent’s Board of Directors, whereby proposals are solicited or received from, or being negotiated with, more than one Third Party for a transaction which, if effected, would result in

**[\*\*\*] Redacted pursuant to a confidential treatment request.**

the Acquisition of Protalix Parent, Pfizer shall be afforded the opportunity to participate in such process on substantially the same terms as any Third Party invited to so participate, including with respect to the making available of information to, and the terms of confidentiality agreements entered into with, such Third Parties.

#### **Section 17. GOVERNING LAW AND JURISDICTION**

17.1. Governing Law. This Agreement shall be governed by and construed in accordance with the substantive laws of the State of New York, without regard to conflicts of law rules.

17.2. Jurisdiction. With the exception of those matters referred for resolution by independent accountants under Section 7.5, in the event of any controversy, claim or counterclaim arising out of or relating to this Agreement, the parties shall first attempt to resolve such controversy or claim through good faith negotiations for a period of not less than thirty (30) days following notification of such controversy or claim to the other party. If such controversy or claim cannot be resolved by means of such negotiations during such period, then such controversy or claim shall be resolved by the United States District Court for the Southern District of New York or, in the event federal subject matter jurisdiction is lacking, a New York State court sitting in New York, New York (the "Court"). Each party (a) irrevocably submits to the exclusive jurisdiction of the Court for purposes of any action, suit or other proceeding relating to or arising out of this Agreement and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in the Court, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that the Court does not have any jurisdiction over such party. The provisions of the U.N. Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. Protalix hereby irrevocably designates, appoints and empowers CT Corporation System, 111 Eighth Avenue, New York, NY 10011, as its true and lawful agent and attorney-in-fact in its name, place and stead to receive and accept on its behalf service of process in any action, suit or proceeding in the Court with respect to any matters as to which it has submitted to jurisdiction as set forth in the immediately preceding sentence.

#### **Section 18. MISCELLANEOUS**

18.1. Force Majeure. Neither party hereto shall be liable to the other party for any losses or damages attributable to a default under or breach of this Agreement that is the result of war (whether declared or undeclared), acts of God, revolution, acts of terror, fire, earthquake, flood, pestilence, riot, enactment or change of Law (following the Effective Date), accident(s), labor trouble, shortage of or inability to obtain material equipment or transport or any other cause beyond the reasonable control of such party (each, a "Force Majeure Event"); provided that if such a cause occurs, then the party affected will promptly notify the other party of the nature and likely result and duration (if known) of such cause and use its Commercially Reasonable Efforts

[\*\*\*] Redacted pursuant to a confidential treatment request.

to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence. If the event lasts for a period of longer than one (1) month, the parties shall meet and work diligently to implement appropriate remedial measures.

18.2. Severability. If and solely to the extent that any provision of this Agreement shall be invalid or unenforceable, or shall render this entire Agreement to be unenforceable or invalid, such offending provision shall be of no effect and shall not affect the enforceability or validity of the remainder of this Agreement or any of its provisions; provided, however, the parties shall use their respective reasonable efforts to mutually agree to replace the invalid provisions in a manner that best accomplishes the original intentions of the parties.

18.3. Waivers. Any term or condition of this Agreement may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition. Neither the waiver by any party of any term or condition of this Agreement nor the failure on the part of any party, in one or more instances, to enforce any of the provisions of this Agreement or to exercise any right or privilege, shall be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

18.4. Entire Agreements; Amendments. This Agreement, together with the Quality Agreement(s), sets forth the entire agreement and understanding between the parties as to the subject matter hereof and supersedes all agreements or understandings, verbal or written, made between Protalix and Pfizer before the date hereof with respect to the subject matter hereof, including the Confidential Disclosure Agreement between the parties, dated June 11, 2009. All Confidential Information disclosed by either party to the other party prior to the Effective Date will be deemed to have been disclosed pursuant to this Agreement. None of the terms of this Agreement shall be amended, supplemented or modified except in writing signed by the parties.

18.5. Survival. The provisions of Section 3.3(a) (Non-Assertion of Rights), Section 5.2(b), with respect Pfizer's obligation to reimburse Protalix's out-of-pocket expenses, Section 7.1(f) (Reconciliation after Termination), Section 7.5 (Inspection of Records), Sections 9.1 and 9.2 (Confidentiality), Section 10.5 (Disclaimer of Warranty), Sections 14.3 and 14.4 (Continuing and Accrued Obligations; Effect of Termination), Section 15 (Indemnification) and Sections 17.1 and 17.2 (Governing Law and Jurisdiction), as well as (x) any other Sections or defined terms referred to in such Sections or necessary to give them effect and (y) any other provision that by its terms expressly survives termination of this Agreement, shall survive termination of this Agreement and remain in force until discharged in full. Furthermore, any other provisions required to interpret and enforce the parties' rights and obligations or to wind up their outstanding obligations under this Agreement shall survive to the extent required.

**\*\*\* Redacted pursuant to a confidential treatment request.**

18.6. Assignment; Binding Effect.

(a) Neither this Agreement nor any rights or obligations of either party to this Agreement may be assigned or otherwise transferred by either party without the consent of the other party; provided, however, either party may, without such consent, assign this Agreement, in whole or in part: (i) to any of its respective Affiliates, provided that such assigning party shall remain jointly and severally liable with such Affiliate in respect of all obligations so assigned; (ii) to a Third Party where a party or its Affiliate is required, or makes a good faith determination based on advice of counsel, to divest a Licensed Product in order to comply with Law or the order of any Governmental Authority as a result of a merger or acquisition; or (iii) to a Third Party successor to all or substantially all of the assets of such party whether by merger, sale of stock, all or substantially all of a party's assets or other similar transaction, so long as such Third Party agrees in writing to be bound by the terms of this Agreement.

(b) Any purported assignment in violation of this Section 18.5 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

(c) Pfizer may assume this Agreement in any proceeding under the U.S. Bankruptcy Code upon satisfaction of the conditions set forth in U.S. Bankruptcy Code Section 365(b)(1).

18.7. Independent Contractor. The relationship between Protalix and Pfizer is that of independent contractors. Protalix and Pfizer are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties.

18.8. Notices. Each communication and document made or delivered by one party to another under this Agreement shall be made in the English language. All notices, consents, approvals, requests or other communications required hereunder given by one party to the other hereunder shall be in writing and made by registered or certified air mail, facsimile, express overnight courier or delivered personally to the following addresses of the respective parties:

If to Protalix: Protalix Ltd.  
2 Snunit Street  
Science Park  
P.O.B 455  
Carmiel 20100, Israel  
Attention: Chief Executive Officer  
Facsimile: 972-4-988-9489

If to Pfizer: Pfizer Inc.  
235 East 42nd Street  
New York, New York, 10017-5755  
U.S.A.  
Attention: President and General Manager of the Established Business Products Unit  
Facsimile: +1 (212) 351-1049

with a copy to:

Attention: Chief Counsel, Established Products Business Unit  
Facsimile: +1 (212) 351-1049

Notices hereunder shall be deemed to be effective (a) upon receipt if personally delivered, (b) on the tenth (10th) Business Day following the date of mailing if sent by registered or certified air mail and (c) on the second (2nd) Business Day following the date of transmission or delivery to the overnight courier if sent by facsimile or overnight courier. A party may change its address listed above by sending notice to the other party in accordance with this Section 18.8.

18.9. Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either party.

18.10. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, successors and permitted assigns.

18.11. Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a party, such party agrees to cause its Affiliates to perform such obligations. Pfizer may use one or more of its Affiliates to exercise its rights or perform its obligations and duties hereunder, provided that Pfizer shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

18.12. Corporate Integrity Agreement. Protalix acknowledges that (a) Pfizer develops and promotes its products in compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) and with the statutes, regulations, and written directives of the Food and Drug Administration, and (b) Pfizer shall not be obligated to take any action pursuant to this Agreement that it believes, in its sole discretion, constitutes a violation of any of Pfizer's obligations set forth in subsection (a) above or such Corporate Integrity Agreement.

18.13. Counterparts. This Agreement may be executed in any counterparts, each of which, when executed, shall be deemed to be an original and which together shall constitute one and the same document.

18.14. Headings. Headings in this Agreement are included herein for ease of reference only and shall have no legal effect. References to the parties, Sections, Schedules, and Exhibits are to the parties, Sections, Schedules and Exhibits to and of this Agreement unless otherwise specified.

18.15. Equitable Remedies. The parties agree that irreparable damage may occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that, without limitation of other remedies which may be available to a party for breach of this Agreement by the other party, the parties shall be entitled to seek an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement.

IN WITNESS WHEREOF the parties hereto have caused this Agreement to be executed by their duly authorized officers upon the date set out below.

Protalix Ltd.

Pfizer Inc.

By: /s/ David Aviezer

Name: David Aviezer

Title: President and CEO

By: /s/ David Simmons

Name: David Simmons

Title: President and General Manager, Established Products BU

Date: November 30, 2009

Date: November 30, 2009

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Reference is hereby made to the Exclusive License and Supply Agreement between Protalix Ltd. (“Protalix”) and Pfizer Inc. (“Pfizer”) dated November 30, 2009 (the “Agreement”). Protalix Biotherapeutics, Inc., a Florida corporation (“Protalix Parent”), hereby agrees to unconditionally guarantee the obligations and liabilities of Protalix under the Agreement, including Protalix’s obligations under Section 18.11 to cause its Affiliates to perform obligations imposed on such Affiliates. Protalix Parent hereby acknowledges and agrees that (a) Protalix and Pfizer may amend or modify the Agreement without the requirement of providing notice of such amendment or modification to Protalix Parent or of obtaining Protalix Parent’s consent thereto and (b) Pfizer shall be entitled to interact and deal with Protalix on all matters relating to the Agreement (and any modifications and amendments hereto) without regard to the guaranty made by Protalix Parent hereunder, and that, in each such case, the obligations and liabilities of Protalix Parent under this guaranty shall not be released or otherwise affected or impaired as a result thereof. Protalix Parent hereby confirms to Pfizer that Protalix is a wholly-owned subsidiary of Protalix. If at any time during the Term Protalix ceases to be a wholly-owned subsidiary of Protalix, Protalix Parent will obtain and deliver to Pfizer within thirty (30) days of such event a written agreement of the Person(s) who have become holders of equity securities of Protalix to comply with and be bound by the terms of this guaranty. Protalix Parent agrees that the provisions of Section 17.1 and 17.2 of the Agreement shall apply to this guaranty to the same extent to which they apply to the Agreement.

Protalix Biotherapeutics, Inc.

By: \_\_\_\_\_  
Name: David Aviezer  
Title: President and CEO

Date: November 30, 2009

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EXHIBIT A

AMINO ACID SEQUENCE FOR DRUG SUBSTANCE

61	EFARPCIPKS	FGYSSVVCVC	NATYCDSFDP	PTFPALGTFS	RYESTRSGRR	MELSMGPIQA
121	NHTGTGLLLT	LQPEQKFQKV	KGFGGAMTDA	AALNILALSP	PAQNLLLSY	FSEEGIGYNI
181	IRVPMASCD	SIRTYTYADT	PDDFQLHNFS	LPEEDTKLKI	PLIHRALQLA	QRPVSLASP
241	WTSPTWLKTN	GAVNGKGS	GQPGDIYHQT	WARYFVKFLD	AYAEBKLQFW	AVTAENEPSA
301	GLLSGYPFQC	LGFTPEHQ	FIARDLGPTL	ANSTHHNVRL	LMLDDQRL	PHWAKVVLTD
361	PEAAKYVHGI	AVHWYLD	PAKATLG	RLFPNTMLFA	SEACVGSKFW	EQSVRLGSWD
421	RGMQYSHSII	TNLLYHVVGW	TDWNLALNPE	GGPNWVRNFV	DSPIIVDITK	DTFYKQPMFY
481	HLGHFSKFIP	EGSQRVGLVA	SQKNDLDAVA	LMHPDGS	VVLNRSSKDV	PLTIKDP
	FLETISPGYS	IHTYLWHRQD	LLVDTM			

EXHIBIT B

PROTALIX PATENT RIGHTS

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\*\*\* Redacted pursuant to a confidential treatment request.

EXHIBIT C

THIRD PARTY LICENSES

\*\*\*

\*\*\* Redacted pursuant to a confidential treatment request.

EXHIBIT D  
DEVELOPMENT PLAN  
[\*\*\*]

[\*\*\*] Redacted pursuant to a confidential treatment request.

EXHIBIT E

CALCULATION OF NET PROFIT/NET LOSS

\*\*\*

\*\*\* Redacted pursuant to a confidential treatment request.

EXHIBIT F

PRESS RELEASE

For Immediate Release:  
December 1, 2009

**Pfizer Contacts:**

Joan Campion (Media)  
212 733-2798  
Joan.Campion@Pfizer.com

Suzanne Harnett (Investors)  
212 733-8009  
Suzanne.Harnett@Pfizer.com

**Protalix Contacts:**

Brad Miles (Media)  
BMC Communications Group, LLC  
Bmiles@bmccommunications.com  
917 570 7340

Marcy Nanus (Investors)  
The Trout Group, LLC  
646 378 2927  
Mnanus@troutgroup.com

**Pfizer And Protalix Enter Into Agreement To Develop And Commercialize  
Gaucher's Disease Treatment**

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***New Drug Application (NDA) expected to be filed with FDA for novel enzyme replacement therapy with Fast Track Orphan Drug designation***

**New York, NY, 2009** — Pfizer (NYSE: PFE) and Protalix (NYSE-Amex: PLX) today announced that they have entered into an agreement to develop and commercialize taliglucerase alfa, a plant-cell expressed form of glucocerebrosidase (GCD) in development for the potential treatment of Gaucher's disease. Under the terms of the agreement, Pfizer will receive exclusive worldwide licensing rights for the commercialization of taliglucerase alfa, while Protalix will retain the exclusive commercialization rights in Israel. Taliglucerase alfa is the first enzyme replacement therapy derived from a proprietary plant cell-based expression platform using genetically engineered carrot cells. With the successful completion of Phase III clinical studies, Protalix is preparing to complete a rolling New Drug Application (NDA) with the

U.S. Food and Drug Administration (FDA). The FDA has granted Orphan Drug designation and Fast Track status, facilitating the development and expediting the review of drugs to treat rare conditions or diseases, as well as an Emergency Use Authorization. The FDA has also requested, and subsequently approved, an Expanded Access Program (EAP) treatment protocol. Taliglucerase alfa is currently being provided to Gaucher's patients in the U.S. under the EAP protocol, as well as to patients in the European Union under a compassionate use protocol.

"We are excited about this collaboration, which represents a significant step towards bringing, for the first time, a plant-based enzyme replacement treatment option to patients affected by Gaucher's disease," commented Dr. David Aviezer, president and CEO of Protalix. "By joining our advances in biologics manufacturing and protein development with Pfizer's global strengths in patient services and reimbursement we expect to help make taliglucerase alfa an important and cost-effective treatment choice for Gaucher's patients throughout the world."

Under the agreement, Pfizer will make an upfront payment of \$60 million to Protalix. In addition, Protalix is eligible to receive additional regulatory milestone payments of up to \$55 million. Pfizer and Protalix will share future revenues and expenses for the development and commercialization of taliglucerase alfa on a 60 percent/40 percent basis respectively.

"By combining our respective strengths to advance this innovative therapy, Pfizer and Protalix expect to quickly deliver an alternative treatment for people suffering from Gaucher's disease," said David Simmons, president and general manager of Pfizer's Established Products Business Unit. "This agreement supports our goal to meet the needs of many patient populations, including those affected by rare diseases, and brings the best minds together to challenge the most feared diseases of our time."

Peter L. Saltonstall, President and CEO, National Organization for Rare Disorders (NORD) stated, "NORD is always pleased when treatment options are expanded for people with rare diseases. We welcome Pfizer's commitment to the rare disease arena, and look forward to



working with both Pfizer and Protalix in support of increased options for patients and families affected by rare diseases.”

#### **About Gaucher’s disease**

Gaucher’s disease, an inherited condition, is the most prevalent lysosomal storage disorder, with an incidence of about 1 in 20,000 live births. People with Gaucher’s disease do not have enough of an enzyme,  $\beta$ -glucosidase (glucocerebrosidase) that breaks down a certain type of fat molecule. As a result, lipid engorged cells (called Gaucher cells) amass in different parts of the body, primarily the spleen, liver and bone marrow. Accumulation of Gaucher cells may cause spleen and liver enlargement, anemia, excessive bleeding and bruising, bone disease and a number of other signs and symptoms.

#### **About Protalix**

Protalix is a biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins expressed through its proprietary plant cell based expression system. Protalix’s ProCellEx<sup>(TM)</sup> presents a proprietary method for the expression of recombinant proteins that Protalix believes will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins in an environment free of mammalian components and viruses. Protalix is also advancing additional recombinant biopharmaceutical drug development programs. Taliglucerase alfa is an enzyme replacement therapy in development under a Special Protocol Assessment with FDA for Gaucher’s disease.

#### **Pfizer Inc.: Working together for a healthier world<sup>TM</sup>**

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world’s best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to

advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at [www.pfizer.com](http://www.pfizer.com).

*DISCLOSURE NOTICE: The information contained in this release is as of December 1, 2009, and neither Pfizer nor Protalix assume any obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about taliglucerase alfa, a product candidate that is the subject of a global development and commercialization agreement between Pfizer and Protalix, including its potential benefits and the anticipated filing of a new drug application with the FDA that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.*

*A further description of risks and uncertainties with respect to Pfizer can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K. A further description of risks and uncertainties with respect to Protalix can be found in Protalix's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and its reports on Form 10-Q.*

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EXHIBIT G

INITIAL COMMERCIALIZATION PLAN

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\*\*\* Redacted pursuant to a confidential treatment request

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EXHIBIT H

FORM OF TRADEMARK ASSIGNMENT

**TRADEMARK ASSIGNMENT**

WHEREAS, Protalix Ltd., a limited liability company incorporated under the laws of Israel with offices located at 2 Snunit Street, Science Park, P.O.B 455, Carmiel 20100, Israel (“Assignor”), is the owner of the Uplyso trademark which has been registered and applied for by Protalix in those countries shown in the attached Schedule.

WHEREAS, Pfizer Inc., a Delaware corporation with offices located at 235 East 42nd Street, New York, New York, 10017, U.S.A. (“Assignee”) desires to acquire all rights and goodwill associated with the Uplyso trademark worldwide, including but not limited to registrations and applications shown in the attached Schedule.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor hereby transfers, releases and assigns to Assignee, effective as of the latest date signed below, all right, title and interest in and to the Uplyso mark, worldwide, together with (1) the goodwill of the business symbolized by this mark, (2) the registrations and/or applications for the Uplyso mark as shown in the attached Schedule, (3) any common law rights in the mark, (4) the right of priority, and (5) all claims for damages by reason of past infringement of the mark and of the respective registrations, and/or applications, with the right to sue for and collect the same for its own use and behalf and for the use and behalf of its successors, assigns and other legal representatives. This Trademark Assignment is intended to be effective worldwide.

**Protalix Ltd.**

Date: November 30, 2009

By: \_\_\_\_\_  
Name: David Aviezer  
Title: President and CEO

SUBSCRIBED TO AND SWORN  
BEFORE ME ON THIS \_\_\_\_DAY  
OF \_\_\_\_\_, \_\_\_\_\_

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Notary Public

**Pfizer Inc.**

Date: November 30, 2009

By: \_\_\_\_\_

Name: David Simmons

Title: President and General Manager, Established Products BU

SUBSCRIBED TO AND SWORN

BEFORE ME ON THIS \_\_\_\_DAY

OF \_\_\_\_\_, \_\_\_\_\_

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Notary Public

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**Schedule for Trademark Assignment**

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**\*\*\* Redacted pursuant to a confidential treatment request**

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EXHIBIT I

COMPLIANCE CERTIFICATE

Reference is hereby made to the Exclusive License and Supply Agreement between Protalix Ltd. ("Protalix") and Pfizer Inc. ("Pfizer") dated November 30, 2009 (the "Agreement").

Pursuant to Section 10.1(t) of this Agreement, Protalix shall certify to Pfizer that:

1. It has been provided with a copy of Pfizer's International Anti-Bribery and Anti-Corruption Procedure; and
2. In connection with this Agreement, it has not made any payments or provided any benefit to a Government Official, as defined in Pfizer's International Anti-Bribery and Anti-Corruption Principles, to induce such Government Official to make any governmental act or decision to help the Parties obtain or retain business and have not made a payment or offered any item or benefit, regardless of values as improper inducement for such Government Official to approve reimburse, prescribe, or purchase a Product, to influence the outcome of a clinical trial, or other wise improperly to benefit the Pfizer's business activities.

PROTALIX LTD.

\_\_\_\_\_  
Name: David Aviezer  
Title: President and CEO

Date: November 30, 2009

EXHIBIT J

FORM OF [\*\*\*] LETTER AGREEMENT

[\*\*\*]

[\*\*\*] Redacted pursuant to a confidential treatment request



EXHIBIT K

[\*\*\*]

[\*\*\*]

[\*\*\*] Redacted pursuant to a confidential treatment request

Subsidiaries of Protalix BioTherapeutics, Inc.

Entity Name	State or Country of Organization
Protalix Ltd.	Israel
Protalix B.V.	Netherlands

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-148983) of Protalix BioTherapeutics, Inc. of our report dated February 25, 2010, relating to the consolidated financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ Kesselman & Kesselman

Tel Aviv, Israel  
February 25, 2010

## CERTIFICATION

I, David Aviezer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Protalix BioTherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2010

/s/ David Aviezer

David Aviezer, Ph.D.

President and Chief Executive Officer

## CERTIFICATION

I, Yossi Maimon, certify that:

1. I have reviewed this Annual Report on Form 10-K of Protalix BioTherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2010

/s/ Yossi Maimon

Yossi Maimon

Chief Financial Officer, Treasurer

**PROTALIX BIOTHERAPEUTICS, INC.****CERTIFICATION**

In connection with the Annual Report of Protalix BioTherapeutics, Inc. (the “Company”) on Form 10-K for the period ended December 31, 2009 as filed with the Securities and Exchange Commission (the “Report”), I, David Aviezer, President and Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, “filed” with the Securities and Exchange Commission.

Date: February 25, 2010

/s/ David Aviezer

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David Aviezer, Ph.D.

President and Chief Executive Officer

**PROTALIX BIOTHERAPEUTICS, INC.****CERTIFICATION**

In connection with the Annual Report of Protalix BioTherapeutics, Inc. (the “Company”) on Form 10-K for the period ended December 31, 2009 as filed with the Securities and Exchange Commission (the “Report”), I, Yossi Maimon, Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, “filed” with the Securities and Exchange Commission.

Date: February 25, 2010

/s/ Yossi Maimon

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Yossi Maimon

Vice President and Chief Financial Officer