Protalix BioTherapeutics, Inc.
Form 10-K
March 08, 2016

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)

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

For the fiscal year ended December 31, 2015

OR

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

For the transition period from _____ to _____

001-33357

(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

972-4-988-9488

Registrant's telephone number, including area code

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

Title of each class	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	**NYSE MKT**

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 x

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 x

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 x 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 x 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 Form 10-K. þ

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 definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer ¨ Accelerated filer x

Non-accelerated filer ¨(Do not check if a smaller reporting company) 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 ¨ No x

The aggregate market value of the voting common equity held by non-affiliates of the Registrant, as of June 30, 2015 was approximately $115 million (based upon a per share price equal to $1.95, the closing price for shares of the Registrant's common stock reported by the NYSE MKT for such date). Shares of common stock held by each officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 1, 2016, approximately 99,808,238 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 meanings of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to our company 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 or revise, nor do we have a policy of updating or revising, 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:

- failure or delay in the commencement or completion of our preclinical studies and clinical trials which 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; or lack of sufficient funding to finance our clinical trials;

- the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy and that our product candidates will not have the desired effects or will have undesirable side effects or other unexpected characteristics;

- our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services;

- risks relating to our ability to finance our research programs;

- delays in preparing and filing applications for regulatory approval of our product candidates in the United States, the European Union and elsewhere;

- any lack of progress of our research and development activities and our clinical activities with respect to any product candidate;

- the impact of development of competing therapies and/or technologies by other companies;

- the risk that products that are competitive to our product candidates may be granted orphan drug status in certain territories and, therefore, will be subject to potential marketing and commercialization restrictions;

- risks relating to the compliance by Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health, with its purchase obligations under our supply and technology transfer agreement which may result in the termination of such agreement, which may have a material adverse effect on our company;

- risks related to our supply of drug product to Pfizer Inc., or Pfizer, pursuant to our amended and restated exclusive license and supply agreement with Pfizer;

- risks related to the commercialization efforts for taliglucerase alfa in Brazil;

- risks related to our supply of drug product to Fiocruz pursuant to our supply arrangement with Fiocruz;

- the risk that we will not be able to develop a successful sales and marketing organization for taliglucerase alfa in Brazil, or for any other product candidate, in a timely manner, if at all;

- risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our 2018 convertible notes or any other indebtedness;

- our expectations with respect to the potential commercial value of our product and product candidates;

- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;

- potential product liability risks, and risks of securing adequate levels of product liability and clinical trial insurance coverage;

- 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;

- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; and

- the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

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 from clinical trials of a drug product, the U.S. Food and Drug Administration or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

These forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These and other risks and uncertainties are detailed under the heading “Risk Factors” in this Annual Report and are described from time to time in the reports we file with the U.S. Securities and Exchange Commission, or the Commission.

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. We developed our first commercial drug product, Elelyso™, using our ProCellEx system and we are now focused on utilizing the system to develop a pipeline of proprietary, clinically superior versions of recombinant therapeutic proteins that primarily target large, established pharmaceutical markets and that in most cases rely upon known biological mechanisms of action. With our experience to date, we believe ProCellEx will enable us to develop additional proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications. We are now also applying the unique properties of our ProCellEx system for the oral delivery of therapeutic proteins.

The following table summarizes our current product candidates and our current projections regarding their respective stages of clinical development.

On May 1, 2012, the U.S. Food and Drug Administration, or the FDA, approved for sale our first commercial product, taliglucerase alfa for injection, an enzyme replacement therapy, or ERT, for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Subsequently, taliglucerase alfa was approved for marketing by the regulatory authorities of other countries. Taliglucerase alfa is being marketed under the name Uplyso™ in Brazil and certain other Latin American countries, and as Elelyso in all other territories.

Since its approval by the FDA, taliglucerase alfa has been marketed mainly in the United States by Pfizer Inc., or Pfizer, as provided in the exclusive license and supply agreement by and between Protalix Ltd., our wholly-owned subsidiary, and Pfizer, which we refer to as the Pfizer Agreement. In October 2015, we entered into an Amended and Restated Exclusive License and Supply Agreement, or the Amended Pfizer Agreement, which amends and restates the Pfizer Agreement in its entirety. Pursuant to the Amended Pfizer Agreement, we sold to Pfizer our share in the collaboration created under the initial Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36.0 million. As part of the sale, we agreed to transfer our rights to Elelyso in Israel to Pfizer, while gaining full rights to Elelyso in Brazil. We will continue to manufacture drug substance for Pfizer, subject to certain terms and conditions. Under the initial Pfizer Agreement, Pfizer shared revenues and expenses for the development and commercialization of Elelyso with us on a 60%/40% basis globally, excluding Israel and Brazil. Under the Amended Pfizer Agreement, Pfizer is responsible for 100% of expenses, and entitled to all revenues globally for Elelyso, excluding Brazil, where we are responsible for all expenses and retain all revenues. The Amended Pfizer Agreement eliminates Pfizer’s entitlement to annual payments of up to $12.5 million in relation to commercialization of Elelyso in Brazil.

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For the first 10-year period after the execution of the Amended Pfizer Agreement, we have agreed to sell drug substance to Pfizer for the production of Elelyso, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods subject to certain terms and conditions. Any failure to comply with our supply commitments may subject us to substantial financial penalties which will have a material adverse effect on our business, results of operations and financial condition. The Amended Pfizer Agreement also includes customary provisions regarding cooperation for regulatory matters, patent enforcement, termination, indemnification and insurance requirements.

On October 12, 2015, we also entered into a Stock Purchase Agreement with Pfizer, pursuant to which we issued in a private placement 5,649,079 shares of our common stock for an aggregate purchase price equal to $10.0 million subject to certain other terms set forth in the Stock Purchase Agreement. As part of the Stock Purchase Agreement, Pfizer agreed to a 180-day lock-up with respect to the purchased shares of common stock.

On June 18, 2013, we entered into a Supply and Technology Transfer Agreement, or the Brazil Agreement, with Fiocruz, an arm of the Brazilian Ministry of Health for taliglucerase alfa. Fiocruz’s purchases of Uplyso to date have been significantly below certain agreed upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, we are, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. We are discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, we will determine what we believe to be the course of action that is in the best interest of our company.

Our Strategy

Our operations are focused on our new strategy for accelerated growth, which was implemented in January 2015. The strategy centers around prioritizing existing and new pipeline candidates to focus on products that offer a clear competitive advantage over existing treatments. The strategy was the culmination of two months of intensive review by our management of the company's internal resources and of the markets in which we think we can operate. The following highlights the details of the strategic plan as it relates to our development of an innovative product pipeline using our ProCellEx protein expression system.

PRX-102 for the Treatment of Fabry disease. PRX-102, or alpha-GAL-A, is designed to be an improved enzyme replacement therapy product for the treatment of Fabry disease given its potential for clinically superior outcomes and enhanced safety when compared to currently marketed enzyme replacement therapies. The product candidate is a key focus for our company. PRX-102 is currently the subject of an ongoing phase I/II clinical trial and we expect to commence phase III clinical trials of PRX-102 during the first half of 2016. We have applied to the FDA for a special protocol assessment (SPA) in connection with our proposed protocol for the trial, and we intend to aggressively push PRX-102 through the anticipated phase III clinical trials.

AIR DNase™ (PRX-110) for Cystic Fibrosis. AIR DNase, our proprietary plant cell recombinant human Deoxyribonuclease 1, is under development for the treatment of cystic fibrosis (CF), to be administered by inhalation. AIR DNase has an actin inhibition resistance that is designed to improve lung function and lower the incidence of recurrent infections by enhancing the enzyme's efficacy in patients' sputa. It has demonstrated improved disease parameters in animal models and human sputum testing when compared to the currently marketed product. We have commenced a phase I clinical trial of AIR DNase in healthy volunteers and plan to initiate clinical efficacy trials of AIR DNase for the treatment of CF in mid-year, 2016. Upon review of the results of the trial, we intend to identify and collaborate with a well-suited partner for further development.

Oral Anti-TNF (OPRX-106) Anti Inflammatory. Oral anti-TNF represents a novel mode of administering a recombinant anti-TNF protein. It is under development as an orally-delivered anti-inflammatory treatment using plant cells as a natural capsule for the expressed protein. We completed a phase I clinical trial oPRX-106, which demonstrated that the drug was safe and well tolerated, showing biological activity in the gut and inducement of regulatory T cells. We plan to initiate a proof of concept efficacy study for the treatment of ulcerative colitis in mid-year, 2016. Upon review of the proof of concept data, we intend to identify and collaborate with a well-suited partner for further development. If approved, oPRX-106 will be the first ever oral enzyme treatment.

Potential Pipeline Candidates. We aim to expand our pipeline by leveraging the advantages of our proprietary ProCellEx protein expression technology. The focus is expected to be on biologics with improved clinical profiles than the currently marketed proteins for these indications. Biosimilars will not be a market on which we focus, and

will only be considered in the case of proteins that are highly difficult to express or that represent opportunities for early market entry arising from the intellectual property advantages arising from ProCellEx.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Brazil), which we licensed to Pfizer, we hold the worldwide commercialization rights to all of our proprietary development candidates. We continuously evaluate potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutes.

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. The IMS Institute for Healthcare Informatics reports that global biologic spending was $169 billion in 2012 and anticipated to reach $221 billion in 2017 (Report by the IMS Institute for Healthcare Informatics, Nov. 2013).

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®, Humira®, Enbrel®, Neulasta®, Remicade® and Herceptin®. Mammalian cell-based expression technology is based on the introduction of a human gene encoding for a specific therapeutic protein into the genome of a mammalian cell. The cells most often used in connection with mammalian cell-based protein expression are Chinese hamster ovary (CHO) cells.

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

approved therapeutic proteins, as well as those under development, are produced in mammalian cell-based systems.

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Despite the utility and widespread use of mammalian cell-based systems, they are subject to a number of disadvantages. CHO (Chinese Hamster Ovary) 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 and none of these technologies have been approved by the regulatory agencies with jurisdiction over any substantial market.

ProCellEx: Our Proprietary Protein Expression System

ProCellEx is our proprietary production system. We have developed ProCellEx based on our plant cell culture technology for the development, expression and manufacture of recombinant proteins. ProCellEx 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. This 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. 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 when compared to mammalian

cell-based protein expression systems.

Our ProCellEx system is capable of producing proteins with an amino acid sequence and three dimensional structure practically equivalent to that of the desired human protein, and with a very similar, although not identical, glycan, or sugar, structure, as demonstrated in our internal research and external laboratory studies. In collaboration with the 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.

We believe that the ProCellEx system 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.

We have successfully demonstrated the feasibility of our ProCellEx system through: the FDA's approval of taliglucerase alfa, and its subsequent approval by other regulatory authorities; the clinical and preclinical studies we have performed to date, including the positive efficacy and safety data in our clinical trials for both Elelyso and PRX-102 for the treatment of Fabry disease; preclinical results in well-known models in our enzyme for each of Fabry disease, DNase and antiTNF; 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 FDA's approval of taliglucerase alfa represents a strong proof-of-concept of our ProCellEx system and plant cell-based protein expression technology. We also believe that the significant benefits of our ProCellEx system, if further substantiated in clinical trials and in the successful commercialization of taliglucerase alfa and our other product candidates, have the potential to transform the industry standard for the development of complex therapeutic proteins.

We are also using our ProCellEx system to produce active recombinant proteins through oral administration of plant cells expressing biotherapeutic proteins. In such method, an enzyme is naturally encapsulated within carrot cells genetically engineered to express the targeted enzyme. Plant cells have the unique attribute of a cellulose cell wall which makes them resistant to enzyme degradation when passing through the digestive tract. The plant cell itself serves as a delivery vehicle, once released and absorbed, to transport the enzyme in active form to the bloodstream. With initial proof of concept now demonstrated, this would be the first time an enzyme will be administered orally rather than through intravenous therapy. To date we have completed successful preclinical animal studies for oral GCD and oral antiTNF, and early clinical trials of oral GCD in Gaucher patients and oral antiTNF in a phase I clinical trial in healthy volunteers.

To date, our manufacturing facility, in which we utilize our ProCellEx system, was determined to be acceptable by each of the FDA, European Medicines Agency, or the EMA, ANVISA, the Israeli MOH, the Australian Therapeutic Goods Administration, or the TGA, and Health Canada, after GMP inspections were performed as part of their respective reviews for marketing approval of taliglucerase alfa.

Competitive Advantages of Our ProCellEx Protein Expression System

We intend to continue to leverage the multiple unique advantages of our proprietary ProCellEx protein expression system, including our advanced genetic engineering technology and plant cell-based protein expression methods, to develop our pipeline. Significant advantages of ProCellEx over mammalian, bacterial, yeast and transgenic cell-based expression technologies, include the following:

Biologic Optimization. ProCellEx has internal capabilities developed to improve the biologic dynamics of an expressed protein. For example, the proteins produced through our system 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. 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 expressed protein to bind to a target cell and subsequently be taken into the target cell for therapeutic benefit. 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. We believe this quality increases the potency and consistency of the expressed proteins, and thus, the effectiveness of the protein which presents an additional cost advantage of ProCellEx over competing protein expression methodologies.

Ability to Penetrate Certain Patent-Protected Markets. ProCellEx has the potential to provide workaround manufacturing that does not infringe the method-based patents or other intellectual property rights of third parties. Certain biotherapeutic proteins available for commercial sale are not protected by patents that cover the compound and are available for use in the public domain. Rather, 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 ProCellEx, 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 U.S. and international composition of matter patents for PRX-102 and certain of our other product candidates.

Broad Range of Expression Capabilities. ProCellEx is able to produce a broad array of complex glycosilated proteins, which are difficult to produce in other systems, such as bacterial and yeast cell-based systems, as well as CHO systems. 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.

Significantly Lower Capital and Production Costs. ProCellEx entails a lower cost of scale-up and of production. Plant cells grow rapidly under a variety of conditions and are not as sensitive as mammalian cells are to temperature, pH and oxygen levels. Our system, therefore, does not require the 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 can 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 associated with 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 proteins, plant cells require only simple and much less expensive solutions based on sugar, water and microelements at infrequent intervals to achieve target yields.

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 and product candidates to future patients, whether from known or unknown mammalian viruses, is eliminated. Because our product and product candidates do not bear the risk of mammalian 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 are required in mammalian cell-based production. In addition, the production process of our ProCellEx 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 ProCellEx compared to mammalian cell-based expression systems.

Potential ability to administer active therapeutic enzymes orally. We are using ProCellEx to produce active recombinant proteins through oral administration of plant cells expressing biotherapeutic proteins. Plant cells have the unique attribute of a cellulose cell wall which makes them resistant to enzyme degradation when passing through the digestive tract. The plant cell itself serves as a delivery vehicle, once released and absorbed, to transport the enzyme in active form to the bloodstream. If proven effective, this would be the first time an enzyme will be administered orally rather than through intravenous therapy. To date we have completed successful preclinical animal studies for oral GCD and oral anti TNF, and early clinical trials of oral GCD in Gaucher patients.

Our First Commercial Product – Elelyso for the Treatment of Gaucher Disease

Elelyso (taliglucerase alfa), our first commercial product, is a plant cell expressed recombinant glucocerebrosidase enzyme (GCD) for the treatment of Gaucher disease. On May 1, 2012, the FDA approved Elelyso for injection as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. It was subsequently approved by the Israeli MOH, ANVISA and the regulatory authorities of other countries. In August 2014, the FDA approved Elelyso for injection for pediatric patients and in other jurisdictions thereafter.

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). Patients with Gaucher disease lack or otherwise have dysfunctional GCD and, accordingly, are not able to break down GlcCer. The GlcCer accumulates in lysosomes of certain white blood cells called macrophages which consequently become highly enlarged. The enlarged 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.

The standard of care for Gaucher disease is enzyme replacement therapy using recombinant GCD to replace the mutated or deficient natural GCD enzyme. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are injected into patients in whom the enzyme is lacking or dysfunctional. Cerezyme® and VPRIV® are the only other ERTS currently available for the treatment of Gaucher disease. In addition, Cerdelga® (eliglustat) is a substrate reduction therapy for Gaucher disease that was approved for marketing by the FDA in August 2014 and by the European Commission in January 2015. Finally, Zavesca (miglustat) is a small molecule drug for the treatment of Gaucher disease. 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 ERT, and, accordingly, have no other treatment alternative. As a result, Zavesca's use has been limited with respect to treating Gaucher disease. However, Zavesca is also used to treat other rare disorders.

Our Pipeline Drug Candidates

PRX-102 for the Treatment of Fabry Disease

We are developing PRX-102, our proprietary plant cell expressed chemically modified version of the recombinant alpha-GAL-A protein, a therapeutic enzyme, for the treatment of Fabry disease, a rare genetic lysosomal storage disorder. We believe that PRX-102 has the potential to be an improved version of the currently marketed Fabry disease enzymes, Fabrazyme® and Replagal®, with improved activity in the Fabry disease target organs and significantly longer half-life due to higher stability, which together can potentially lead to improved substrate clearance and significantly lower formation of antibodies, as observed in our phase I/II clinical trial in Fabry patients. We believe that the treatment of Fabry disease is a specialty clinical niche with the potential for high growth as there is a significant unmet medical need for Fabry disease treatments.

Fabry Disease Background

Fabry disease is characterized by subnormal or absent enzymatic activity of alpha-GAL-A, a lysosomal enzyme, which primarily catalyses the hydrolysis of terminal alpha-galactosyl groups of glycolipids, mainly the glycosphingolipid globotriaosylceramide (Gb3). The accumulation of Gb3 in body tissues results in Fabry disease. The ultimate consequence of glycosphingolipid deposition in the vasculature and other tissues is end-organ failure, particularly of the kidney, but also of the heart and cerebrovascular system. In addition, involvement of the central, peripheral and autonomic nervous systems results in episodes of pain and impaired peripheral sensation. In PRX-102, the prh-alpha-GALA, naturally occurring as a homodimer, is PEGylated and cross-linked to support and reinforce the homodimeric structure, which is crucial for the enzymatic activity of this enzyme. PRX-102 has been shown to be taken up by Fabry patients' cells where it localizes to the lysosome, in which Gb3 accumulates. PRX-102 is characterized by higher stability under physiologically relevant conditions, and extended circulation residence time as compared to current ERTs for Fabry disease.

Current Treatments of Fabry Disease

Currently there are two drugs available on the market to treat Fabry disease. Fabrazyme, marketed by Genzyme Corporation (acquired by Sanofi), is approved for the treatment of Fabry disease in the United States and the European Union. Sanofi reported €592 million (approximately $643 million) in worldwide sales of Fabrazyme in 2015. The other approved drug for the treatment of Fabry disease in the European Union is Replagal, which is marketed by Shire. Shire reported $442 million in sales of Replagal in 2015.

PRX-102 Development Program

In February 2015, we announced the completion of enrollment in our phase I/II clinical trial in adult Fabry patients. The phase I/II clinical trial is a worldwide, multi-center, open label, dose ranging study to evaluate the safety, tolerability, pharmacokinetics and exploratory efficacy parameters of PRX-102 in adult Fabry patients. There were 18 adult Fabry patients (11 male and 7 female) enrolled in the trial, each in one of three dosing groups, 0.2 mg/kg, 1mg/kg and 2mg/kg. Each patient receives intravenous infusions of PRX-102 every two weeks for 12 weeks, with a six-month efficacy follow up period. All patients that completed the trial have opted to continue to receive PRX-102 in an open-label extension trial.

0.2 mg/kg dose six months' results:

PRX-102 demonstrated meaningful clinical benefits across the following key disease parameters already in this low dose, including a major reduction in Gb3 in Renal Peritubular Capillaries, significant improvement in all pain parameters, stabilization of cardiac and kidney function and very low level of antibody formation.

The interim efficacy analysis includes six Fabry patients enrolled in the 0.2mg/kg dose group at six months of treatment (for Gb3 in renal peritubular capillaries n=5).

Based on an analysis of kidney biopsies with randomized blinded scoring, PRX-102 demonstrated a reduction in renal peritubular capillary Gb3 of 82.2% for males and 65.4% for females using a quantitative Barisoni Lipid Inclusion Scoring System (BLISS) for a combined reduction of 75.5%. Applying the semi-quantitative scoring method, commonly used by approved enzyme replacement therapies, PRX-102 demonstrated a reduction of 69.6% in abnormal capillary score. Using the well-accepted Brief Pain Inventory scale, a 100% reduction in Worst Pain and an average of 78.8% improvement on patients' Impact On Functioning were observed. Furthermore, all patients had stable cardiac function, with favorable trends after only six months, as measured by left ventricular mass (LVM), left ventricular mass index (LVMI) and ejection fraction (EF). Stable kidney function was also observed, with favorable trends after only six months, as measured by estimated glomerular filtration rate (eGFR) and urine protein.

The safety analysis for adverse events represents a total of 6.7 patient years. PRX-102 was well tolerated, with the majority of events being mild and moderate. Only one of the 12 patients evaluated for safety experienced hypersensitivity. Six patients receiving the 0.2mg/kg dose and two patients receiving the 1m/kg dose were evaluated for antibody formation. Of these eight patients, only two patients, or 33% of the 0.2 mg/kg dose cohort, developed antibodies. The interim safety analysis includes twelve patients; six patients enrolled in the 0.2mg/kg dose group and six patients enrolled in the 1mg/kg dose group.

1mg/kg dose, six months’ results:

The interim analysis includes six patients enrolled in the 1mg/kg dose group at six months of treatment. Based on an analysis of kidney biopsies with randomized blinded scoring (n=4), PRX-102 demonstrated a reduction in renal peritubular capillary Gb3 of 86% using a quantitative Barisoni Lipid Inclusion Scoring System (BLISS).

Reductions of plasma Lyso-Gb3 and plasma Gb3 concentrations were also observed. Males (n=4) demonstrated a -67.5 ng/mL and a -5.3 µg/mL change, Females (n=2) demonstrated a -9.2 ng/mL mean change in Lyso-Gb3 and a -0.23 µg/mL mean change in plasma Gb3, respectively.

Furthermore, all patients had stable cardiac function after only six months, as measured by left ventricular mass (LVM), left ventricular mass index (LVMI) and ejection fraction (EF). Stable kidney function was also observed, as measured by estimated glomerular filtration rate (eGFR) and urine protein.

PRX-102 was well tolerated, with the majority of adverse events being mild and moderate. Only one of the patients evaluated for safety experienced hypersensitivity, and only three patients, or approximately 19%, developed antibodies.

The interim safety analysis includes 18 patients enrolled in three dose cohorts of 0.2mg/kg, 1mg/kg and 2mg/kg and represents a total of 15 patient years.

0.2 mg/kg dose 12 months' results:

On average, patients that participated in the 0.2mg/kg cohort of the PRX-102 phase I/II trial exhibited stability in kidney function with favorable trends shown, as measured by estimated Glomerular filtration rate (eGFR). After dosing with 0.2mg/kg of PRX-102 for 12 months, a majority of the patients (4/6) experienced a stabilization or improvement in kidney function; a reversal of the decline shown by annualized eGFR slope was observed. Throughout the study, continuous and durable reduction of up to 61.8% of plasma lyso-Gb3 levels from base line was observed in patients in the 0.2mg/kg cohort. In addition, Fabry patients of the 0.2mg/kg cohort of the PRX-102 trial showed a continuous reduction and durable improvement in Mainz Severity Score Index (MSSI), a tool for disease status evaluation of a variety of signs and symptoms of Fabry disease including cardiovascular, renal and neurological.

PRX-102's unique and enhanced PK properties resulted in long half-life, high AUC and measured levels of enzyme found throughout the entire two weeks infusion intervals in all patients of the 0.2mg/kg cohort of the trial, potentially contributing to an immune tolerance phenomenon. This resulted in low incidence of antibody formation with low titers in general, and moreover, in antibody positive patients it resulted in a transient and reversible shift of overall drug availability. Mean values for Cmax, and AUC were found to have briefly shifted at three and six months in antibody positive patients, where at 12 months, PK parameters returned to the high AUC levels observed at baseline, demonstrating that the antibody presence and its impact was transient, leading to full active dose availability for effective treatment.

In addition, PRX-102 continued to be well tolerated with a favorable safety profile, with the majority of adverse events being mild and moderate in severity with a very low rate of antibody formation.

We held an End-of-Phase II meeting with the FDA in the last quarter of 2015 to discuss our proposed Biologics License Application, or BLA, plan for PRX-102. Official FDA meeting minutes indicate the FDA's acceptance of our path forward for a phase III clinical trial to support a full BLA approval. The intended phase III clinical trial will be a randomized, multi-center, placebo-controlled, safety and efficacy study in treatment-naïve Fabry patients evaluating the 1 mg/kg dose of PRX-102. We anticipate a small sample size of patients will be needed to achieve statistical significance with a study duration of approximately six months. The primary endpoint will be gastrointestinal symptoms, with key secondary endpoints including renal function. In the official FDA meeting minutes, the FDA noted that we reported interim analysis results from the phase I/II clinical trial of PRX-102 that preliminarily show a favorable trend in the severity and frequency of abdominal pain and frequency of diarrhea after six months of treatment with PRX-102. According to the FDA, during a recent ERT shortage, patients who reduced or discontinued ERT dosing developed worsening of GI signs and symptoms within a few weeks to months.

In addition to the phase III clinical trial described above, we and the FDA also agreed to a phase III head-to-head superiority trial comparing PRX-102 versus Fabrazyme. The primary endpoint for this head-to-head trial will be an improvement in eGFR. The trial will enroll patients who are currently treated with Fabrazyme; such patients will be treated with 1mg/kg of PRX-102 for a two-year period. Interim results from this head-to-head trial will also provide supportive safety data for the BLA submission.

Guidance from the official FDA minutes, suggests no additional non-clinical studies are required to support a BLA for PRX-102. We submitted a request for a Special Protocol Assessment (SPA) to the FDA later this year, and expect to commence both phase III trials in early 2016.

PRX-110; AIR DNase™ for the Treatment of Cystic Fibrosis

PRX-110, or AIR DNase, is our plant cell recombinant form of human deoxyribonuclease I (DNase I) that we are developing for the treatment of CF to be administered by inhalation. DNase I cleaves extracellular DNA and thins the thick mucus that accumulates in the lungs of CF patients. Currently, Pulmozyme® is the only DNase I commercially available, with annual sales of approximately CHF 652 million (approximately $652 million) in sales for 2015, an increase of 10%, according to public reports by F. Hoffman-La Roche Ltd.

In vitro studies with PRX-110 demonstrated improved enzyme kinetics, significantly reduced sensitivity to inhibition by actin and improved ex vivo efficacy when compared to Pulmozyme. Preclinical studies of PRX-110 administered

by inhalation showed substantial enzymatic activity in lungs.

AIR DNase has an actin inhibition resistance that is designed to improve lung function and lower the incidence of recurrent infections by enhancing the enzyme's efficacy in patients' sputa.

Actin, a potent inhibitor of DNase, is found in high concentration in CF patients' sputum. As demonstrated in Figure 1, the activity of AIR DNase remains almost with no change in the relevant actin concentration found in CF patients while Pulmozyme is degraded significantly.

Figure 1. Actin and DNase concentrations in human sputum tested in *in vitro* assays

In addition, the product candidate has demonstrated improved disease parameters in human models sputum testing when compared to the currently marketed product. In particular, AIR DNase has demonstrated a reduction in mucus viscosity in human sputum sample when compared to the currently marketed product. See Figure 2.

Figure 2. Rheology Data Analysis in in human sputum samples

PRX-110 AIR DNase Development Program

AIR DNase is the subject of a phase I clinical trial involving 18 healthy volunteers. We anticipate commencing a proof of concept study in mid-2016 which we expect to include 15 to 20 CF patients. The study will be designed to involve once daily inhalations with an eight-week study duration. The study will evaluate safety and tolerability; pharmacokinetics; efficacy parameters: change from baseline in FEV1 (Forced Expiratory Volume in One Second) and FVC (Forced Vital Capacity); DNA parameters in sputum; and sputum rheology parameters.

OPRX-106; Oral antiTNF as an Anti-Inflammatory

OPRX-106, our oral antiTNF product candidate, is a recombinant antiTNF (Tumor, Necrosis Factor) protein that we are expressing through ProCellEx. AntiTNF drugs represent the biggest category of biological drugs in the world today with combined sales of over $20 billion a year. Well-known antiTNF drugs include Humira®, Remicade® and Enbrel®. antiTNFs are used to treat a number of indications including rheumatoid arthritis, psoriasis, crohn's disease and others.

OPRX-106 is a plant cell-expressed form of the fused protein that is naturally encapsulated within BY-2 cells genetically engineered to express the enzyme. Plant cells have the unique attribute of a cellulose cell wall which makes them resistant to enzyme degradation when passing through the digestive tract. The plant cell itself serves as a delivery vehicle, once released and absorbed, to transport the enzyme in active form to the bloodstream. If proven effective, our experimental oral antiTNF would be the first protein to be administered orally rather than through injectable therapy. We believe that our oral delivery mechanism could be applied to additional proteins and has the potential to change the method of protein administration in certain indications.

We are developing oral antiTNF an orally-administered anti-inflammatory treatment using plant cells as a natural capsule for the expressed protein. In preclinical studies, oral PRX-106 alleviated immune-mediated hepatitis and reduced interferon gamma levels in a concanavalin A (ConA) inflammatory mouse model. Furthermore, the drug was shown to alleviate liver damage and reduce liver necrosis and liver enzymes, ALT and AST, thus leading to an improvement in liver biopsies. In a high fat diet model (NASH), OPRX-106 demonstrated a reduction of liver enzymes, ALT and AST, reduction of serum triglycerides, along with a trend for reduction of liver fat. Additionally, oral administration of OPRX-106 alleviated immune mediated colitis in a well-established mouse model, promoting serum levels of anti-inflammatory IL-10 and regulatory T-cells.

pr-antiTNF is a plant cell-expressed recombinant fusion protein made from the binding domain of the human TNF receptor (TNFR), fused to the Fc component of a human antibody domain. It has an identical amino acid sequence to Enbrel and our in vitro and preclinical animal studies have demonstrated that pr-antiTNF exhibits similar or better activity to Enbrel. See Figure 3.

Figure 3. IBD Animal Model

OPRX-106 Development Program

We have concluded a phase I clinical trial of OPRX-106, which demonstrated that the drug was safe and well tolerated, showing biological activity in the gut and inducement of regulatory T cells. The primary objective of the phase I clinical trial was to test the safety and pharmacokinetics of OPRX-106 in healthy volunteers, with an exploratory objective of analyzing the immunomodulatory effect. The study consisted of 15 healthy volunteers divided into three dosing cohorts, equivalent to 2mg, 8mg or 16mg Tumor Necrosis Factor receptor-Fc fusion protein. Study subjects received daily oral administration for five consecutive days. Evaluations included pharmacokinetics, serum cytokines and an FACS analysis of T-cell population.

We anticipate commencing a proof of concept study in mid-2016 which we expect to include 20 mild to moderate untreated ulcerative colitis patients. The study will be designed to involve once daily administrations with an eight-week treatment duration. The study will evaluate two different doses for safety and tolerability; pharmacokinetics; and efficacy parameters (vs. baseline): Mayo score, rectal bleeding, hHistopathological improvement (Geboes), hs-CRP levels, and fecal calprotectin level.

Technology Transfer Agreement with Fiocruz

We entered into the Brazil Agreement with Fiocruz in June 2013, which became effective in January 2014. The technology transfer is designed to be completed in four stages and is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high-quality, and cost-effective supply of taliglucerase alfa. The initial term of the technology transfer is seven years. Under the agreement, Fiocruz committed to purchase at least approximately $40 million worth of taliglucerase alfa during the first two years of the term and in subsequent years, at least approximately $40 million worth of taliglucerase alfa per year. We are not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately $280 million worth of taliglucerase alfa. If Fiocruz fails to comply with certain of its purchase commitments under the agreement, we may terminate the agreement, and all of our rights to the technology will be returned.

Since the agreement went into effect, Fiocruz's purchases of taliglucerase alfa have been significantly below certain agreed upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, we are, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. We are discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, we will determine what we believe to be the course of action that is in the best interest of our company.

The Brazil Agreement may be extended for an additional five-year term, as needed, to complete the technology transfer. All of the terms of the arrangement, including the minimum annual purchases, will apply during the additional term. Upon completion of the technology transfer, and subject to Fiocruz receiving approval from ANVISA to manufacture taliglucerase alfa in its facility in Brazil, the agreement will enter into the final term and will remain in effect until our last patent in Brazil expires. During such period, Fiocruz will be the sole provider of this important treatment option for Gaucher patients in Brazil and shall pay us a single-digit royalty on net sales.

We have agreed to pay a fee equal to 5% of the net proceeds generated in Brazil to our agent for services provided in assisting us complete the Brazil Agreement pursuant to an agency agreement between us and the agent. The agency agreement will remain in effect with respect to the Brazil Agreement until the termination thereof.

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. As of December 31, 2015, we held, or had license rights

to, 67 patents and 75 pending patent applications with respect to various compositions, methods of production and methods of use relating to our ProCellEx protein expression system and our proprietary product pipeline. As of December 31, 2015, we held, with a third party, one joint patent and one joint patent application, and licensed rights to two patents.

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.

As of December 31, 2015, our patent portfolio consisted of several patent families (consisting of patents and/or patent applications) covering our technology, protein expression methodologies and system and product candidates, as follows:

- With respect to our ProCellEx protein expression system, we held 14 issued patents in the United States, Australia, the European Union, Israel, Canada, Mexico, Hong Kong, India and Korea, and hold one pending patent applications. Among other things, the patents cover the methods that we use for culturing and harvesting plant cells and/or tissues in consecutive cycles. Of the issued patents in this family, seven are expected to expire in 2017 and seven are expected to expire in 2025.

- With respect to our ProCellEx protein expression system, we held six issued patents and eight patent applications relating to the large scale production of proteins in cultured plant cells. The issued patents and any patents to issue in the future based on pending patent applications in this patent family are expected to expire in 2028.

- We held a patent family containing 25 issued patents in India, South Africa, Russian Federation, Australia, China, the United States, Ukraine, Singapore, Japan, Europe, Hong Kong, Mexico, Korea Canada, Brazil and Israel and five patent applications relating to the production of recombinant glycosylated lysosomal proteins in our plant culture platform, including taliglucerase alfa, and uses of these proteins and cells containing these proteins for the treatment of lysosomal disorders. The issued patents and any patents to issue in the future based on pending patent applications in this patent family are expected to expire in 2024.

- We held a patent family containing three granted patents relating to a system and method for production of antibodies in a plant cell culture, and antibodies produced in such a system. The issued patents in this patent family are expected to expire in 2025.

- We held a patent family containing three issued patents in South Africa, Australia and Israel, and one pending patent application relating to a new method for delivering active recombinant proteins systemically through oral administration of transgenic plant cells. The issued patents and any patents to issue in the future based on patent applications in this patent family are expected to expire in 2026.

- We held a patent family containing three granted patents in the United States, South Africa and Australia, and two pending patent applications relating to saccharide containing protein conjugates. The issued patents and any patents to issue in the future based on the patent applications in this patent family are expected to expire in 2028.

- We held a patent family containing nine pending patent application relating to Nucleic Acid construct for expression of alpha-galactosidase enzyme in plants and plant cells. The patents to issue in the future based on the patent applications in this patent family, if at all, are expected to expire in 2031.

- We held a patent family containing nine granted patents in Europe, United States, Japan, China, Hong Kong, Singapore, New Zealand and South Africa and 12 pending patent applications relating to multimeric protein structures of -galactosidase and to uses thereof in treating Fabry disease. The issued patents and any patents to issue in the future based on the patent applications in this patent family are expected to expire in 2031.

- We held a granted patent in Europe relating to therapeutic proteins with stabilized quaternary structure. The patent is expected to expire in 2031.

- We held a patent family containing one granted patent in Europe and one pending patent application relating to multimeric protein structures of glucocerebrosidase and to uses thereof in treating Gaucher disease. The issued patent and any patent applications to issue in the future based on the patent applications in this patent family, if at all, are expected to expire in 2031.

- We held two patent families relating to the oral delivery of plant cells comprising recombinant glucocerebrosidase for the treatment of Gaucher disease. The patents to issue in the future based on patent application in this patent family,

if at all, are expected to expire in 2033 and 2035.

- We held three patent families containing eight pending applications relating to plant recombinant human DNase I and uses in therapy. The patents to issue in the future based on these patent applications, if at all, are expected to expire in 2033.

- We held three families containing nine patent applications relating to plant recombinant TNF alpha inhibitor polypeptides. The patents to issue in the future based on these patent applications, if at all, are expected to expire in 2034/2035.

- Our patent portfolio includes a patent that we co-own that covers human glycoprotein hormone and chain splice variants, including isolated nucleic acids encoding these variants. More specifically, this patent covers a new splice variant of human FSH. This patent was issued in the United States and is expected to expire in 2024.

- With respect to taliglucerase alfa, we have licensed the rights to two patents from Virginia Tech Intellectual Properties, Inc., or Virginia Tech, that are expected to expire in 2016.

- We co-own a patent family containing eight pending applications that covers use of plant cells expressing a TNF alpha polypeptide inhibitor in therapy.

We are aware of U.S. 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.

In April 2005, Protalix Ltd. entered into a license agreement with Icon Genetics AG, or Icon, 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. We are also entitled to a non-exclusive worldwide license to make and have made other proteins expressed by using Icon's technology in our technology. As consideration for the license, we are obligated to make royalty payments equal to varying low, single-digit percentages of net sales of products by us, our affiliates, or any sublicensees under the agreement. In addition, we are obligated to make milestone payments equal to $350,000, in the aggregate, for each product developed under the license, upon the achievement of certain milestones.

Our license agreement with Icon remains in effect until the earlier of the expiration of the last patent under the agreement or, if all of the patents under the agreement expire, 20 years after the first commercial sale of any product under the agreement. Icon may terminate the agreement upon written notice to us that we are in material breach of our obligations under the agreement and we are unable to remedy such material breach within 30 days after we receive such notice. Further, Icon may terminate the agreement in connection with certain events relating to a wind up or bankruptcy, if we make a general assignment for the benefit of our creditors, or if we cease to conduct operations for a certain period. Icon may also terminate the exclusivity granted to us by written notice if we fail to reach certain milestones within a designated period of time. Notwithstanding the termination date of the agreement, our obligation to pay royalties to Icon under the agreement may expire prior to the termination of the agreement, subject to certain conditions.

In January 2005, Protalix Ltd. entered into a license agreement with Virginia Tech, pursuant to which we received a non-exclusive worldwide license to make, have made, use, sell, offer for sale and import certain of Virginia Tech's patents. As consideration for the license, we made a one-time license fee payment to Virginia Tech, and we are obligated to make royalty payments equal to varying low, single-digit percentages of net sales of licensed products by Protalix Ltd., its subsidiaries and/or their affiliates. Upon commercialization of a licensed product, the royalty payment is subject to a low, annual minimum amount. In addition, we were obligated to make milestone payments equal to $150,000, in the aggregate, upon the achievement of certain milestones, which milestone payments have been satisfied. We have the right to grant sublicenses under the agreement.

Our license agreement with Virginia Tech remains in effect until the earlier of the expiration of the last patent under the agreement or 10 years after the first commercial sale of any licensed product. Virginia Tech may terminate the agreement upon written notice to us that we are in material breach of our obligations under the agreement if we are unable to remedy such material breach within a fixed number of days after we receive such notice, which number may be doubled if we are making good faith efforts to achieve a cure and the extension will not increase the damages suffered by Virginia Tech. We have the right to terminate the agreement at any time upon prior written notice delivered an agreed-upon number of days prior to the date of termination.

Manufacturing

We are obligated to manufacture all of the taliglucerase alfa drug product needed under the Amended Pfizer Agreement, subject to certain terms and conditions. Our drug product candidates, as well as 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 intend to use our current manufacturing space to produce all of the taliglucerase alfa we need in the near future, included the taliglucerase alfa to be purchased by Pfizer. In addition, we intend to use our manufacturing space to produce all of the drug substance needed in connection with the clinical trials for our product candidates.

In addition, we are currently producing Fabry drug substance for our planned phase III trial as part of the process of converting our current approved manufacturing facility to an approved multi product facility, thereby introducing potentially significant operational savings. Our facility’s current capacity can serve all of our current and expected commercial and clinical needs, and we believe it will be sufficient to serve our production needs for the anticipated commercialization of PRX-102.

Our manufacturing facilities in Carmiel, Israel, have undergone successful audits by the Israeli MOH, the FDA, ANVISA, and the European Union under the European Union's centralized marketing authorization procedure, the Australian TGA and Health Canada.

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 10-year period commencing with the year in which we first generate taxable income from the relevant Approved Enterprise and after we use our NOLs. We expect to be entitled to similar tax benefits for a number of years thereafter. 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 Elelyso, PRX-102 and our other current and potential drug product candidates are widely available from numerous suppliers and are generally considered to be generic industrial biological supplies. We rely on a single approved supplier for certain materials relating to the current expression of our proprietary biotherapeutic proteins through ProCellEx. We have identified additional suppliers for most of the materials required for the production of our product candidates.

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 continue 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 further 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.

There are two approved ERTs for the treatment of Fabry disease; Fabrazyme which is marketed by Genzyme and Replagal, which is marketed by Shire. Fabrazyme is available in the United States and the European Union. Replagal is available in the European Union. In addition, we are aware of other clinical stage, early clinical stage and experimental drugs which are being developed for the treatment of Fabry disease by Amicus Therapeutics, Inc. and other companies.

With respect to PRX-110 AIR DNase, we face competition from Genentech Inc., a member of the Roche Group, which markets Pulmozyme®, and from the producers of CFTR protein potentiation such as Vertex Pharmaceuticals Incorporated (Kalydeco® and Orkambi®).

With respect to PRX-106, we face competition from AbbVie Inc. (Humira®), Johnson & Johnson and Merck & Co. (Remicade) and Pfizer and Amgen Inc. (Enbrel).

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. (which was acquired by Johnson & Johnson during 2010), Shire and GlycoFi, Inc. (which was acquired by Merck & Co. Inc.). Other companies are developing alternate plant-based technologies, include, among others, iBio, Inc., Medicago Inc., and Greenovation Biotech GmbH, none of which are cell-based. Rather, such companies base their product development on transgenic plants or whole plants.

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, results of operations and financial condition.”

Scientific Advisory Board

We have reorganized our scientific advisory board by establishing a core team of advisors. The scientific advisory board may invite additional experts to attend meetings on a case-by-case basis. Members of our scientific advisory board consult with our management within their professional areas of expertise; exchange strategic and business development ideas with our management; attend scientific, medical and business meetings with our management, such as meetings with the FDA and comparable foreign regulatory authorities, meetings with strategic or potential strategic partners and other meetings relevant to their areas of expertise; and attend meetings of our scientific advisory board. We expect our scientific advisory board to convene at least twice annually, and we frequently consult with the individual members of our scientific advisory board. Our scientific advisory board currently includes the following people:

Name	**Affiliations (selected)**
Roger D. Kornberg, Ph.D. (Chairman)	Laureate of the Nobel Prize in Chemistry
	Member, U.S. National Academy of Sciences
	Winzer Professor of Medicine, Department of Structural Biology at Stanford University
	2001 Welch Prize (highest award granted in the field of chemistry in the United States)

	2002 Leopold Mayer Prize (the highest award granted in the field of biomedical sciences from the French Academy of Sciences)
	Laureate of the Nobel Prize in Chemistry
Professor Aaron Ciechanover, M.D., D.Sc.	Distinguished research Professor at the Cancer and Vascular Biology Research Center of the Rappaport Research Institute and Faculty of Medicine at the Technion, Israel's Institute of Technology
	American Academy of Arts and Sciences, Member
	Wolfson Family Professor of Biochemistry in the Department of Biological Chemistry of The Alexander Silberman Institute of Life Sciences, Hebrew University of Jerusalem
	American Association for Cancer Research, 2013 Award for Outstanding Achievement in Chemistry in Cancer Research.
	1990 Israel Prize in Biochemistry
Alexander Levitzki, Ph.D.	1990 Rothschild Prize in Biology
	2002 Hamilton-Fairley Award, European Society of Medical Oncology
	2005 Wolf Prize for Medicine
	2012 Nauta Award in Pharmacochemistry, The European Federation of Medicinal Chemistry (EFMC) (the highest award from the European Federation for Medicinal Chemistry)

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	Regent’s Profession and Florence Ely Nelson Presidential Chair
	Biodesign Institute, CIDV, Arizona State University
	Member, National Academy of Sciences, USA
	American Society of Plant Biology Leadership in Science Public Service Award (2004)
Charles J. Arntzen, Ph.D.	Botanical Society of America Centennial Award (2006)
	Fellow of American Society of Plant Biologists (2007)
	Doctor of Science *honoris causa.*, Hebrew University of Jerusalem
	Chair, Section O “Agriculture, Food, and Renewable Resources,” American Association for the Advancement of Science (AAAS) (2011-2012)

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, or NDA, or a BLA is submitted to the FDA for 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. 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. If a significant therapeutic advantage over existing treatments is shown in the marketing application, the FDA may grant orphan drug approval and provide a seven-year period of marketing exclusivity.

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 or BLA 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 or BLA 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 or BLA. We used the rolling submission option for our taliglucerase alfa NDA, which we completed in April 2010.

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.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Key provisions of PPACA specific to the pharmaceutical industry, among others, include the following:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents into the United States, apportioned among these entities according to their market share in certain federal government healthcare programs (excluding sales of any drug or biologic product marketed for an orphan indication), beginning in 2011;

- An increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

- A new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;

- Extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;

- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective January 2010;

- New requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013;

- A new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

- A licensure framework for follow-on biologic products; and

- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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 MOH 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 EMA. 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 EU regulations and must allow the reviewer to evaluate the quality, safety and efficacy of the medicinal product. 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.

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

The income of Protalix Ltd., other than income from “Approved Enterprises,” is taxed in Israel at the regular rates which were 25% in 2013 and 26.5% for 2014 and 2015.

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No. 216) was published, enacting a reduction of corporate tax rate beginning in 2016 and thereafter, from 26.5% to 25%.

Capital gains on the sale of assets are subject to capital gain tax according to the corporate tax rate in effect in the year which the assets are sold.

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%.

Law for the Encouragement of Capital Investments, 1959

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

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, the percentage of foreign investments is determined based on the percentage of foreign investment in the parent company. The tax rates and related levels of foreign investments are set forth in the following table:

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

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

qualify for its benefits.

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.

Under 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 14 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 manner that maximizes utilization of the potential benefits available under the Investment Law.

From time to time, the Israeli Government has considered 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

To date, Protalix Ltd. has received grants from the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor, or the OCS, for the financing of a portion of its research and development expenditures in Israel. As of December 31, 2015, the OCS approved grants in respect of Protalix Ltd.'s continuing operations totaling approximately $41.8 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, 2015, Protalix Ltd. either paid or accrued royalties payable of $7.8 million and Protalix Ltd.'s contingent liability to the OCS with respect to grants received was approximately $33.3 million.

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

Additionally, under the Research Law, Protalix Ltd. is prohibited from transferring the OCS-financed technologies and related intellectual property rights outside of the State of Israel, except under limited circumstances and only with the approval of the OCS' Research Committee. 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 assurance can be made that approval to any such transfer, if requested, will be granted.

Under the Research Law, 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 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 a 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.

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.

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 and incorporated 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” operating in Israel (including Judea & Samara territories and the Gaza strip), 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, 2015, we had 223 employees, of whom 29 have a Ph.D. or an M.D.in their respective scientific fields. We believe that our relations with these employees are good. 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, or Expansion Orders, that apply to types of industries or employees including ours. 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."

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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. We were originally incorporated in the State of Florida in April 1992, and Protalix Ltd., our wholly-owned subsidiary and sole operating unit, is an Israeli company and was originally incorporated in Israel 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 registered 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. We make available on our website, free of charge, our Commission filings, including our Annual Reports 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 from time to time 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.

We are also listed on the Tel Aviv Stock Exchange, or the TASE, and, accordingly, we submit copies of all our filings with the Commission to the Israeli Securities Authority and the TASE. Such copies can be retrieved electronically through the TASE's internet messaging system (www.maya.tase.co.il) and through the MAGNA distribution site of the Israeli Securities Authority (www.magna.isa.gov.il).

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, free of charge, to any shareholder who requests a copy by addressing a request to:

Protalix BioTherapeutics, Inc.

2 Snunit Street, Science Park

P.O. Box 455

Carmiel 20100, Israel

Attn: Mr. Yossi Maimon, Chief Financial Officer

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Item 1A. Risk Factors

You should carefully consider the risks described below together with the other information included in this Annual Report on Form 10-K. Our business, financial condition or results of operations could be adversely affected by any of these risks. If any of these risks occur, the value of our common stock could decline.

Risks Related to Our Financial Condition and Capital Requirements

We currently have no significant product revenues and may 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 not generated significant revenues from product sales and only minimal revenues from research and development services and other fees, other than the milestone and other payments we have received in connection with our license and supply agreement with Pfizer. For the years ended December 31, 2015, 2014 and 2013, we had net losses from continuing operations of $27.3 million, $33.3 million and $34.7 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. We fund all of our operations and capital expenditures from the revenues we generate from licensing fees and grants, the net proceeds of equity or debt offerings and other sources. Based on our current plans and capital resources, we believe that our cash and cash equivalents will be sufficient to enable us to meet our planned operating needs for at least 12 months. However, changes may occur that could consume our existing capital at a faster rate than projected, including, among others, the cost and timing of regulatory approvals, changes in the progress of our research and development efforts 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 source 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 delays in achieving profitability, if at all, will 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 losses for the foreseeable future. We also expect to continue to incur significant operating expenditures, and we anticipate that our expenses will increase 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; and
- seek to license-in additional technologies.

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 foreseeable future, if at all. Delays in achieving profitability, or subsequent failures to maintain profitability, will have a material adverse effect on our business and results of operations and could negatively impact the value of our common stock.

Risks Related to Clinical Trials and Regulatory Matters

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, results of operations and financial condition.

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, all of our other drug candidates are in the clinical, preclinical or research stages and 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:

- slower than expected rates of patient recruitment, particularly with respect to trials of rare diseases such as Fabry disease;
- determination of dosing issues;
- unforeseen safety issues;
- lack of effectiveness during clinical trials;
- 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, results of operations and financial condition. 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 a clinical trial may have a material adverse effect on our business, results of operations and financial condition.

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 NDAs and BLAs with the FDA, or other filings with other foreign regulatory authorities, 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, results of operations and financial condition.

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.

Some of the diseases or disorders that our drug candidates are intended to treat, such as Fabry disease, are relatively rare and we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Our clinical trials generally mandate that a patient cannot be involved in another clinical trial for the same indication. Therefore, subjects that participate in ongoing clinical trials for products that are competitive with our drug candidates are not available for our clinical trials. An 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 will have a material adverse effect on our business, results of operations and financial condition.

Patients may discontinue their participation in our clinical trials, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.

Patients enrolled in our clinical trials may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged related to our drug candidates under evaluation. The discontinuation of patients in any one of our studies may cause the results from that study not to be positive or to not support a filing for regulatory approval of the applicable drug candidate, which would have a material adverse effect on our business, results of operations and financial condition.

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 anticipated NDAs, BLAs and other marketing applications, 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.

We are subject to extensive governmental regulation including the requirement of FDA or comparable approval before our drug candidates may be marketed.

Both before and after approval of our drug candidates, we, our drug candidates, our suppliers, our contract manufacturers and our contract testing laboratories are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. Failure to comply with applicable requirements of the FDA or comparable foreign regulatory authorities could result in, among other things, any of the following actions:

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in the FDA's or other foreign regulatory authorities' approving, or the refusal of any regulatory authority to approve, any drug candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

In addition to the approval requirements, other numerous and pervasive regulatory requirements apply, both before and after approval, to us, our drug candidates, and our suppliers, contract manufacturers, and contract laboratories. These include requirements related to:

- testing;
- manufacturing;
- quality control;
- labeling;
- advertising;
- promotion;
- distribution;
- export;
- reporting to the FDA certain adverse experiences associated with use of the drug candidate; and
- obtaining additional approvals for certain modifications to the drug candidate or its labeling or claims.

We also are subject to inspection by the FDA and comparable foreign regulatory authorities, to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories, and there can be no assurance that the FDA or any other comparable foreign regulatory authority, will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. We may be required to make modifications to our manufacturing operations in response to these inspections which may require significant resources and may have a material adverse effect upon our business, results of operations and financial condition.

The approval process for any drug candidate may also be delayed by changes in government regulation, future legislation or administrative action or changes in policy of the FDA and comparable foreign authorities that occur prior to or during their respective regulatory reviews 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 any regulatory-related milestone payments payable under outstanding collaboration agreements;
- 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.

Delays in the approval process for any drug candidate may have a material adverse effect upon our business, results of operations and financial condition.

We may not obtain the necessary U.S., EMA or other 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, results of operations and financial condition.

We need FDA approval to commercialize our drug candidates in the United States, EMA approval to commercialize our drug candidates in the European Union and approvals from other 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 an NDA or 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. In the European Union, we must submit an MAA to the EMA. Satisfaction of the FDA's, the EMA's and foreign regulatory authorities' regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the drug candidate and requires substantial resources for research, development and testing. Even if we comply with all the requests of regulatory authorities, the authorities may ultimately reject the marketing applications that we file for our product candidates in the future, if any, or we might not obtain regulatory clearance in a timely manner. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings or other comparable authorities for such clinical trials. Further, even if favorable testing data is generated by the clinical trials of a drug candidate, the applicable regulatory authority may not accept or approve the marketing application filed by a pharmaceutical or biotechnology company for the drug candidate. Failure to obtain approval of the FDA, EMA or comparable foreign authorities of any of our drug candidates in a timely manner, if at all, will severely undermine our business, financial condition and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues.

Our research and clinical efforts may not result in drugs that the FDA, EMA or foreign regulatory authorities consider safe for humans and effective for indicated uses, which would have a material adverse effect on our business, results

of operations and financial condition. After clinical trials are completed for any drug candidate, if at all, the FDA, EMA and foreign regulatory authorities have substantial discretion in the drug approval process of the drug candidate in their respective jurisdictions and may require us to conduct additional clinical testing or perform post-marketing studies which would cause us to incur additional costs. Incurring such costs may have a material adverse effect on our business, results of operations and financial condition.

We have only limited experience in regulatory affairs, and some of our drug candidates may be based on new technologies. These factors may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals for medical devices and drug candidates. Moreover, some of the drug candidates that are likely to result from our development programs may be based on new technologies that have not been extensively tested in humans. The regulatory requirements governing these types of drug candidates may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any products that we develop.

If any of our other competitors are able to obtain orphan drug exclusivity for any products that are competitive with our products, we may be precluded from selling or obtaining approval of our competing products by the applicable regulatory authorities for a significant period of time.

In the United States, the European Union and other countries, a drug may be designated as having orphan drug status, subject to certain conditions. There can be no assurance that a drug candidate that receives orphan drug designation will receive orphan drug marketing exclusivity and more than one drug can have orphan designation for the same indication.

Foreign regulations regarding orphan drugs are similar to those in the United States but there are several conceptual differences. For example, the exclusivity period in the European Union is generally 10 years. From time to time, we may apply to the FDA or any comparable foreign regulatory authority for orphan drug designation for any one or more of our drug candidates. None of our currently developed drug candidates have been designated as an orphan drug and there is no guarantee that the FDA or any other regulatory authority will grant such designation in the future. In addition, neither orphan drug designation nor orphan drug exclusivity prevents competitors from developing or marketing different drugs for that indication. Even if we obtain orphan drug exclusivity for one or more indications for one of our drug candidates, we may not be able to maintain the exclusivity. For example, if a competitive product that is the same drug or biologic as one of our drug candidates is shown to be clinically superior to the drug candidate, any orphan drug exclusivity granted to the drug candidate will not block the approval of the competitive product.

Risks Related to Our Business

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

Taliglucerase alfa is our only product with commercial approvals. The successful commercialization of our other drug candidates will require us to perform a variety of functions, including:

- continuing to perform 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. These operations provide a limited basis for investors to assess our ability to commercialize our drug candidates and whether to invest in our company.

Any failure by us to supply drug substance to Pfizer may have a material adverse effect on our business, results of operations and financial condition.

Under our Amended Pfizer Agreement, was have agreed, for the first 10-year period after the execution of the agreement, to sell drug substance to Pfizer for the production of Elelyso, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods subject to certain terms and conditions. As part of that obligation, we agreed to substantial financial penalties in case we fail to comply with the supply commitments, or are delayed in doing so. The amounts of the penalties depend on when any such failure occurs and for how long it persists, if at all, and other considerations. If any such failure to comply with the supply commitments under the Amended Pfizer Agreement may have a material adverse effect on our business, results of operations and financial condition.

Our strategy, in certain 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 certain 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. If we or any of our current or future 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, which may have a material adverse effect on our business, results of operations and financial condition.

If we are unable to develop and commercialize our 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 seek 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:

- a product candidate is not capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted by patients, the medical community or third-party payors;
- competitors may develop alternatives that render our product candidates obsolete;
- the research methodology used may not be successful in identifying potential product candidates; or
- 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.

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.

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, results of operations and financial condition.

Our ProCellEx protein expression system is based on our proprietary plant cell-based expression technology. The success of our business is dependent upon the successful development and approval of our product and product candidates produced through this technology. Although taliglucerase alfa is produced through ProCellEx, the technology remains novel. Accordingly, the technology remains subject to certain risks. Mammalian cell-based protein expression systems have been used in connection with recombinant therapeutic protein expression for more than 20 years and are the subject of a wealth of data; in contrast, there is not a significant amount of data generated regarding plant cell-based protein expression and, accordingly, plant cell-based protein expression systems may be subject to unknown risks. In addition, the protein glycosilation pattern created by our protein expression system is not identical to the natural human glycosilation pattern and, although to date clinical data for up to five years of follow-up on taliglucerase alfa has not demonstrated any sign of any effect, the longer term effect of the protein glycosilation pattern created by our protein expression system on human patients, if any, 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, results of operations and financial condition.

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. To date, our current facility has passed audits by the FDA and a number of other regulatory authorities but remains subject to audit by other foreign regulatory authorities. 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 facility we may establish in the future, and the failure to so comply will have a material adverse effect on our business, results of operations and financial condition.

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

We have no experience in the final filling and freeze drying steps of the drug manufacturing process. We have engaged a European contract manufacturer to act as an additional source of fill and finish activities for taliglucerase alfa and have engaged other parties for our product candidates. We currently rely primarily on 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/or 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 manufacturer and/or 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. In addition, contract manufacturers are subject to the rules and regulations of the FDA and comparable foreign regulatory authorities and face the risk that any of those authorities may find that they are not in compliance with applicable regulations. 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 and 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.

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

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. See Business – Competition.

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 marketing approvals from the FDA and other regulatory authorities;
- 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, results of operations and financial condition.

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 candidate, 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 materially and adversely impact our business, results of operations and financial condition.

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

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 materially and adversely 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 of 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, Moshe Manor, as well as the Chairman of our Board of Directors, Shlomo Yanai, our other 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, clinical development and regulatory programs. We have employment agreements with Moshe Manor and our other executive 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, the applicable noncompetition provisions can be difficult and costly to monitor and enforce. The loss of any of these persons' services may 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 medical experts, 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 regarding 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, which may have a material adverse effect on our business, results of operations and financial condition.

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 substantially 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, which may have a material adverse effect on our business, results of operations and financial condition.

Our internal computer systems, or those used by our third-party contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our present and future contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

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

The clinical testing, marketing and use of our products and product candidates exposes us to product liability claims if the use or misuse of those products or product candidates cause injury or disease, or results in adverse effects. Use of our products or product candidates, whether in clinical trials or post approval, could result in product liability claims. We presently carry clinical trial liability insurance with coverages of up to $10.0 million per occurrence and $10.0 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 product candidates; 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, may adversely affect our cash available for other purposes, such as research and development, which may have a material adverse effect on our business, results of operations and financial condition. Product liability claims, even if without merit, may result in reduced demand for our products, if approved, which would have a material adverse effect on our business, results of operations and financial condition. In addition, the existence of a product liability claim could affect the market price of our common stock.

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 healthcare expenditures 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 result in 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. Legislation passed in recent years has imposed certain changes to the way in which drugs, including our product candidates, are covered and reimbursed in the United States. For example, federal legislation and regulations have implemented new reimbursement methodologies for certain drugs, created a voluntary prescription drug benefit, Medicare Part D, and have imposed significant revisions to the Medicaid Drug Rebate Program. The PPACA imposes yet additional changes to these programs. 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 member states, 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, results of operations and financial condition. 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 which could have a material adverse effect on our business, results of operations and financial condition.

Our ability to utilize net operating loss carryforwards may be limited.

Our net operating loss carryforwards, or "NOLs," as of December 31, 2015, are equal to approximately $124 million, of which approximately $19 million may be restricted under Section 382 of the Internal Revenue Code of 1986, as amended, or the "Code." Section 382 of the Code imposes limitations on a corporation's ability to utilize NOLs to offset taxable income if the corporation experiences an "ownership change." In general terms, an "ownership change" may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50% over a three-year period. In the event that an ownership change has occurred, or were to occur, utilization of our NOLs would be subject to an annual limitation under Section 382, which is generally the fair market value of the pre-change entity multiplied by the long-term tax exempt rate, which is published monthly by the Internal Revenue Service.

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, results of operations and financial condition.

Risks Related to the Commercialization of Drug Products

Fiocruz may not comply with the terms and conditions of the Supply and Technology Transfer Agreement.

Uplyso was first approved for marketing in Brazil in March 2013. Under our Supply and Technology Transfer Agreement with Fiocruz, we are not required to complete the final stage of the technology transfer for the production of Uplyso until Fiocruz purchases at least approximately $280 million worth of Uplyso. However, we do not control and may not be able to effectively influence Fiocruz's ability to distribute Uplyso in Brazil. If Fiocruz fails to comply with the purchase requirements of the Supply and Technology Transfer Agreement, we may terminate the agreement and market Uplyso in Brazil on our own. Any failure by Fiocruz to comply with the purchase requirements of the Supply and Technology Transfer Agreement, or any other material breach by Fiocruz of the agreement, may have a material adverse effect on our business, results of operations and financial condition.

Fiocruz's purchases of Uplyso to date have been significantly below certain agreed upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, we are, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. We are discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, we will determine what we believe to be the course of action that is in the best interest of our company.

We cannot accurately predict the amount of revenues we will generate under our Supply and Technology Transfer with Fiocruz in future periods, if any. Any failure by Fiocruz to distribute Uplyso in Brazil, or the experience of significant delays in doing so, may have a material adverse effect on our business, results of operations and financial condition.

We have limited experience in selling, marketing or distributing products and limited internal capability to do so.

We currently have very limited sales, marketing or distribution capabilities and no experience in building a sales force and distribution capabilities. If we market any of our other products directly, if any, 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:

- the inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to an adequate numbers of physicians or to pursuance them 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 or retaining the sales and marketing personnel necessary to sell any of our products upon approval, if at all, which would have a material adverse effect on our business, results of operations and financial condition.

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.

We will need to establish a sales force to market our product candidates, if approved. We do not anticipate having the resources in the foreseeable future to develop global sales and marketing capabilities for all of the products we are developing. We may pursue arrangements regarding the sales and marketing and distribution of one or more of our product candidates, and our future revenues may depend, in part, on our ability to enter into and maintain arrangements with other companies having sales, marketing and distribution capabilities and the ability of such companies to successfully market and sell any such products. Any failure to enter into such arrangements and

marketing alliances on favorable terms, if at all, could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. 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.

If physicians, patients, third party payors and others in the medical community do not accept and use taliglucerase alfa, or any of our other product candidates, if approved, our ability to generate revenue from product sales will be materially impaired.

Physicians and patients, and other healthcare providers, may not accept and use taliglucerase alfa or any of our other product candidates, if approved for marketing. Future acceptance and use of taliglucerase alfa or any of our other product candidates, if approved, 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 taliglucerase alfa or our other 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 benefits of taliglucerase alfa or our other drug candidates 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 taliglucerase alfa or our other drug candidates or competing products and treatments;
- coverage and reimbursement of our products by third party payors; and
- the price for our products and competing products.

A lack of market acceptance of taliglucerase alfa in Brazil, or globally for any of our other products candidates, if approved, would have a material adverse effect on our business, results of operations and financial condition.

If the market opportunities for other product candidates, and for taliglucerase alfa in Brazil, are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

To date, our development efforts have focused mainly 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.

Coverage and reimbursement may not be available for taliglucerase alfa or any of our other product candidates, if approved, in all territories which could diminish our sales or affect our ability to sell taliglucerase alfa or any other products profitably.

Market acceptance and sales of taliglucerase alfa in Brazil, or for any of our other product candidates globally, if approved, will depend on coverage and reimbursement policies in the countries in which they are approved for sale. 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. Obtaining reimbursement approval for an approved product from governments and other third party payors is a time consuming and costly process that requires our collaborators or us, as the case may be, 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 coverage and reimbursement or we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of approved products, if any, to such payors' satisfaction. Such studies might require our collaborators or 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, 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, limited reimbursement amounts may 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 covered and reimbursed by government or third-party payors. If coverage and reimbursement are not available or are 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.

We and our collaborating partners may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. If we or our collaborating partners are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

All marketing activities associated with drug products that are approved for sale in the United States, if any, will be, directly or indirectly through our customers, subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products in the United States, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and HIPAA. These laws may adversely impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of co-payments and deductibles, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other state or federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages

sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. Moreover, to the extent that taliglucerase alfa, or any of our products, if approved for marketing, will be sold in a foreign country, we and our future collaborators, may be subject to similar foreign laws and regulations. If we or any of our future collaborators are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring or our operations, any of which could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Intellectual Property Matters

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, 2015, we had 67 pending patent applications and eight joint pending patent applications with a third party. 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, results of operations and financial condition. 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 and other product candidates. 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, 2015, we held, or had license rights to, 67 patents. If patent rights covering our products or technologies 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, and the patents that may be issued in the future based on patent applications from the patent families, relating to our ProCellEx protein expression system are expected to expire between 2017 and 2025.

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 and 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 may 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, results of operations and financial condition.

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, results of operations and financial condition.

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 product candidates. 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, results of operations and financial condition.

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 and product development. 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. Starting in December 2008, for approximately three weeks, Israel engaged in an armed conflict with Hamas in the Gaza Strip. Armed conflicts have taken place between Israel and Hamas in the Gaza Strip in 2008, 2012 and 2014. Our facilities in northern Israel are in range of rockets that were fired from Lebanon into Israel during a 2006 war with the Hizbollah in Lebanon, and suffered minimal damages during one of the rocket attacks. Our insurance policies do not cover us for the damages incurred in connection with these conflicts or for any resulting disruption in our operations. The Israeli government, as a matter of law, provides coverage for the reinstatement value of direct damages that are caused by terrorist attacks or acts of war; however, the government may cease providing such coverage or the coverage might not be enough to cover potential damages. If our facilities are damaged as a result of hostile action, our operations may be materially adversely affected.

In addition to the foregoing, since the end of 2010, numerous acts of protest and civil unrest have taken place in several countries in the Middle East and North Africa, many of which involved significant violence. Civil unrest in Egypt, which borders Israel, has resulted in significant changes to the country’s government. There is currently a civil war in Syria, also bordering Israel, and Israel has been hit by rockets and mortars originating from Syria. The ultimate effect of these developments on the political and security situation in the Middle East and on Israel’s position within the region is not clear at this time.

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. Although most of our expenses are incurred in U.S. dollars, we pay a portion of our expenses in New Israeli Shekels, or NIS, and 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.

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 Research Law. Under the Research Law we 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. We may not receive the required approvals for any proposed transfer of manufacturing activities. Even if we do receive approval to manufacture products developed with government grants outside of Israel, we may 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. This restriction may impair our ability to outsource manufacturing or engage in similar arrangements for those products or technologies.

Additionally, under the Research Law, we are 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 OCS' Research Committee. We may not receive the required approvals for any proposed transfer and, if received, we may be required to pay the OCS a portion of the consideration that we receive upon any sale of such technology by a non-Israeli entity. The scope of the support received, the royalties that we have 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 assurance can be made that approval to any such transfer, if requested, will be granted.

These restrictions may impair our ability to sell our technology assets or to outsource manufacturing outside of Israel. The restrictions will continue to apply for a certain period of time even after we have repaid the full amount of royalties payable for the grants. For the years ended December 31, 2014 and 2015, we recorded grants totaling $5.1 million and $4.9 million from the OCS, respectively. The grants represent 18.7% and 19.5%, respectively, of our gross research and development expenditures for the years ended December 31, 2014 and 2015. If we fail to satisfy the conditions of the Research Law, we may be required to refund certain grants previously received together with interest and penalties, and may become subject to criminal charges, any of which could have a material adverse effect on our business, results of operations and financial condition.

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 all of our executive officers are residents of Israel, and accordingly, 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 results of our ongoing studies regarding PRX-102 and our other product candidates;
- announcements regarding partnerships or collaborations by us or our competitors;
- purchases of Uplyso by Fiocruz;
- developments concerning intellectual property rights and regulatory approvals;
- the announcement of new products or product enhancements by us or our competitors;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities 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.

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. A substantial majority of our 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, 2015, there were options to purchase common stock issued and outstanding and unvested restricted shares covering 7,717,376 shares of our common stock with a weighted average exercise price of $3.99 per share. Also at December 31, 2015, there were 760,844 shares of common stock remaining available for future for issuance in connection with future grants of incentives under our amended 2006 stock incentive plan.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to pay interest on, or to make any scheduled payment of the principal of, our 2018 4.5% convertible notes, or the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. If we raise additional debt, it would increase our interest expense, leverage and operating and financial costs. In addition, the terms of the indenture governing the Notes and the agreements governing future indebtedness may restrict us from adopting any of these alternatives. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. The failure to generate sufficient cash flow or to effect any of these alternatives could significantly adversely affect the value of the Notes and our ability to pay amounts due under the Notes.

Our significant level of indebtedness could adversely affect our business, results of operations and financial condition and prevent us from fulfilling our obligations under the Notes and our other indebtedness.

The outstanding Notes represent a significant amount of indebtedness with substantial debt service requirements. We may also incur additional indebtedness to meet future financing needs. Our substantial indebtedness could have material adverse effects on our business, results of operations and financial condition. For example, it could:

- make it more difficult for us to satisfy our financial obligations, including with respect to the Notes;

- result in an event of default if we fail to comply with the financial and other restrictive covenants contained in agreements governing any future indebtedness, which event of default could result in all of our debt becoming immediately due and payable;
- increase our vulnerability to general adverse economic, industry and competitive conditions;
- reduce the availability of our cash flow to fund working capital, capital expenditures, acquisitions and other general corporate purposes because we will be required to dedicate a substantial portion of our cash flow from operations to the payment of principal and interest on our indebtedness;
- limit our flexibility in planning for, or reacting to, and increasing our vulnerability to changes in our business, the industry in which we operate and the general economy;
- prevent us from raising funds necessary to purchase Notes surrendered to us by holders upon a fundamental change (as described in the indenture governing the Notes), which failure would result in an event of default with respect to the Notes;
- place us at a competitive disadvantage compared to our competitors that have less indebtedness or are less highly leveraged and that, therefore, may be able to take advantage of opportunities that our debt levels or leverage prevent us from exploiting; and
- limit our ability to obtain additional financing.

Each of these factors may have a material and adverse effect on our business, results of operations and financial condition and our ability to meet our payment obligations under the Notes and our other indebtedness. Our ability to make payments with respect to the Notes and to satisfy any other debt obligations depends on our future operating performance and our ability to generate significant cash flow in the future, which will be affected by prevailing economic conditions and financial, business, competitive, legislative and regulatory factors as well as other factors affecting our company and industry, many of which are beyond our control.

Any conversion of the Notes will dilute the ownership interest of our existing stockholders, including holders who had previously converted their notes.

The conversion of some or all of the Notes will dilute the ownership interests of our existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could depress the price of our common stock.

Our common stock is listed for trade on more than one stock exchange, and this may result in price variations.

Our common stock is listed for trade on both the NYSE MKT and the TASE. Dual-listing may result in price variations between the exchanges due to a number of factors. First, our common stock is traded in U.S. dollars on the NYSE MKT and in NIS on the TASE. In addition, the exchanges are open for trade at different times of the day and on different days. For example, the TASE opens generally during Israeli business hours, Sunday through Thursday,

while the NYSE MKT opens generally during U.S. business hours, Monday through Friday. The two exchanges also have differing vacation schedules. Differences in the trading schedules, as well as volatility in the exchange rate of the two currencies, among other factors, may result different trading prices for our common stock on the two exchanges. Other external influences may have different effects on the trading price of our common stock on the two exchanges.

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 38.3% 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 MKT 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, results of operations and financial condition.

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.

Under the rules of the TASE, other than incentives under our amended 2006 stock incentive plan, we were prohibited from issuing any securities of any class or series different than the common stock that is listed on the TASE for the 12-month period immediately succeeding our initial listing, which occurred on September 6, 2010. As of the date hereof, the rules of the TASE allow us to issue securities with preferential rights with respect to dividends but such other securities may not include voting rights. The foregoing does not limit our liability to issue and grant options and warrants for the purchase of shares of our common stock.

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 20,000 sq/ft of manufacturing space and additional 48,000 sq/ft of laboratory, warehouse and office space and are leased at a rate of approximately $85,000 per month. In addition, we are entitled to use an additional 13,000 sq/ft in the same facility, which we intend to utilize in connection with an anticipated expansion of our manufacturing facilities. 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 2016, 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 $2,500 per month.

Item 3. Legal Proceedings

We are not involved in any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Our common stock is traded on the NYSE MKT (formerly, the American Stock Exchange) under the symbol "PLX." Our common stock is also listed on the TASE under the symbol "PLX." The following table sets forth the quarterly high and low closing prices for our common stock on the NYSE MKT.

	Price Range	
	High	**Low**
Fourth Quarter 2015	$1.14	$0.78
Third Quarter 2015	$1.96	$1.18
Second Quarter 2015	$2.24	$1.80
First Quarter 2015	$2.34	$1.72
Fourth Quarter 2014	$2.65	$1.80
Third Quarter 2014	$3.60	$2.37
Second Quarter 2014	$4.84	$3.65
First Quarter 2014	$5.26	$3.85

These quotations reflect prices between dealers and do not include retained mark-ups, mark-downs and commissions and may not necessarily represent actual transactions. There were approximately 83 holders of record of our common stock at March 1, 2016. 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, 2010 through December 31, 2015 to the cumulative return over such time period of (i) The NYSE MKT Composite Index and (ii) The Nasdaq Biotechnology Index. The graph assumes an investment of $100 on December 31, 2010 in each of our common stock, the stocks comprising the NYSE MKT Composite Index and the stocks comprising the Nasdaq 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. Notwithstanding anything to the contrary set forth in any of our previous filings under the Securities Act 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.

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Item 6. Selected Financial Data

The selected consolidated financial data below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. The selected consolidated statements of operations data for the years ended December 31, 2015, 2014 and 2013 and the selected consolidated balance sheet data as of December 31, 2015 and 2014, are derived from the audited consolidated financial statements included elsewhere in this Annual Report. The statement of operations data for the years ended December 31, 2012 and 2011 and the balance sheet data as of December 31, 2013, 2012 and 2011 are derived from audited financial statements not included in this Annual Report. We adopted, retrospectively, ASU 2014-08 during 2015 regarding discontinued operations which resulted in the reclassification of prior year amounts. The historical results presented below are not necessarily indicative of future results.

	Year Ended December 31,				
	2011	2012	2013	2014	2015
	(in thousands, except share and per share amounts)				
Consolidated Statement of Operations Data:					
Revenues	$-	$-	$-	$3,523	$4,364
Cost of revenues	-	-	-	630	730
Gross profit	-	-	-	2,893	3,634
Research and development expenses, net	17,792	23,224	26,012	22,224	20,025
Selling, general and administrative expenses	6,785	9,568	8,051	9,228	7,279
Financial income (expenses), net	2	554	(674)	(4,739)	(3,612)
Loss from continuing operations	$24,575	$32,238	$34,737	$33,298	$27,282
Income (loss) from discontinued operations	(11,954)	20,620	6,947	3,355	85,319
Net income (loss) for the year	(36,529)	(11,618)	(27,790)	(29,943)	58,037
Net income (loss) per share of common stock, basic and Diluted:					
Loss from continuing operations	$(0.29)	$(0.35)	$(0.38)	$(0.36)	$(0.29)
Income (loss) from discontinued operations	(0.14)	0.22	0.08	0.04	0.90
Net Income (loss) per share of common stock	(0.43)	(0.13)	(0.30)	(0.32)	0.61
Weighted average number of shares of common stock used in computing net loss per share of common stock	84,645,364	90,845,901	92,368,138	92,891,846	94,922,390
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$27,001	$52,035	$86,398	$54,767	$76,374
All other assets	24,804	26,692	26,935	23,590	20,879
Total assets	51,805	78,727	113,192	78,357	97,253
Current liabilities	18,693	25,755	26,696	64,354	11,235
Total liabilities	77,882	82,084	140,138	133,958	86,380
Total shareholders' equity (capital deficiency)	(26,077)	(3,357)	(26,946)	(55,601)	10,873

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read "Risk Factors" in Item 1A of this Annual Report on Form 10-K 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. We developed our first commercial drug product, Elelyso™, using our ProCellEx system and we are focused on utilizing the system to develop a pipeline of proprietary, clinically superior versions of recombinant therapeutic proteins that primarily target large, established pharmaceutical markets and that in most cases rely upon known biological mechanisms of action. With our experience to date, we believe ProCellEx will enable us to develop additional proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications. We are now also applying the unique properties of our ProCellEx system for the oral delivery of therapeutic proteins.

On May 1, 2012, the FDA approved for sale our first commercial product, taliglucerase alfa for injection, an enzyme replacement therapy, or ERT, for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Subsequently, taliglucerase alfa was approved for marketing by the regulatory authorities of other countries. Taliglucerase alfa is being marketed under the name Uplyso™ in Brazil and certain other Latin American countries, and as Elelyso in all other territories.

Since its approval by the FDA, taliglucerase alfa has been marketed mainly in the United States by Pfizer, as provided in the exclusive license and supply agreement by and between Protalix Ltd., our wholly-owned subsidiary, and Pfizer. Under our current arrangement with Pfizer, which was amended in October 2015, Pfizer has the rights to market Elelyso globally except for Brazil, where we have the sole marketing rights; Pfizer is responsible for 100% of expenses, and entitled to all of the revenues, globally, for Elelyso, excluding Brazil, and we are responsible for all expenses and retain all revenues from sales in Brazil. Pfizer is no longer entitled to any payments with respect to sales of Elelyso in Brazil.

For the first 10-year period after the execution of the Amended Pfizer Agreement, we have agreed to sell drug substance to Pfizer for the production of Elelyso, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods subject to certain terms and conditions. The Amended Pfizer Agreement also includes provisions regarding cooperation for regulatory matters, supply of the drug substance to Pfizer, including provisions addressing failure to supply, and patent enforcement, and contains customary provisions regarding termination, indemnification and insurance requirements.

On October 12, 2015, we also entered into a Stock Purchase Agreement with Pfizer pursuant to which we issued 5,649,079 shares of our common stock for an aggregate purchase price equal to $10.0 million subject to certain other terms set forth in the Stock Purchase Agreement. As part of the Stock Purchase Agreement, Pfizer agreed to a 180-day lock-up with respect to the purchased shares of common stock.

On June 18, 2013, we entered into the Brazil Agreement with Fiocruz. Fiocruz's purchases of Uplyso to date have been significantly below certain agreed upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, we are, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. We are discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, we will determine what we believe to be the course of action that is in the best interest of our company.

We are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates:

(1) PRX-102, or alpha-GAL-A, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, currently in an ongoing phase I/II clinical trial. We expect to commence phase III clinical trials of PRX-102 during the first half of 2016 shortly after we finalize the ongoing special protocol assessment (SPA) process with the FDA in connection with our proposed protocol for the trial.

(2) PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or AIR DNase™, under development for the treatment of cystic fibrosis, to be administered by inhalation. We have commenced a phase I clinical trial of AIR DNase in healthy volunteers and intend to initiate a proof of concept efficacy study in patients in mid-year, 2016.

(3) OPRX-106, our oral antiTNF product candidate which is being developed as an orally-delivered anti-inflammatory treatment using plant cells as a natural capsule for the expressed protein. We concluded the phase I clinical trial, which demonstrated that the drug was safe and well tolerated, showing biological activity in the gut and inducement of regulatory T cells. We expect to initiate a proof of concept efficacy study in Ulcerative Colitis in mid-year, 2016.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Brazil), which we licensed to Pfizer, we hold the worldwide commercialization rights to all of our proprietary development candidates. In addition, we continuously evaluate potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutes.

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 on Form 10-K. 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 U.S. dollar. Most of our revenues are derived in dollars. In addition, most of our expenses and capital expenditures are incurred in dollars, and the major source of our financing has been provided in dollars.

Revenues

Until we entered into the Amended Pfizer Agreement, our sole source of revenues came from sales of taliglucerase alfa pursuant to our license with Pfizer, our sales of taliglucerase alfa in Israel and Brazil and from milestone payments under the Pfizer Agreement. Following entry into the Amended Pfizer Agreement, our primary source of revenues will be our sales of taliglucerase alfa in Brazil, which have not been substantial to date. We recognize revenue when the earnings process is complete, which is when revenue is realized or realizable and earned, there is persuasive evidence a revenue arrangement exists, delivery of goods or services has occurred, the sales price is fixed or determinable and collectability is reasonably assured.

We recognized revenue from milestone payments received pursuant to the Pfizer Agreement in accordance with guidance regarding revenue recognition and accounting for revenue arrangements with multiple deliverables. Pursuant to this guidance, we determined whether our arrangement with Pfizer 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 we 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. As the arrangement with Pfizer required our continued involvement with respect to the proposed commercialization of taliglucerase alfa, the non-refundable, up-front license payments we received from Pfizer to date have been deferred and recognized over the related performance period. For this purpose, we estimated the performance period of 14 years based on the date that the last relevant patent relating to taliglucerase alfa expires.

Under the terms and conditions of the initial Pfizer Agreement, we were entitled to 40% of the net profits or loss from sales of taliglucerase alfa by Pfizer and reimbursement of our certain related expenses we incur in connection with Pfizer’s sales (other than those related to sales in Israel and Brazil). We recognized our share of net profit or loss under the initial Pfizer Agreement (prior to its amendment) based on reports we receive from Pfizer summarizing the results of the collaborative activities under the former agreement for the applicable period. Under the terms of the initial Pfizer Agreement, for its subsidiaries operating outside the United States, financial information is included based on the fiscal year ending November 30, while financial information for the U.S. entity is included based on the fiscal year ending December 31.

We recognize revenues received from the sale of a product when the sales price is fixed or determinable and collectability is reasonably assured. The revenues represent our cost with respect to the product sold.

We recognize net product revenue from our sales of Elelyso in Israel when persuasive evidence of an arrangement exists, the product has been delivered to the customer, title and risk of loss have passed to the customer, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured. Product sale transactions

are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents. Amounts collected from customers and remitted to governmental authorities, which represents value-added taxes related to Elelyso sales in Israel, are presented on a net basis in our Consolidated Statements of Operations, in that taxes billed to customers are not included as a component of net product revenues.

Discontinued Operations

Pursuant to the Amended Pfizer Agreement, we sold to Pfizer our share in the collaboration created under the initial Pfizer Agreement for the commercialization of Elelyso. As part of the sale, we agreed to transfer our rights to Elelyso in Israel to Pfizer while gaining full rights to Elelyso in Brazil. Under the Amended Pfizer Agreement, Pfizer is responsible for 100% of expenses, and entitled to all of the revenues, globally, for Elelyso, excluding Brazil where we are responsible for all expenses and retain all revenues. The Amended Pfizer Agreement eliminates Pfizer's entitlement to annual payments of up to $12.5 million in relation to commercialization of Elelyso in Brazil. For further details please see notes 2 and 12 to the financial statements.

We accounted for the sale of our share in the collaboration created under the initial Pfizer Agreement, including the transfer of our rights to Elelyso in Israel, in accordance with ASU No. 2014-08.

The following assets and liabilities associated with our share in the former collaboration, including our rights to Elelyso in Israel, have been segregated and classified as assets and liabilities of discontinued operations, as appropriate, in the consolidated balance sheets as of December 31, 2014 and 2015, respectively (in thousands):

	December 31,	
	2014	2015
CURRENT ASSETS:		
Accounts receivable - Trade	$1,884	$1,993
Inventories*	3,216	80
Total current assets of discontinued operation	5,100	2,073
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$115	
Other	8,694	$1,568
Deferred revenues	43,109	
Liability in connection with collaboration operation	912	
Total current liabilities of discontinued operation	52,830	1,568

* During the years ended December 31, 2014 and 2015, we recorded approximately $1.6 million and $0, respectively, for write-down of inventory under the cost of revenues.

The following summarized financial information related to our share in the former collaboration, including our rights to Elelyso in Israel, have been segregated from continuing operations and have been reported as discontinued operations in our consolidated statements of operations (in thousands):

	Year ended December 31,		
	2013	2014	2015
REVENUES	$10,479	$10,128	$48,674
COMPANY'S SHARE IN COLLABORATION AGREEMENT	1,034	1,509	5,048
COST OF REVENUES	(5,428)	(8,423)	(7,697)
GROSS PROFIT	6,085	3,214	46,025
RESEARCH AND DEVELOPMENT EXPENSES	(4,088)	(2,409)	(586)
Less –reimbursements	5,284	2,983	545
RESEARCH AND DEVELOPMENT EXPENSES, NET	1,196	574	(41)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(334)	(433)	(564)
NET LOSS FOR THE YEAR FROM DISCONTINUED OPERATIONS	$6,947	$3,355	$45,420
GAIN ON THE DISPOSAL			39,899
NET INCOME	$6,947	$3,355	$85,319

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

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

Project	Status	Expected Near Term Milestones
PRX 102 – alpha-GAL-A	Phase I/II clinical trial, ongoing	Commence phase III clinical trials in the first half of 2016
PRX-110 – AIR DNase	Phase I clinical trial, ongoing	Initiate proof of concept efficacy study in mid-2016
OPRX-106 – Oral antiTNF	Phase I clinical trial	Initiate proof of concept efficacy study in mid-2016

We anticipate incurring increasing costs in connection with the continued development of all of the product candidates in our pipeline. 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—If we are unable to develop and commercialize our product candidates, our business will be adversely affected” and “—We may not obtain the necessary U.S., EMA or other 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, results of operations and financial condition.”

We expect our research and development expenses to continue to be our primary expense in the future as we continue the advancement of our clinical trials and preclinical product development programs for our product candidates. 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. Due to 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, results of operations and financial condition."

Share-Based Compensation

The discussion below regarding share-based compensation relates to our share-based compensation.

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 restricted shares of common stock granted to employees during the fiscal year ended December 31, 2013, our management used the fair value of our common stock which was the closing sale price of our common stock on the NYSE MKT on the date of grant.

The guidance requires 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.

The risk-free interest rate used in the valuation of the options is 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.

Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

Revenues

We recorded revenues of $4.4 million for the year ended December 31, 2015, an increase of approximately $841,000, or 24%, compared to revenues of $3.5 million for the year ended December 31, 2014. Revenues represent products sold in Brazil.

Cost of Revenues

Cost of revenues was $730,000 for the year ended December 31, 2015, an increase of $100,000, or 16%, compared to the cost of revenues of $630,000 for the year ended December 31, 2014. Cost of revenues consists primarily of products we sold in Brazil for which revenues were recognized during the period and royalties payable to the OCS and to a certain academic institution in connection with such sales.

Research and Development Expenses

Research and development expenses were $24.9 million for the year ended December 31, 2015, a decrease of $2.5 million, or 9% from $27.4 million for the year ended December 31, 2014. The decrease resulted primarily from a decrease of $2.3 million in costs related to salaries expense, mainly due to higher bonuses that were paid during the year ended December 31, 2014 and the devaluation of the New Israeli Shekel against the U.S. dollar during the period ended December 31, 2015.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $7.3 million for the year ended December 31, 2015, a decrease of $1.9 million, or 21%, from $9.2 million for the year ended December 31, 2014. The decrease resulted primarily from a decrease of $885,000 in sales and marketing expenses and $532,000 in costs related to salaries expense.

Financial Expenses and Income

Financial expenses were $3.6 million for the year ended December 31, 2015, compared to $4.7 million for the year ended December 31, 2014. Financial expenses resulted primarily from interest expense of $3.1 million for the notes. The decrease in financial expense resulted primarily from the devaluation of the New Israeli Shekel against the U.S. dollar during the year ended December 31, 2015 which was partially offset by financial income which resulted primarily from interest earned on short term deposits.

Year Ended December 31, 2014 Compared to the Year Ended December 31, 2013

Revenues

We recorded revenue of $3.5 million for the year ended December 31, 2014, and no revenues for the year ended December 31, 2013. Revenues for the year ended December 31, 2014 represent products sold in Brazil.

Cost of Revenues

Cost of revenues was $630,000 for the year ended December 31, 2014. Cost of revenues consists primarily of products we sold in Brazil for which revenues were recognized during the period, and royalties payable to the OCS and to a certain academic institution in connection with such sales.

Research and Development Expenses

Research and development expenses were $27.4 million for the year ended December 31, 2014, a decrease of $1.9 million, or 6% from $29.2 million for the year ended December 31, 2013. The decrease resulted primarily from a decrease of $1.5 million in payroll and related expenses primarily due to a decrease in share-based compensation and a decrease of $1.0 million in cost of materials.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $9.2 million for the year ended December 31, 2014, an increase of $1.2 million, or 15%, from $8.1 million for the year ended December 31, 2013. The increase resulted primarily from sales and marketing expenses of approximately $1.5 million, which was partially offset by a decrease of $470,000 in salaries expense.

Financial Expenses and Income

Financial expenses were $4.7 million for the year ended December 31, 2014, compared to $674,000 for the year ended December 31, 2013. Financial expenses resulted primarily from interest expense of $3.1 million for the 4.5% convertible note and from the devaluation of the New Israeli Shekel against the U.S. dollar in the amount of $1.5 million, which was partially offset by financial income which resulted primarily from interest earned on short term deposits.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of significant revenue from sales of taliglucerase alfa, we have generated operating losses from our continuing operations since our inception. To date, we have funded our operations primarily with proceeds equal to $31.3 million from the sale of shares of convertible preferred and ordinary shares of Protalix Ltd., and an additional $14.1 million in connection with the exercise of warrants issued in connection with the sale of such 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 and on each of March 23, 2011 and February 22, 2012, we generated gross proceeds of $22.0 million and $27.2 million, respectively, in connection with underwritten public offerings of our common stock. We believe that the funds currently available to us as are sufficient to satisfy our capital needs for at least 12 months.

The following table summarizes our public funding sources since 2007:

Security	Year	Number of Shares	Amount
Common Stock	2007	10,000,000	$50,000,000
Common Stock	2011	4,000,000	$22,000,000
Common Stock	2012	5,175,000	$27,168,750

In addition to the foregoing, on September 18, 2013, we completed a private placement of $69.0 million in aggregate principal amount of 4.50% convertible notes due 2018, or the Notes, including $9.0 million aggregate principal amount of Notes related to the offering's initial purchaser's over-allotment option, which was exercised in full.

Pfizer paid Protalix Ltd. $60.0 million as an upfront payment in connection with the execution of the Pfizer Agreement and subsequently paid to Protalix Ltd. an additional $5.0 million upon Protalix Ltd.'s meeting a certain milestone. Protalix Ltd. also received a milestone payment of $25.0 in connection with the FDA's approval of taliglucerase alfa in May 2012. Pfizer has also paid Protalix Ltd. $8.3 million in connection with the successful achievement of certain milestones under a clinical development agreement between Pfizer and Protalix Ltd. In connection with the execution of the Amended Pfizer Agreement, we received a $36.0 million payment from Pfizer, and Pfizer purchased 5,649,079 shares of our common stock for $10.0 million.

Cash Flows

Net cash used in operations was $24.2 million for the year ended December 31, 2015. The net loss from continuing operations for the year ended December 31, 2015 of $27.2 million was further increased by an increase of $2.3 million in inventories and a decrease of $1.9 million in accounts payable, but was partially offset by $2.4 million in depreciation and $1.8 million in share based compensation. Net cash provided by investing activities for the year ended December 31, 2015 was $39.4 million and consisted primarily of proceeds from the sale of our share in collaboration to Pfizer. Net cash provided by financing activities was $6.6 million and consisted primarily from the issuance of shares to Pfizer in connection with the sale of our share in collaboration to Pfizer. Net cash used in operations was $29.3 million for the year ended December 31, 2014. The net loss from continuing operations for the year ended December 31, 2014 of $33.3 million was further increased by an increase of $3.5 million in inventories, but was partially offset by $3.1 million in depreciation, $1.4 million in accounts payable. Net cash used in investing activities for the year ended December 31, 2014 was $1.0 million and consisted primarily of purchases of property and equipment.

Future Funding Requirements

We expect to continue to incur significant expenditures in the near future, including significant research and development expenses related primarily to the clinical trials of PRX-102 and the advancement of our other product candidates into anticipated later stage clinical trials.

We believe that our existing cash and cash equivalents will be sufficient for at least 12 months. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many factors, including our progress in commercializing Uplyso in Brazil, the progress and results of our clinical trials, 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, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

We may need to finance our future cash needs through corporate collaboration, licensing or similar arrangements, public or private equity offerings or debt financings. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. Any 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, 2013, 2014 or 2015.

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, 2013, 2014 or 2015.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2014 and 2015.

Recently Issued Accounting Pronouncements

Certain recently issued accounting pronouncements are discussed in Note 1(p) of the financial statements included in Item 8 of this Annual Report on Form 10-K.

Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2015:

(U.S. dollars in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Convertible notes	$78,315	$ 3,105	$75,210		-
Operating lease obligations	$1,651	$ 1,156	$495	-	-
Purchase obligations (1)	$1,673	$ 1,673			
Certain clinical contract	$765	$ 695	$70	-	-
Liability for employee rights upon retirement	$2,304				$ 2,304
Total	$84,708	$ 6,629	$75,775	-	$ 2,304

(1) Represents open purchase orders issued to certain suppliers and other vendors mainly in connection with our research and development activities that were outstanding as of December 31, 2015.

The foregoing table does not include (i) annual license fees, which are immaterial, (ii) payments we may be required to make to certain of our licensors in the time periods set forth above upon the achievement of agreed-upon milestones and (iii) royalty payments payable by us to certain of our licensors in connection with the commercial sale of our product candidates, if any. If all of the contingencies with respect to milestone payments under our research and license agreements are met, the aggregate milestone payments payable would be approximately $8.7 million and would be payable, if at all, as our projects progress over the course of a number of years. The royalty payments payable in connection with sales of each of our product candidates, if any, shall not exceed low, single-digit percentages of net sales of the product.

Selected Quarterly Financial Data (unaudited)

	Three Months Ended							
	2014				2015			
	(U.S. dollars in thousands)							
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31
Revenues	$3,523	-	-	-	$1,692	$1,336	$1,336	-
Gross profit	2,893	-	-	-	1,410	1,111	1,113	-
Loss from continuing operations	(7,749)	(7,370)	(9,754)	(8,425)	(6,513)	(6,183)	(6,015)	(8,571)
Income (loss) from discontinued operations	404	1,251	1,744	(44)	541	1,112	2,195	81,471
Net profit (loss) for the period	$(7,345)	$(6,119)	$(8,010)	$(8,469)	$(5,972)	$(5,071)	$(3,820)	$72,900
Earnings (loss) per share of common stock, basic and diluted:								
Loss from continuing operations	$(0.08)	$(0.08)	$(0.11)	$(0.09)	$(0.07)	$(0.06)	$(0.06)	$(0.08)
Income (loss) from discontinued operations	*	0.01	0.02	*	0.01	0.01	0.02	0.82
Net income (loss) per share of common stock	$(0.08)	$(0.07)	$(0.09)	$(0.09)	$(0.06)	$(0.05)	$(0.04)	$0.74

*represents amount less than $0.01

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. Most of our revenues and 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 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 loss 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,		
	2013	2014	2015
Average rate for period	3.611	3.578	3.887
Rate at year-end	3.471	3.889	3.902

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.

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 subsidiaries are 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, 2015, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). 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.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by Kesselman & Kesselman, an independent registered public accounting firm, as stated in their report 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 year ended December 31, 2015 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Our Board of Directors has resolved to change our state of incorporation from the State of Florida to the State of Delaware, on or around the end of March, 2016, which we refer to herein as the Reincorporation. The principal effects of the Reincorporation will be that:

- The affairs of the Company will cease to be governed by Florida corporation laws and will become subject to Delaware corporation laws.

- The resulting Delaware corporation will be the same entity as the company currently incorporated in Florida, and will continue with substantially all of the rights, privileges and powers of the company as it was incorporated in Florida.

The resulting Delaware corporation will continue to possess all of the assets we currently possess, and will continue to be subject to all of the debts, liabilities and obligations to which we are currently subject. There will be no change of officers or directors as a result of the Reincorporation.

When the Reincorporation becomes effective, each outstanding share of our common stock will continue to be an outstanding share of the common stock of the resulting Delaware corporation, and each outstanding option or right to acquire shares of our common stock will continue to be an option or right to acquire shares of the common stock of the resulting Delaware corporation.

We will effect the Reincorporation by entering into a plan of conversion, a copy of which is filed as exhibit to this Annual Report on Form 10-K. The Reincorporation will involve the filing of articles of conversion with the Secretary of State of the State of Florida, a certificate of conversion with the Secretary of State of the State of Delaware, and a certificate of incorporation with the Secretary of State of the State of Delaware. In addition, bylaws for the resulting Delaware corporation have been adopted. All of these documents are filed as exhibits to this Annual Report on Form 10-K.

After the Reincorporation, we will continue to be a publicly-held company and the shares of our common stock will continue to be traded, without interruption, on the NYSE MKT under the same symbol (PLX). We will continue to file periodic reports and other documents with the U.S. Securities and Exchange Commission and the Israeli Securities Authority, and provide to our shareholders the same type of information that we have previously filed and provided. Shareholders who own shares of our common stock that are freely tradable prior to the Reincorporation will continue to have freely tradable shares, and shareholders holding restricted shares of our common stock will continue to hold their shares subject to the same restrictions on transfer to which their shares are presently subject. In summary, the Reincorporation will not change the respective positions under U.S. federal securities laws of us or our shareholders.

The Reincorporation itself will not result in any change in headquarters, business, jobs, management, location of any of our offices or facilities, number of employees, assets, liabilities or net worth (other than as a result of the costs incident to the Reincorporation) or our officers and directors.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information in our 2016 Proxy Statement regarding directors and executive officers appearing under the headings "Security Ownership of Certain Beneficial Owners and Management— Section 16(a) Beneficial Ownership Reporting Compliance" and "Proposal 1: Election of Directors" is incorporated by reference in this section.

Item 11. Executive Compensation

The information appearing in our 2016 Proxy Statement under the headings "Director Compensation," "Compensation Discussion and Analysis," "Report of the Compensation Committee," and "Executive Compensation" is incorporated by reference in this section.

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

The information appearing in our 2016 Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management" is incorporated by reference in this section.

Equity Compensation Plan Information

The following table provides information as of December 31, 2015 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**

	Outstanding Options		**Under Equity Compensation Plans (Excluding Securities Reflected in Column A)**
Equity Compensation Plans Approved by Shareholders	7,085,510	$ 3.43	760,844
Equity Compensation Plans Not Approved by Shareholders	631,866	$ 10.24	-
Total	7,717,376	$ 3.99	760,844

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

The information appearing in our 2016 Proxy Statement under the headings “Proposal 1: Election of Directors—Corporate Governance” and “—Certain Relationships and Related Transactions” is incorporated by reference in this section.

Item 14. Principal Accountant Fees and Services

The information appearing in our 2016 Proxy Statement under the heading “Proposal 4: Ratification of Appointment of Independent Registered Public Accounting Firm” is incorporated by reference in this section.

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

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

3. *Exhibits.*

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File Number**	**Exhibit**	**Date**	**Filed Herewith**

3.1	Amended and Restated Articles of Incorporation of the Company	S-4	333-48677	3.4	March 26, 1998	
3.2	Article of Amendment to Articles of Incorporation dated June 9, 2006	8-A	001-33357	3.2	March 9, 2007	
3.3	Article of Amendment to Articles of Incorporation dated December 13, 2006	8-A	001-33357	3.3	March 9, 2007	
3.4	Article of Amendment to Articles of Incorporation dated December 26, 2006	8-A	001-33357	3.4	March 9, 2007	
3.5	Article of Amendment to Articles of Incorporation dated February 26, 2007	8-A	001-33357	3.5	March 9, 2007	
3.6	Article of Amendment to Articles of Incorporation dated December 17, 2014	10-K	001-33357	3.6	March 12, 2015	
3.7	Amended and Restated Bylaws of the Company	10-K	001-33357	3.6	March 12, 2015	
3.8	Certificate of Incorporation of the Company (to go into effect upon Reincorporation)					X
3.9	Articles of Merger of the Company (to go into effect upon Reincorporation)					X
3.10	Bylaws of the Company (to go into effect upon Reincorporation)					X
4.1	Form of Restricted Stock Agreement/Notice	8-K	001-33357	4.1	July 18, 2012	

4.2	Indenture, dated as of September 18, 2013, between Protalix BioTherapeutics, Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee	8-K		4.1	September 18, 2013
4.3	Form of 4.50% Convertible Note due 2018	8-K	001-33357	4.2	September 18, 2013
10.1	2006 Stock Incentive Plan, as amended	Def 14A	001-33357	Annex A	October 9, 2014
10.2	Employment Agreement between Protalix Ltd. and Yoseph Shaaltiel, dated as of September 1, 2004	8-K	001-33357	10.3	January 8, 2007
10.3	Employment Agreement between Protalix Ltd. and Einat Almon, dated as of December 19, 2004	8-K	001-33357	10.3	January 8, 2007
10.4	Employment Agreement between Protalix Ltd. and Yossi Maimon, dated as of October 15, 2006	8-K	001-33357	10.5	January 8, 2007
10.5	Lease Agreement between Protalix Ltd. and Angel Science Park (99) Ltd., dated as of October 28, 2003 as amended on April 18, 2005	8-K	001-33357	10.9	January 8, 2007
10.6	Stock Option Award Agreement grant by and between the Company and Steven Rubin, dated as of December 31, 2006	10-K	001-33357	10.13	March 30, 2007
10.7	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	10-K	001-33357	10.16	March 30, 2007
10.8	Scientific Advisory Board Agreement dated August 5, 2007 by and between the Company and Aaron Ciechanover, M.D.	8-K	001-33357	10.1	August 6, 2007
10.9	Unprotected Lease Agreement	10-K	001-33357	10.21	March 17, 2008
10.10		8-K	001-33357	10.1	

	Employment Agreement by and between Protalix Ltd., and Tzvi Palash dated as of August 29, 2010				September 7, 2010
10.11†	License Agreement between Protalix BioTherapeutics Ltd. and Virginia Tech Intellectual Properties, Inc.	10-Q	001-33357	10.2	November 8, 2010

10.12†	Amended and Restated Agreement between Protalix Ltd. and Comercio e Serviços Ltda. dated June 17, 2013	10-Q	001-33357	10.1	May 8, 2014	
10.13†	Technology Transfer and Supply Agreement made as of June 18, 2013 by and between Protalix Ltd. and Fundação Oswaldo Cruz	10-Q	001-33357	10.3	May 8, 2014	
10.14	Employment Agreement with Moshe Manor dated September 28, 2014	8-K	001-33357	10.1	September 29, 2014	
10.15†	Amended and Restated Exclusive License and Supply Agreement by and between Pfizer Inc. and Protalix Ltd., dated October 12, 2015	10-Q/A	001-33357	10.1	December 11, 2015	
21.1	Subsidiaries	10-K	001-33357	21.1	February 26, 2010	
23.1	Consent of Kesselman & Kesselman, Certified Public Accountants (Isr.), A member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant					X
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					X
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					X
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					X
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					X
101.INS	XBRL INSTANCE FILE					X
101.SCH	XBRL SHEMA FILE					X
101.CAL	XBRL CALCULATION FILE					X

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101.DEF	XBRL DEFINITION FILE	X
101.LAB	XBRL LABEL FILE	X
101.PRE	XBRL PRESENTATION FILE	X

† 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 March 8, 2016.

PROTALIX
BIOTHERAPEUTICS,
INC.

By: /s/ Moshe Manor
Moshe Manor

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Moshe Manor 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 Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	**Title**	**Date**
/s/ Moshe Manor Moshe Manor	President, Chief Executive Officer (Principal Executive Officer) and Director	March 8, 2016
/s/ Yossi Maimon Yossi Maimon	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 8, 2016

/s/ Shlomo Yanai Shlomo Yanai	Chairman of the Board	March 8, 2016
/s/ Amos Bar Shalev Amos Bar Shalev	Director	March 8, 2016
/s/ Zeev Bronfeld Zeev Bronfeld	Director	March 8, 2016
/s/ Yodfat Harel Buchris Yodfat Harel Buchris	Director	March 8, 2016
/s/ Roger D. Kornberg Roger D. Kornberg, Ph.D.	Director	March 8, 2016
/s/ Aharon Schwartz Aharon Schwartz, Ph.D.	Director	March 8, 2016

PROTALIX BIOTHERAPEUTICS, INC.

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

PROTALIX BIOTHERAPEUTICS, INC.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, changes in shareholders' equity (capital deficiency) and cash flows present fairly, in all material respects, the financial position of Protalix BioTherapeutics, Inc. and its subsidiaries at December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, 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, 2015, based on criteria established in Internal Control - Integrated Framework (2013) 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's 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 /s/ Kesselman & Kesselman
March 8, 2016 Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers
International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel, P.O Box 5005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.co.il

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

	December 31,	
	2014	2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$54,767	$76,374
Other assets	2,202	1,667
Inventories	3,451	5,767
Assets of discontinued operation	5,100	2,073
Total current assets	65,520	85,881
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,555	1,628
PROPERTY AND EQUIPMENT, NET	11,282	9,744
Total assets	$78,357	$97,253
LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$3,836	$3,629
Other	6,802	5,534
Deferred revenues	886	504
Liabilities of discontinued operation	52,830	1,568
Total current liabilities	64,354	11,235
LONG TERM LIABILITIES:		
Convertible notes	67,351	67,796
Deferred revenues		744
Liability for employee rights upon retirement	2,253	2,304
Promissory note		4,301
Total long term liabilities	69,604	75,145
Total liabilities	133,958	86,380
COMMITMENTS (Note 6)		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):		
Common Stock, $0.001 par value:		
Authorized - as of December 31, 2014 and 2015, 150,000,000 shares; issued and outstanding - as of December 31, 2014 and 2015, 93,603,819 shares and 99,800,397 shares, respectively	94	100

Additional paid-in capital	185,633	194,064
Accumulated deficit	(241,328)	(183,291)
Total shareholders' equity (capital deficiency)	(55,601)	10,873
Total liabilities and shareholders' equity (net of capital deficiency)	$78,357	$97,253

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 share and per share amounts)

	Year ended December 31,		
	2013	2014	2015
REVENUES	$0	$3,523	$4,364
COST OF REVENUES	0	(630)	(730)
GROSS PROFIT	0	2,893	3,634
RESEARCH AND DEVELOPMENT EXPENSES	(29,225)	(27,352)	(24,889)
Less – grants	3,213	5,128	4,864
RESEARCH AND DEVELOPMENT EXPENSES, NET	(26,012)	(22,224)	(20,025)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(8,051)	(9,228)	(7,279)
OPERATING LOSS	(34,063)	(28,559)	(23,670)
FINANCIAL EXPENSES	(1,065)	(4,935)	(3,735)
FINANCIAL INCOME	391	196	123
FINANCIAL EXPENSES – NET	(674)	(4,739)	(3,612)
LOSS FROM CONTINUING OPERATIONS	(34,737)	(33,298)	(27,282)
INCOME FROM DISCONTINUED OPERATIONS	6,947	3,355	85,319
NET INCOME (LOSS) FOR THE YEAR	$(27,790)	$(29,943)	$58,037
NET INCOME (LOSS) PER SHARE OF COMMON STOCK – BASIC AND DILUTED			
Loss from continuing operations	$(0.38)	$(0.36)	$(0.29)
Income from discontinued operations	0.08	0.04	0.90
Net income (loss) per share of common stock	$(0.30)	$(0.32)	$0.61
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE OF COMMON STOCK, BASIC AND DILUTED	92,368,138	92,891,846	94,922,390

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

PROTALIX BIOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(CAPITAL DEFICIENCY)

(U.S. dollars in thousands, except share data)

	Common Stock	Common Stock	Additional paid–in Capital	Accumulated deficit	Total
	Number of shares	Amount			
Balance at January 1, 2013	93,489,809	93	180,145	(183,595)	(3,357)
Changes during 2013:					
Share-based compensation related to stock options			1,013		1,013
Share-based compensation related to restricted stock award, net of forfeitures of 17,834 shares	(17,834)		3,076		3,076
Exercise of options granted to employees	79,123	*	112		112
Net loss from continuing operations				(34,737)	(34,737)
Net income from discontinued operations				6,947	6,947
Balance at December 31, 2013	93,551,098	93	184,346	(211,385)	(26,946)
Changes during 2014:					
Share-based compensation related to stock options			467		467
Share-based compensation related to restricted stock award, net of forfeitures of 185,709 shares	(81,209)		775		775
Exercise of options granted to employees (includes net exercise)	133,930	1	45		46
Net loss from continuing operations				(33,298)	(33,298)
Net income from discontinued operations				3,355	3,355
Balance at December 31, 2014	93,603,819	94	185,633	(241,328)	(55,601)
Changes during 2015:					
Issuance of common stock	5,649,079	6	6,095		6,101
Share-based compensation related to stock options			1,273		1,273
Share-based compensation related to restricted stock award, net of forfeitures of 2,501 shares	(2,501)		529		529
Exercise of options granted to employee	550,000	*	534		534
Net loss from continuing operations				(27,282)	(27,282)
Net income from discontinued operations				85,319	85,319
Balance at December 31, 2015	99,800,397	100	194,064	(183,291)	10,873

* Represents an amount less than $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,		
	2013	2014	2015
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$(27,790)	$(29,943)	$58,037
Income from discontinued operations	6,947	3,355	85,319
Loss from continuing operations	(34,737)	(33,298)	(27,282)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Share based compensation	4,089	1,242	1,802
Depreciation	3,539	3,140	2,370
Financial expenses (income), net	(264)	1,446	124
Changes in accrued liability for employee rights upon retirement	200	140	59
Loss (gain) on amounts funded in respect of employee rights upon retirement	(58)	(22)	18
Gain on sale of fixed assets		(3)	(2)
Financial expenses in respect to convertible notes	127	444	445
Changes in operating assets and liabilities:			
Increase in deferred revenues		886	362
Decrease (increase) in other assets	2,238	(1,006)	523
Increase in inventories		(3,451)	(2,316)
Increase (decrease) in accounts payable and accruals (including long term)	869	1,367	(1,873)
Net cash used in continuing operations	(23,997)	(29,115)	(25,770)
Net cash provided by (used in) discontinued operations	(6,656)	(166)	1,486
Net cash used in operating activities	$(30,653)	$(29,281)	$(24,284)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	$(1,890)	$(785)	$(464)
Proceeds from sale of property and equipment		11	3
Decrease (increase) in restricted deposit	(42)	(90)	45
Amounts funded in respect of employee rights upon retirement, net	(170)	(137)	(96)
Net cash used in continuing operations	$(2,102)	$(1,001)	(512)
Net cash provided by discontinued operations			39,899
Net cash provided by (used in) investing activities	$(2,102)	$(1,001)	$39,387
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net proceeds from issuance of convertible notes	$66,780		
Issuance of shares, net of issuance cost			6,101
Exercise of options	112	$46	$534
Net cash provided by financing activities	$66,892	$46	$6,635
EFFECT OF EXCHANGE RATE CHANGES ON CASH	226	(1,395)	(131)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	34,363	(31,631)	21,607
	52,035	86,398	54,767

BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR			
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	$86,398	$54,767	$76,374

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,		
	2013	2014	2015
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Purchase of property and equipment	$ 186	$ 120	$ 489
Issuance of promissory note			4,301
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS			
Interest paid		$ 3,079	$ 3,105

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

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the “Company”), and its wholly-owned subsidiaries, Protalix Ltd. and Protalix B.V. ("Subsidiaries"), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company’s proprietary ProCellEx® protein expression system (“ProCellEx”). To date, the Company has successfully developed taliglucerase alfa (marketed under the name Uplyso™ in Brazil and certain other Latin American countries and Elelyso™ in the rest of the territories) for the treatment of Gaucher disease that has been approved for marketing in the United States, Brazil, Israel and other markets. The Company has a number of product candidates in varying stages of the clinical development process. The Company’s current strategy is to develop proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications. The Company’s product pipeline currently includes, among other candidates:

(1) PRX-102, or alpha-GAL-A, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans;

(2) PRX-106, the Company’s oral antiTNF product candidate which is being developed as an orally-delivered anti inflammatory treatment using plant cells as a natural capsule for the expressed protein; and

(3) PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or DNase, under development for the treatment of cystic fibrosis, to be administered by inhalation. Obtaining marketing approval with respect to any product candidate in any country is directly dependent on the Company’s ability to implement the necessary regulatory steps required to obtain such approvals. The Company cannot reasonably predict the outcome of these activities.

Since its approval by the FDA, taliglucerase alfa has been marketed mainly in the United States by Pfizer Inc. (“Pfizer”), as provided in the exclusive license and supply agreement by and between Protalix Ltd. and Pfizer, which is referred to herein as the Pfizer Agreement. In October 2015, the Company entered into an Amended and Restated Exclusive License and Supply Agreement (the “Amended Pfizer Agreement”) which amends and restates the Pfizer Agreement in

its entirety. Pursuant to the Amended Pfizer Agreement, the Company sold to Pfizer its share in the collaboration created under the Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36.0 million. As part of the sale, the Company agreed to transfer its rights to Elelyso in Israel to Pfizer while gaining full rights to it in Brazil. Under the Pfizer Agreement, Pfizer and the Company shared revenues and expenses for the development and commercialization of Elelyso on a 60%/40% basis globally, excluding Israel and Brazil. Under the Amended Pfizer Agreement, Pfizer is entitled to all of the revenues, and responsible for 100% of expenses globally for Elelyso, excluding Brazil where the Company is responsible for all expenses and retains all revenues. For further details see note 2.

On June 18, 2013, the Company entered into a Supply and Technology Transfer Agreement (the “Brazil Agreement”) with Fundação Oswaldo Cruz (“Fiocruz”), an arm of the Brazilian Ministry of Health for taliglucerase alfa. The agreement became effective in January 2014. The technology transfer is designed to be completed in four stages and is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high-quality, and cost-effective supply of taliglucerase alfa. The Company is not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately $280 million worth of taliglucerase alfa. The Company has recorded revenues of approximately $4 million for sales of taliglucerase alfa to Fiocruz in 2015.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Fiocruz's purchases of Uplyso to date have been significantly below certain agreed upon purchase milestones and, accordingly, the Company has the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, the Company is, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. Approximately 10% of adult Gaucher patients in Brazil are currently treated with Uplyso. The Company is discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, the Company will determine what it believes to be the course of action that is in the best interest of the Company.

The Company will pay a fee equal to 5% of the net proceeds generated in Brazil to an agent for services provided in assisting the Company complete the Brazil Agreement pursuant to an agreement between the agent and the Company. The agreement will remain in effect with respect to the Brazil Agreement until the termination thereof.

Based on its current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least 12 months, although no assurance can be given that it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, the Company may need to seek additional financing.

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").

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 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. Most of 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 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 and losses are recorded as financial income or expenses, as appropriate.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. Inventories

Inventories are valued at the lower of cost or market. Cost of raw and packaging materials and purchased products is determined using the “moving average” basis.

Cost of finished products is determined as follows: the value of the raw and packaging materials component is determined primarily using the “moving average” basis; the value of the labor and overhead component is determined on an average basis over the production period.

Inventory is written down for estimated obsolescence based upon management assumptions about future demand and market conditions.

g. 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.

h. 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 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.

i. 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. See note 10.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

2. Uncertainty in income taxes

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

j. Revenue Recognition

The Company recognizes revenue when the earnings process is complete, which is when revenue is realized or realizable and earned, there is persuasive evidence that a revenue arrangement exists, delivery of goods or services has occurred, the sales price is fixed or determinable and collectability is reasonably assured.

1. Revenues from the license agreements with Pfizer

a. Pfizer Agreement
The Company recognized revenue from milestone payments received pursuant to the Pfizer Agreement in accordance with guidance regarding arrangements with multiple deliverables. As the first Pfizer Agreement required the Company's continued involvement with respect to the proposed commercialization of taliglucerase alfa, the non-refundable, up-front license payment the Company received from Pfizer was deferred and was recognized over the related performance period. The Company estimated the performance period of 14 years based on the date the last relevant patent expires. As to the final release of the deferred revenue, see b. below. Each milestone payment that was considered to be substantive for purposes of revenue recognition was recorded as revenue during the period during which the milestone was achieved.

b. Amended Pfizer Agreement
The Company recognized revenue from the final sale of the license by selling its share in the collaboration arrangement upon closing of the transaction. In addition, since the Amended Pfizer Agreement terminated the prior Pfizer Agreement and no continuing involvement is required by the Company, the remaining deferred revenue from the original Pfizer Agreement was recorded to the Statement of Operations within discontinued operations.

2. Company’s share in the collaboration agreement with Pfizer

The Company recognized its share of net profit or loss from the Pfizer Agreement based on reports it received from Pfizer summarizing the results of the collaborative activities under the agreement for the applicable period. Under the terms of the Pfizer Agreement, for its subsidiaries operating outside the United States, financial information was included based on the fiscal year ending November 30, while financial information for the U.S. entity was included based on the fiscal year ending December 31.

3. Revenues from supply agreements and from selling products

The Company recognizes revenues from supply agreements and from selling products upon delivery, when the sales price is fixed or determinable and collectability is reasonably assured.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

4. Revenues from the Pfizer Agreements as well as revenues from sales of Elelyso in Israel are presented as discontinued operations, see note 12.

k. Research and development costs

Research and development costs are expensed as incurred and consist primarily of personnel, subcontractors and consultants (mainly in connection with clinical trials), 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") are recognized when the grant becomes receivable, provided there is reasonable assurance that the Company or the Subsidiaries 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 research and development expenses as the applicable costs are incurred. 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 consumed or the related services are performed.

l. Concentration of credit risks and trade receivable

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.

The Company's trade receivables represent amounts to be received from Pfizer and the Company's customers in Israel. The Company does not require Pfizer or any of its Israeli customers to post collateral with respect to receivables. The Company performs periodic credit evaluations of Pfizer's financial condition and believes there is no significant risk with respect to Pfizer's payment of the receivables. As all Israeli customers are government entities, the Company believes there is no significant risk with respect to its receivables from such entities.

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 estimates 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 grant is accounted for based on the fair value of the stock options issued. 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.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

n. Net earnings (loss) per share

Basic and diluted loss per share ("LPS") are computed by dividing net loss by the weighted average number of shares of the Company's Common Stock, par value $0.001 per share (the "Common Stock") outstanding for each period.

Diluted LPS calculated on continuing operations. The calculation of diluted LPS does not include 10,675,304, 18,850,724 and 19,778,424 shares of Common Stock underlying outstanding options, restricted shares of Common Stock and shares issuable upon conversion of the convertible notes (issued in September 2013) for the fiscal years ended December 31, 2013, 2014 and 2015, respectively, because the effect would be anti-dilutive.

o. Convertible notes

The convertible notes are accounted for using the guidance provided set forth in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification (ASC) 815 requiring that the Company determine whether the embedded conversion option must be separated and accounted for separately. The Company accounts for the convertible notes as a liability, on an aggregated basis, in their entirely.

p. Recently adopted standards

In April 2014, the FASB issued Accounting Standards Update (ASU) 2014-08, which includes amendments that change the requirements for reporting discontinued operations and require additional disclosures about discontinued operations. Under the new guidance, only disposals representing a strategic shift in operations - that is, a major effect on the organization's operations and financial results - should be presented as discontinued operations. Additionally, the ASU requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations.

In August 2015, the FASB issued ASU No. 2015-15, which clarifies the treatment of debt issuance costs from line-of-credit arrangements after the adoption of ASU No. 2015-03. The ASU clarifies that the staff of the Securities and Exchange Commission would not object to an entity deferring and presenting debt issuance costs related to a line-of-credit arrangement as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of such arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. The Company adopted this standard in the fourth quarter on a retrospective basis and the implementation of this ASU did not have a material impact on our consolidated financial statements.

q. Recently issued accounting pronouncements

In July 2015, the FASB issued guidance on current accounting for inventory measurement. The new guidance requires entities to measure inventory at the lower of cost or net realizable value. Net realizable value is defined by the guidance as estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The guidance is effective for the interim and annual periods beginning on or after December 15, 2016 (early adoption is permitted). The Company does not expect this guidance to have material effect on the consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

In May 2014, the FASB issued guidance on revenues from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions require capitalization of certain contracts costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance is also required in enhanced disclosures regarding the nature, amount timing and uncertainty of revenues and cash flows arising from an entity's contracts with customers. The guidance is effective for the interim and annual periods beginning on or after December 15, 2017 (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The guidance permits the use of either retrospective or cumulative effect transition method. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

In January 2016, the FASB issued ASU, No. 2016-01, Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities. The guidance affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. The guidance is effective in the first quarter of fiscal year 2019. Early adoption is permitted for the accounting guidance on financial liabilities under the fair value option. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

NOTE 2 - AGREEMENTS WITH PFIZER

1. On November 30, 2009, Protalix Ltd. and Pfizer entered into the Pfizer Agreement pursuant to which Pfizer was granted 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. In June 2013, Pfizer returned the commercialization rights in Brazil to Protalix Ltd.

Under the Pfizer Agreement and prior to its amendment in October 2015, Pfizer made an upfront payment to Protalix Ltd. of $60.0 million in connection with the execution of the agreement and shortly thereafter paid Protalix Ltd. an additional $5.0 million upon the Company's achievement of a certain milestone. Protalix Ltd. received a $25.0 million milestone payment in connection with the approval of taliglucerase alfa by the FDA in May 2012. Protalix Ltd. was entitled to 40% of the results (profits or losses) earned on Pfizer's sales of taliglucerase alfa. Such result (profit or loss) were to be calculated while, in addition to other adjustments, 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 ("Collaboration Operation"). As of December 31, 2014 and October 12, 2015 (day of signing the Amended Pfizer Agreement), the Company accrued a liability in respect of its share in the accumulated losses of the collaboration operation equal to approximately $7.1 million and $4.3 million, respectively. After deducting the losses, the Company is entitled to receive in cash its share in the profits of the collaboration operation. Upon execution of the Amended Pfizer Agreement, the Company no longer shares Pfizer's profits or losses with respect to Pfizer's sales of taliglucerase alfa.

The Company first determined that the initial, non-refundable upfront license fee payment of $60.0 million together with the first $5.0 million payment were to be recognized on a straight line basis as revenue over the estimated relationship period (approximately $4.6 million per year). The $25.0 million milestone payment received during 2012 in connection with the FDA's approval of taliglucerase alfa in the United States was considered to be a substantive milestone for purposes of revenue recognition and, accordingly, was recorded as revenue during the period in which the milestone was achieved.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 - AGREEMENTS WITH PFIZER (continued)**:**

2. In October 2015 the Company entered into the following agreements:

1. Amended Pfizer Agreement - Pursuant to the amendment, the Company granted Pfizer an exclusive license in the entire world, including Israel but excluding Brazil. Pfizer acquired all the information, knowledge and permission to manufacture and sell Elelyso.

Protalix also agreed to provide Pfizer with:

a. Manufacturing and supply of the drug substance for its incorporation into the licensed product in consideration of an agreed price per unit.

b. Assistance in arranging for the manufacture of the drug substance by Pfizer or by alternative supplier chosen by Pfizer in consideration of an agreed hourly rate plus reimbursement of expenses.

2. Stock Purchase Agreement - the Company issued 5,649,079 shares of Common Stock to Pfizer.

3. Promissory note – as of the date of the amendment, the Company owed Pfizer $4.3 million as a result of the accumulated losses incurred by the collaboration operation. Following the new agreements, the Company committed to pay Pfizer the principal sum of the debt at the earlier of (a) November 12, 2020 and (b) the date upon which it becomes due pursuant to any event of default, as defined.

The three contracts presented above are considered a single arrangement with multiple deliverables. The Company allocated the total consideration of $46.0 million between the license and Common Stock according to each fair value, as follows: $6.1 million was allocated to the issuance of shares and $39.9 million to the license. The Company considered the relevant circumstances in order to determine the appropriate timing of revenue recognition and determined that revenues related to the Amended Pfizer Agreement should be recognized immediately. The Amended Pfizer Agreement terminated the Company's continued involvement according to the original Pfizer Agreement and therefore the pre-existing balance of deferred revenue was recognized in the Statement of Operations.

The Amended Pfizer Agreement results in a discontinued operation as defined under ASU 2014-08 because it represents a strategic shift for the Company that has a major effect on the entity's operations and financial results.

In connection with the payments received under the Pfizer Agreement and the Amended Pfizer Agreement, Protalix Ltd. is committed to pay to other third parties certain royalties. See note 6a.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 - PROPERTY AND EQUIPMENT

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

	December 31,	
(*U.S. dollars in thousands)*	2014	2015
Laboratory equipment	$15,138	$15,493
Furniture and computer equipment	2,154	2,244
Leasehold improvements	15,427	15,635
Equipment under construction	17	175
	$32,736	$33,547
Less – accumulated depreciation and amortization	(21,454)	(23,803)
	$11,282	$9,744

b. Depreciation in respect of property and equipment totaled approximately $3.5 million, $3.1 million and $2.4 million for the years ended December 31, 2013, 2014 and 2015, respectively.

NOTE 4 - INVENTORIES

Inventories at December 31, 2014 and 2015 consisted of the following:

	December 31,	
(*U.S. dollars in thousands)*	2014	2015
Raw materials	$1,616	$1,180
Work in progress	47	
Finished goods	1,788	4,587
Total inventory	$3,451	$5,767

During the years ended December 31, 2014 and 2015 the Company recorded approximately $0.1 million and $1.3 million respectively, for write-down of inventory under the cost of revenues.

NOTE 5 - 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 recorded on the Company's balance sheets 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 from the purchase of insurance policies or by the establishment of pension funds with dedicated deposits in the funds. The amounts used to fund these liabilities are included in the Company's 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 years ended December 31, 2013, 2014 and 2015, the Company deposited approximately $194,000, $195,000 and $168,000, respectively, with insurance companies in connection with its severance payment obligations.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 - LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT (continued)**:**

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 Company's 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 amounts of severance pay expenses were approximately $1.0 million for each of the years ended December 31, 2013 and 2014 and approximately $800,000 for the year ended December 31, 2015, of which approximately $801,000, $779,000 and $675,000 in the years ended December 31, 2013, 2014 and 2015, respectively, were in respect of the Contribution Plans. Gain (loss) on amounts funded in respect of employee rights upon retirement totaled approximately $58,000, $22,000 and ($18,000) for the years ended December 31, 2013, 2014 and 2015, respectively.

The Company expects to contribute approximately $841,000 in the year ending December 31, 2016 to insurance companies in connection with its severance liabilities for its operations for that year, approximately $673,000 of which will be contributed to one or more Contribution Plans.

During the five-year period following December 31, 2015, the Company expects to pay future benefits to three employees upon each such employee's normal retirement age. The Company anticipates that the benefits payable will be approximately $200,000.

NOTE 6 - 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 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.

Royalty expenses to the OCS are included in the statement of operations as a component of the cost of revenues both in continuing and discontinued operations and were approximately $392,000, $951,000 and $2.2 million during the years ended December 31, 2013, 2014 and 2015, respectively.

At December 31, 2015, the maximum total royalty amount payable by the Company under these funding arrangements is approximately $33.3 million (without interest, assuming 100% of the funds are payable).

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 6 - COMMITMENTS (continued)**:**

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. The aggregate royalties payable under all of the agreements is equal to a varying range of percentages of net sales of licensed products. Royalty expenses under the agreements are included in the statement of operations as a component of the cost of revenues both in continuing and discontinued operations and were approximately $80,000, $104,000 and $51,000 during the years ended December 31, 2013, 2014 and 2015, respectively.

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 total payable would be approximately $8.7 million and would be payable, if at all, as the Company's projects progress over the course of a number of years. No milestone payments were made during 2013, 2014 and 2015.

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 and consultants in Israel, the United States and certain other countries in connection with its primary product development process. As of December 31, 2015, total commitments under said agreements were approximately $800,000.

c. Lease Agreements

The Company is a party to a number of lease agreements for its facilities, the latest of which expires in 2016. The Company has the option to extend certain of such agreements on three occasions for additional five-year periods each, for a total of 15 additional years. Under the leases, the aggregate monthly rental payments are approximately $85,000. As of December 31, 2015, the Company provided bank guarantees of approximately $312,000, in the aggregate, to secure the fulfillment of its obligations under the lease agreements. The future minimum lease payments required under the operating leases for such premises are approximately as follows: 2016 – $585,000. Lease expenses totaled approximately $1,133,000, $1,044,000 and $1,019,000 for the years ended December 31, 2013, 2014 and 2015, respectively.

d. Vehicle Lease and Maintenance Agreements

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 $54,000. The expected lease payments for the years ending December 31, 2016, 2017 and 2018 are approximately $572,000, $414,000 and $81,000, respectively.

NOTE 7 - SHARE CAPITAL

a. Rights of the Company's Common Stock

The Company's Common Stock is listed on the NYSE MKT and on the Tel Aviv Stock Exchange. Each share of Common Stock is entitled to one vote. The holders of shares 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.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 - SHARE CAPITAL (continued)**:**

b. Stock based compensation

On December 14, 2006, the Board of Directors adopted the Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan, as amended (the "Plan"). The Plan has since been amended to, among other things, increase the number of shares of common stock available under the plan to 13,841,655 shares. 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.

As of December 31, 2015, 760,844 shares of Common Stock remain available for grant under the Plan.

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

From January 1, 2013 through December 31, 2015, the Company granted options and shares of restricted stock to certain employees and non-employees as follows:

1. **Options and restricted stock granted to employees:**

a) Below is a table summarizing all of the options and restricted stock grants to employees for each year of the three-year period ended December 31, 2015:

Year of grant	No. of options granted	Exercise price	Vesting period	Fair value at grant (U.S. dollars in thousands)	Expiration period
2014	900,000	$ 2.37	4 years	$ 1,007	10 years
2015	1,909,000	$ 1.72	4 years	$ 1,900	10 years
	2,809,000				

Set forth below are grants made by the Company to employees (including related parties) during the three-year period ended December 31, 2015 (such grants appear in the table above):

On September 28, 2014, the Company’s Board of Directors approved, subject to certain terms and conditions, the grant of a 10-year option to purchase 900,000 shares of Common Stock to its then newly appointed President and Chief Executive Officer with an exercise price of $2.37 per share. The options vest over a four-year period in 16 equal quarterly increments. Vesting of the options will be accelerated in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan, as amended. 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 million based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 62%; risk-free interest rate of 1.86%; and expected life of six years.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7– SHARE CAPITAL (continued)**:**

On March 23, 2015, the Company's compensation committee approved the grant of a 10-year option to purchase 1,909,000 shares of Common Stock to its officers and other employees with an exercise price equal to $1.72 per share under the Company's 2006 Employee Stock Incentive Plan, as amended (the "Plan"). The options vest over a four-year period; the first 25% shares vest on the first anniversary of the grant date and the remaining shares vest in 12 equal quarterly increments over the subsequent three-year period. Vesting of the options granted to certain executive officers is subject to acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $1.9 million based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 61.7%; risk-free interest rates of 1.6%; and expected life of six years.

b) The total unrecognized compensation cost of employee stock options and restricted stock at December 31, 2015 is approximately $1.6 million (net of forfeiture rate). The unrecognized compensation cost of employee stock options is expected to be recognized over a weighted average period of 1.0 years.

The total cash received from employees as a result of employee stock option exercises for the years ended December 31, 2013, 2014 and 2015 was approximately $112,000, $46,000 and $534,000, respectively. The Company did not realize any tax benefit in connection with these exercises.

During 2015, the Company issued 550,000 shares of Common Stock in connection with the exercise of 550,000 options granted to a certain employee of the Company. The Company received cash proceeds equal to approximately $534,000 in connection with such exercises.

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

On July 24, 2014, the Company's Board of Directors approved, subject to certain terms and conditions, the grant of a 10-year option to purchase 150,000 shares of Common Stock to its then newly elected chairman of the Board of Directors with an exercise price equal to $3.37 per share. The options vest over a three-year period; the first 50,000 shares vest on the first anniversary of the grant date and the remaining shares vest in eight equal quarterly increments over the subsequent two-year period. Vesting of the options are subject to acceleration in full upon a Corporate

Transaction or a Change in Control, as those terms are defined in the Plan. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $193,000 based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 62%; risk-free interest rates of 1.9%; and expected life of six years.

No cash was received from consultants as a result of consultant stock option exercises for the years ended December 31, 2013, 2014 and 2015.

During 2014 and 2015, no shares of Common Stock were issued in connection with the exercise of options by consultants of the Company.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7– SHARE CAPITAL (continued)**:**

3. A summary of share option plans, and related information, under all of the Company's equity incentive plans for the years ended December 31, 2013, 2014 and 2015 are as follows:

a. Options granted to employees:

	Year ended December 31,					
	2013		2014		2015	
	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	5,253,579	$ 3.923	5,153,898	$ 3.951	5,870,309	$ 3.770
Changes during the year:						
Granted			900,000	2.370	1,909,000	1.72
Forfeited and expired	20,558	6.603	44,201	6.833	277,016	5.395
Exercised (*)	79,123	1.418	139,388	0.446	550,000	0.972
Outstanding at end of year	5,153,898	$ 3.951	5,870,309	$ 3.770	6,952,293	$ 3.363
Exercisable at end of year	4,614,148	$ 3.591	4,905,559	$ 3.933	4,477,043	$ 4.182

(*) The total intrinsic value of options exercised during the years ended December 31, 2013, 2014 and 2015, was approximately $306,000, $447,000 and $675,000, respectively.

b. Restricted stock granted to employees:

	Year ended December 31,		
	2013	2014	2015
	Number of Restricted Shares		
Outstanding at beginning of year	1,394,708	970,208	386,124
Changes during the year:			
Granted			
Vested	406,666	398,375	255,749

Forfeited	17,834	185,709	2,501
Outstanding at end of year	970,208	386,124	127,874

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7– SHARE CAPITAL (continued)**:**

c. Options and restricted stocks granted to consultants, directors, and other service providers:

	Year ended December 31,					
	2013		2014		2015	
	Number of Options/ restricted stock	Weighted average exercise price	Number of options/ restricted stock	Weighted average exercise price	Number of options/ restricted stock	Weighted average exercise price
Outstanding at beginning of year	912,425	$ 7.259	912,425	$ 7.259	1,208,592	$ 6.136
Changes during the year-						
Granted			296,167	2.678		
Expired					466,883	0.001
Vested restricted stock					104,500	-
Outstanding at end of year	912,425	$ 7.259	1,208,592	6.136	637,209	11.638
Exercisable at end of year	912,425	$ 7.259	912,425	$ 7.259	549,709	$ 12.954

d. The following tables summarize information concerning outstanding and exercisable options and restricted stock as of December 31, 2015:

December 31, 2015				
Options and restricted stock outstanding			Options exercisable	
Exercise prices	Number of options and restricted stock outstanding at end of year	Weighted average remaining contractual life	Number of options exercisable	Weighted average remaining contractual life
n/a (*)	127,874	n/a	n/a	n/a
$0.001	252,324	0.53	252,324	0.53
$0.120	308,801	1.00	308,801	1.00
$0.972	445,853	0.47	445,853	0.47
$1.720	1,856,500	9.22	—	—

$2.350	40,000	2.82	40,000	2.82
$2.370	900,000	8.75	281,250	8.75
$2.650	336,482	2.47	336,482	2.47
$3.020	50,000	2.10	50,000	2.10
$3.370	150,000	8.56	62,500	8.56
$5.000	1,658,000	1.65	1,658,000	1.65
$6.900	976,000	3.31	976,000	3.31
$7.550	160,000	4.66	160,000	4.66
$9.660	68,000	4.83	68,000	4.83
$16.700	387,542	0.99	387,542	0.99
	7,717,376		5,026,752	

(*) Represents restricted stock.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7– SHARE CAPITAL (continued)**:**

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

	Year ended December 31,		
(U.S. dollars in thousands)	2013	2014	2015
Research and development expenses	$2,655	$936	$904
Marketing, general and administrative expenses	1,434	306	898
	$4,089	$1,242	$1,802

c. Private and 144A Offerings

1. On September 18, 2013, the Company completed a private offering of 4.50% convertible notes due 2018. The net proceeds from the offering, including net proceeds from the exercise in full by the initial purchaser of its option to purchase an additional $9.0 million in aggregate principal amount of the Notes, were $66.8 million (net of the initial purchaser's discount and commission and offering expenses payable by the Company). See also note 8.

2. On October 12, 2015, the Company completed a private offering of 5,649,079 shares of the Company's common stock to Pfizer. See also note 2.

NOTE 8 - CONVERTIBLE NOTES

On September 18, 2013, the Company completed a private placement of $69.0 million in aggregate principal amount of Notes, including $9.0 million aggregate principal amount of Notes related to the initial purchaser's over-allotment option, which was exercised in full. In connection with the completion of the offering, the Company entered into an indenture (the "Indenture") with The Bank of New York Mellon Trust Company, N.A., as trustee, governing the Notes. The Notes accrue interest at a rate of 4.50% per year, payable semiannually in arrears on March 15 and September 15 of each year, beginning on March 15, 2014. The Notes mature on September 15, 2018.

The net proceeds from the offering, including net proceeds from the exercise in full by the initial purchaser of its option to purchase an additional $9.0 million in aggregate principal amount of the Notes, were $66.8 million, after deducting the initial purchaser's discount and commission and offering expenses payable by the Company. The debt discount and debt issuance costs are deferred and amortized over the convertible Notes period (5 years).

Holders may convert their Notes at any time prior to the close of business on the business day immediately preceding September 15, 2018. The initial conversion rate for the Notes is 173.6593 shares of the Common Stock for each $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $5.76 per share of the Common Stock. Upon conversion, the Company will deliver a number of shares of Common Stock, per $1,000 principal amount of Notes, equal to the conversion rate. The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 - CONVERTIBLE NOTES (continued)**:**

Prior to September 19, 2016, the Company may not redeem the Notes, and no sinking fund is provided for the Notes. On or after September 19, 2016, the Company may redeem for cash all or part of the Notes (except for the notes that the Company is then required to repurchase in connection with a fundamental change) if the last reported sale price of the Common Stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on the trading day

immediately preceding the date on which the Company provides the notice of redemption. The redemption price will equal the sum of (i) 100% of the principal amount of the Notes being redeemed, plus (ii) accrued and unpaid interest, including additional interest, if any, to, but excluding, the redemption date, plus (iii) the sum of the present values of each of the remaining scheduled payments of interest that would have been made on the Notes being redeemed had such Notes remained outstanding from the redemption date to the maturity date.

The following table sets forth total interest expense recognized for the years ended December 31, 2013, 2014 and 2015 related to the Notes:

	Year ended December 31,		
(U.S. Dollars in thousands)	2013	2014	2015
Contractual interest expense	$888	$3,105	$3,105
Amortization of debt issuance costs and debt discount	127	444	444
Total	$1,015	$3,549	$3,549

NOTE 9 - FAIR VALUE MEASUREMENT

The Company discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received from the sale of an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The fair value of the financial instruments included in the working capital of the Company is usually identical or close to their carrying value.

The fair value of the convertible notes as of December 31, 2015 is approximately $49 million based on a level 2 measurement.

NOTE 10 - TAXES ON INCOME

a. The Company

Protalix BioTherapeutics, Inc. is taxed according to U.S. tax laws. The Company’s income is taxed in the United States at the rate of up to 39%.

b. Protalix Ltd.

The Israeli Subsidiary is taxed according to Israeli tax laws:

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – TAXES ON INCOME (continued)**:**

1. **Measurement of results for tax purposes**

Since 2008, the Company has measured the results of the Israeli Subsidiary for tax purposes in nominal terms in NIS. Pursuant to the Israel Income Tax Law (Adjustments for Inflation), 1985, the Israeli Subsidiary's results for tax purposes have been measured through 2007 on a real basis, based on changes in the Israel consumer price index.

2. **Tax rates**

The income of the Israeli Subsidiary, other than income from "Approved Enterprises," is taxed in Israel at the regular corporate tax rates which were 25% in 2013 and 26.5% for 2014 and 2015.

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No.216) was published, enacting a reduction of corporate tax rate beginning in 2016 and thereafter, from 26.5% to 25%. There is no impact on the financial statements of the Company as a result of the changes in the Israeli corporate tax rate as the Israeli subsidiary is in a loss position for tax purposes.

Capital gain is subject to capital gain tax according to corporate tax rate for the year during which the assets are sold.

3. **The Law for the Encouragement of Capital Investments, 1959 (the "Encouragement of Capital Investments Law")**

Under the Encouragement of Capital Investments Law, including Amendment No. 60 to the Encouragement of Capital Investments Law as published in April 2005, by virtue of the "Approved Enterprise" or "Benefited Enterprise" status the Israeli Subsidiary is entitled to various tax benefits as follows:

a. **Reduced tax rates**

Income derived from the Approved Enterprise during a 10-year period commencing upon 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 Encouragement of Capital Investments Law has not elapsed.

The Israeli Subsidiary has an "Approved Enterprise" plan since 2004 and "Benefited Enterprise" plan since 2009. The period of benefits in respect of the main enterprise of the Company has not yet commenced. The period during which the Company is entitled to benefits in connection with the Benefited Enterprise expires in 2021.

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

b. **Accelerated depreciation**

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

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – TAXES ON INCOME (continued)**:**

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

The Israeli Subsidiary's entitlement to the benefits described above is subject to its 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. Failure by the Israeli Subsidiary to comply with these conditions, may result in the cancellation of the benefits, in whole or in part, and the Subsidiary may be required to refund the amount of the benefits with interest. The Israeli Subsidiary received a final implementation approval with respect to its "Approved Enterprise" from the Investment Center.

d. **Amendment of the Law for the Encouragement of Capital Investments, 1959**

The Encouragement of Capital Investments Law was amended as part of the Economic Policy Law for the years 2011-2012, which was passed by the Israeli Knesset on December 29, 2010 (the "Capital Investments Law Amendment").

The Capital Investments Law Amendment sets alternative benefit tracks to those currently in effect under the provisions of the Encouragement of Capital Investments Law.

The Company elected not to have the Capital Investments Law Amendment apply to the Company.

c. Tax losses carried forward to future years

As of December 31, 2015, the Company had aggregate net operating loss (NOL) carry-forwards equal to approximately $124 million that are available to reduce future taxable income as follows:

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – TAXES ON INCOME (continued)**:**

1. **The Company**

The NOL carry-forward of the Company equal to approximately $19 million 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, 2015, the Israeli Subsidiary had approximately $105 million 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 assets at December 31, 2014 and 2015 were as follows:

	December 31,	
(U.S. dollars in thousands)	2014	2015
In respect of:		
Research and development expenses	$3,136	$3,235
Property and equipment	(372)	(168)
Provision for vacation	374	352
Severance pay obligation	185	169
Deferred revenues	8,658	-
Net operating loss carry forwards	28,130	33,451
Valuation allowance	(40,111)	(37,039)
	-	-

Deferred taxes are computed using the tax rates expected to be in effect when those differences reverse. The Company used tax rates of 39%, 26.5%, 25% and 0%.

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

The main reconciling item between the statutory tax rate of the Company and the effective rate is the provision for a 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, 2015, all of Protalix Ltd.'s tax assessments through tax year 2011 are considered final.

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

Jurisdiction:	**Years:**
Israel	2012-2015
United States (*)	2012-2015

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

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 11 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Balance sheets:	December 31,	
(U.S. dollars in thousands)	2014	2015
a. Other assets:		
Institutions	$124	$216
State of Israel (see note 6a)	1,229	621
Restricted deposit	416	371
Prepaid expenses	369	408
Sundry	64	51
	$2,202	$1,667

(U.S. dollars in thousands)		
b. Accounts payable and accruals – other:		
Payroll and related expenses	1,243	1,125
Interest payable	914	914
Provision for vacation	1,412	1,406
Accrued expenses	3,113	1,571
Royalties payable		29
Property and equipment suppliers	120	489
	$6,802	$5,534

NOTE 12 - DISCONTINUED OPERATIONS

As mentioned in note 2, the Company accounted for the termination of the Pfizer Agreement and the sale of the license as a discontinued operation, in accordance with ASU No. 2014-08. The following assets and liabilities associated with the Company's discontinued operations, have been segregated and classified as assets and liabilities of discontinued operations, as appropriate, in the consolidated balance sheets as of December 31, 2014 and 2015, respectively (in thousands):

	December 31,	
	2014	2015
CURRENT ASSETS:		

Accounts receivable - Trade	$1,884	$1,993
Inventories*	3,216	80
Total current assets of discontinued operation	5,100	2,073
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$115	
Other	8,694	$1,568
Deferred revenues	43,109	
Liability in connection with collaboration operation	912	
Total current liabilities of discontinued operation	52,830	1,568

* During the years ended December 31, 2014 and 2015, the Company recorded approximately $1.6 million and $0 million, respectively, for write-down of inventory under the cost of revenues.

PROTALIX BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 – DISCONTINUED OPERATIONS (continued)**:**

The following summarizes financial information related to the Company's discontinued operations, in the Company's consolidated statements of operations (in thousands):

	Year ended December 31,		
	2013	2014	2015
REVENUES	$10,479	$10,128	$48,674
COMPANY'S SHARE IN COLLABORATION AGREEMENT	1,034	1,509	5,048
COST OF REVENUES	(5,428)	(8,423)	(7,697)
GROSS PROFIT	6,085	3,214	46,025
RESEARCH AND DEVELOPMENT EXPENSES	(4,088)	(2,409)	(586)
Less –reimbursements	5,284	2,983	545
RESEARCH AND DEVELOPMENT EXPENSES, NET	1,196	574	(41)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(334)	(433)	(564)
NET INCOME FOR THE YEAR FROM DISCONTINUED OPERATIONS	$6,947	$3,355	$45,420
GAIN ON THE DISPOSAL			39,899
NET INCOME	$6,947	$3,355	85,319

NOTE 13 - RELATED PARTY TRANSACTIONS

	Year ended December 31,		
(U.S. dollars in thousands)	2013	2014	2015
Compensation (including share based compensation) to the non-executive directors (includes the interim Chairman of the Board through 2014 and the Chairman of the Board for part of 2014)	$ 509	$ 560	$ 631