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

FORM 10-K

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

For the fiscal year ended May 31, 2014

Commission file number: 000-28385

PROTALEX, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**91-20033490**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

131 Columbia Turnpike, Suite 1,
Florham Park NJ 07932
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: (215) 862-9720

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

Securities registered pursuant to section 12(g) of the Act:

Common Stock, $.00001 par value
(Title of class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ 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 ☑

The approximate aggregate market value of Common Stock held by non-affiliates of the registrant was approximately $48.9 million as of November 30, 2013, the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of the registrant's Common Stock outstanding as of August 4, 2014 was 28,767,582.

DOCUMENTS INCORPORATED BY REFERENCE

None.

PROTALEX, INC.

FORM 10-K

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements made in this Annual Report on Form 10-K are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those which express plan, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. We have based these forward-looking statements on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown which could cause actual results and developments to differ materially from those expressed or implied in such statements. These forward-looking statements include statements about the following:

- the status and anticipated timing of regulatory review and approval, if any, for our products; candidates;
- our product development efforts, including results from clinical trials;
- anticipated dates of clinical trial initiation, completion and announcement of trial results by us;
- anticipated clinical trial results and regulatory submission dates for our product candidates;
- analysis and interpretation of data by regulatory authorities;
- anticipated operating losses and capital expenditures;
- estimates of the market opportunity and the commercialization plans for our product candidates;
- our intention to rely on third parties for manufacturing;
- the scope and duration of intellectual property protection for our products;
- our ability to raise additional capital; and
- our ability to acquire or in-license products or product candidates.

In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “could”, “would”, “expect”, “plan”, “anticipate”, “believe”, “estimate”, “target”, “goal”, “continue”, or the negative of such terms or other similar expressions. Factors that might cause or contribute to differences include, but are not limited to, those discussed in Item 1A. Risk Factors of this Annual Report and discussed in our other Securities and Exchange Commission (“SEC”) filings, which discloses all material factors known to us that we believe could cause actual results to differ materially from those expressed or implied by forward-looking statements.

We urge you to carefully review and consider the disclosures found in these filings, all of which are available in the SEC EDGAR database at www.sec.gov. Given the uncertainties affecting biotechnology companies which are still conducting phase 1 clinical studies , you are cautioned not to place undue reliance on any such forward-looking statements, any of which may turn out to be wrong due to inaccurate assumptions, unknown risks, uncertainties or other factors. We undertake no obligation to (and expressly disclaim any such obligation to) publicly update or revise the statements made herein or the risk factors that may relate thereto whether as a result of new information, future events or otherwise.

The following discussions should be read in conjunction with our audited Financial Statements and related notes thereto, and the Risk Factors in Item 1A included elsewhere in this Annual Report.

PART I

ITEM 1. BUSINESS

We are focused on the development of a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases including rheumatoid arthritis (RA). Our lead product, PRTX-100, is a formulation of a proprietary, highly-purified form of staphylococcal protein A, which is an immunomodulatory protein produced by bacteria. PRTX-100 has demonstrated effectiveness in animal models of autoimmune diseases and has demonstrated activity on cultured human immune cells at very low concentrations, although the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we would see in future human clinical trials. The safety, tolerability and pharmacokinetics ("PK") of PTRX-100 in humans have now been characterized in five clinical studies. We intend to seek regulatory approval to initiate clinical studies in an orphan indication and apply for an orphan drug designation in 2014. We do not anticipate generating operating revenue for the foreseeable future and do not currently have any products that are marketable.

In August 2010, we commenced the PRTX-100-103 Study, a multi-center Phase 1b clinical trial of PRTX-100 in South Africa in adult patients with active RA on methotrexate or leflunomide. The PRTX-100-103 Study served to evaluate safety and potential efficacy of PRTX-100 in patients with active RA and was approved to enroll up to 40 patients in four dose-escalating cohorts. In January 2012, we completed patient dosing in the PRTX-100-103 Study with a total of 37 patients enrolled in four cohorts ranging from 0.15 micrograms/kg to 1.50 micrograms/kg of PRTX-100 or placebo, administered weekly for four weeks. Measures of safety, PK and disease activity were evaluated over 16 weeks following the first dose. The PRTX-100-103 Study results demonstrated that PRTX-100 was generally safe and well-tolerated in patients with active RA at all tested dose levels. More patients in the 0.90 micrograms/kg and 1.50 micrograms/kg cohorts showed improvement in their Clinical Disease Activity Index ("CDAI") than did patients in the lower dose or placebo cohorts.

In November 2012, we commenced enrollment in the United States for the PRTX-100-104 Study, a new multicenter Phase 1b randomized, multiple-dose, dose-escalation study of PRTX-100 in combination with methotrexate or leflunomide in adult patients with active RA. The sequential dose escalation phase of this study was expected to enroll up to 40 patients into five cohorts ranging from 1.50 micrograms/kg up to 18.0 micrograms/kg of PRTX-100 or placebo. Similar to the PRTX-100-103 Study, the primary objective of the PRTX-100-104 Study is to assess the safety and tolerability of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate or leflunomide therapy. The secondary objectives include determining the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the PK parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety and PK.

In August 2013, following a planned interim safety review by our Independent Data Safety Monitoring Committee (SMC) and upon completion of the fourth cohort, we expanded the 3.0 microgram, 6.0 microgram, and 12.0 micrograms/kg dose cohorts of the PRTX-100-104 Study. An additional nine patients were enrolled in the expansion cohort that was completed in October 2013. In total, the first four dose-escalating cohorts of the PRTX-100-104 Study, which included these three expanded cohorts, enrolled 41 patients with doses ranging from 1.5 micrograms/kg up to 12.0 micrograms/kg.

In November 2013, following completion of the Cohort 4 expansion cohorts, we initiated enrollment of the fifth and final cohort (Cohort 5) in the PRTX 100-104 Study. The Cohort 5 sub-study enrolled 20 patients who were to receive five weekly doses of PRTX-100 followed by up to four additional monthly maintenance doses of PRTX-100 in the 3.0 micrograms/kg to 6.0 micrograms/kg range. The primary objective of the Cohort 5 sub-study is to assess safety and tolerability of these doses administered on a modified schedule. Secondary objectives include determining the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the PK parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety, PK and efficacy parameters. In July 2014, the last patient in Cohort 5 received their last dose. In total, 11 out of 20 patients in Cohort 5 will have completed all study visits per protocol by August 2014.

In June 2014, we announced preliminary unblinded findings of certain key parameters from the first four dosing cohorts of the 104 Study through completion of the 25-week study protocol. The preliminary results indicated that PRTX-100 was generally safe and well tolerated and the Adverse Event (AE) profile was consistent with prior trials results. There were no immediate hypersensitivity reactions, nor any treatment-related Serious Adverse Events (SAEs) evident and no expedited reports to the U.S. Food and Drug Administration (FDA) were required.

A total of 61 patients enrolled across all five cohorts in the PRTX-100-104 Study at nine study sites in the United States.

We maintain an administrative office in Florham Park, New Jersey, and currently outsource all of our product development and regulatory activities, including clinical trial activities, manufacturing and laboratory operations, to third-party contract research organizations, consultants and facilities.

In April 2009, under prior management, we ceased all operations and terminated all employees in light of insufficient funds to continue our clinical trials and related product development. Our business was dormant until new management took control of our operations in November 2009 following the "change in control" transaction described below. We are currently actively pursuing the commercial development of PRTX-100 for the treatment of RA.

On December 8, 2010, we effected a reverse stock split of the outstanding shares of our common stock, with par value of $0.00001 per share ("Common Stock"), on the basis of one new share of Common Stock for each five shares of Common Stock outstanding. All references in this Annual Report to number of shares, price per share and weighted average number of shares outstanding of Common Stock prior to this reverse stock split have been adjusted to reflect the reverse stock split on a retroactive basis, unless otherwise noted.

Change in Control Transaction and Incremental Financing

On November 11, 2009 (the "Effective Date"), we consummated a financing transaction (the "Financing") in which we raised $3,000,000 of working capital pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with Niobe Ventures, LLC, a Delaware limited liability company ("Niobe"). Pursuant to the Purchase Agreement, we issued to Niobe (i) 8,695,652 restricted shares of our Common Stock at a purchase price of $0.23 per share (or $2 million in the aggregate) and (ii) a senior secured convertible promissory note in the principal amount of $1 million convertible into shares of our Common Stock at an initial conversion price equal to $0.23 per share (the "$1 Million Secured Note"). On February 11, 2011, Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of Common Stock.

As contemplated by the Purchase Agreement, all of our executive officers and all of the members of our Board of Directors (the "Board") prior to the closing of the Financing, with the exception of Frank M. Dougherty, resigned effective concurrently with the closing of the Financing. Mr. Dougherty resigned effective upon the expiration of the 10-day notice period required by Rule 14f-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In addition, effective upon the closing of the Financing, our Board appointed Arnold P. Kling as a director and then elected him as our president and elected Kirk M. Warshaw as our chief financial officer and secretary.

In addition, on the Effective Date, we terminated (i) the Investor Rights Agreement dated September 18, 2003 among us, vSpring SBIC L.P. ("vSpring") and certain of the investors set forth on Schedule A thereto and the Registration Rights Agreement dated May 25, 2005 among us, vSpring and certain of the investors set forth on Schedule I thereto in accordance with their respective terms and (ii) stock options exercisable for an aggregate of 246,714 shares of Common Stock (approximately 41% of our then outstanding stock options).

On February 11, 2011, for the purpose of providing us with additional working capital, pursuant to an existing Credit Facility Agreement dated as of December 2, 2009 (the "Facility") with Niobe, we issued to Niobe a senior secured convertible promissory note in the principal amount of $2 million (the "$2 Million Secured Convertible Note"). The $2 Million Secured Convertible Note provided for conversion of interest and principal into shares of our Common Stock at a conversion price of $0.23 per share, bore interest at a rate of 3% per annum and had a maturity date of December 31, 2013. The original maturity was December 31, 2012 but in December 2012 Niobe agreed, for no consideration, to extend the maturity date to December 31, 2013.

The $2 Million Secured Convertible Note was convertible at any time, by the holder, subject only to the requirement that we have sufficient authorized shares of Common Stock after taking into account all outstanding shares of Common Stock and the maximum number of shares issuable under all issued and outstanding convertible securities. In addition, the $2 Million Secured Convertible Note would automatically be converted if we undertake certain Fundamental Transactions, as defined in the $2 Million Secured Convertible Note, (such as a merger, sale of all of our assets, exchange or tender offer, or reclassification of our stock or compulsory exchange). The $2 Million Secured Convertible Note also provided for the adjustment of the conversion price in the event of stock dividends and stock splits, and provides for acceleration of maturity, at the holder's option, upon an event of default, as defined in the $2 Million Secured Convertible Note. On August 27, 2013, Niobe elected to convert the principal and accrued interest of $2,155,000 under the $2 Million Secured Convertible Note into 9,369,565 shares of Common Stock.

On February 1, 2012, we raised $1,000,000 of working capital pursuant to a loan from Niobe. We issued to Niobe a secured promissory note in the principal amount of $1,000,000 (the "February 2012 Secured Note"). The February 2012 Secured Note bore interest at a rate of 3% per annum and had a maturity date of February 1, 2014.

On June 5, 2012, we raised an additional $1,000,000 of working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 31, 2014 (the "June 2012 Secured Note").

On October 1, 2012, we raised $800,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $800,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "October 2012 Secured Note").

On December 3, 2012, we raised $700,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $700,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "December 2012 Secured Note").

Collectively, the February 2012 Secured Note, the June 2012 Secured Note, the October 2012 Secured Note and the December 2012 Secured Note are hereinafter referred to as the "2012 Secured Notes."

On January 18, 2013, we raised $2,500,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,500,000, which bore interest at a rate of 3% per annum and had a maturity date of January 15, 2015 (the "January 2013 Secured Note").

On May 13, 2013, we raised $2,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 13, 2015 (the "May 2013 Secured Note").

On August 27, 2013, the Company raised $1,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bears interest at a rate of 3% per annum and matures on August 27, 2015 (the "August 2013 Secured Note").

Collectively, the January 2013 Secured Note, the May 2013 Secured Note, and the August 2013 Secured Note are hereinafter referred to as the "2013 Secured Notes."

Collectively, the 2012 Secured Notes and the 2013 Secured Notes represent a total of $9,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

On October 11, 2013, we issued a Consolidated, Amended and Restated Promissory Note to Niobe in the principal amount of $9,219,366 (the "Consolidated Note"). The face amount of the Consolidated Note reflects the $9.0 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on each note from its respective date of issuance. The terms of the Consolidated Note are identical to the Secured Notes except that: (a) the maturity date is September 1, 2015, which is after the latest maturity date of any of the Secured Notes; and (b) it provides for partial mandatory repayment in the event that the Company receives aggregate gross proceeds in excess of $7.5 million from a single or multiple "Liquidity Events" in an amount equal to twenty-five (25%) percent of such gross proceeds. A "Liquidity Event" means (a) the sale of any of our equity, or equity-linked, securities, and (b) the receipt of proceeds, directly or indirectly related to a development and/or commercialization relationship entered into with an unaffiliated third party. In the Secured Notes, the entire principal amount of each note was due, at Niobe's election, upon the consummation of an equity financing of $7.5 million or greater. Consistent with the terms of the Secured Notes and related security agreements entered into, our obligations under the Consolidated Note are secured by a first priority perfected security interest in all of our assets pursuant to a Consolidated, Amended and Restated Security Agreement dated October 11, 2013 with Niobe.

On January 23, 2014, we consummated a private placement financing to accredited investors of 471,334 shares of Common Stock at $6.00 per share resulting in gross proceeds of $2,828,000. We realized net proceeds, after the costs associated with the private placement, of $2,781,603. No commissions were payable in connection with the financing transaction. Proceeds of the financing will be used for working capital registration rights in connection with certain registration statements filed by us in the future, subject to certain exceptions, including a registration statement filed in connection with a primary offering by us.

All of the securities issued in the aforementioned financings were issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Act") pursuant to Section 4(a)(5) and Rule 506 of Regulation D thereof. The offer, sale and issuance of such securities were made without general solicitation or advertising. The securities were offered and issued only to "accredited investors" as such term is defined in Rule 501 under the Act.

About PRTX-100

PRTX-100 is a formulation of a proprietary, highly purified form of the Staphylococcal bacterial protein known as Protein A which is an immunomodulatory protein produced by bacteria. PRTX-100 has the ability, at very low concentrations, to bind to human B-lymphocytes and macrophages and to modulate immune processes. Pre-clinical studies also demonstrate that low doses of PRTX-100 have potent therapeutic effects in certain models of immune-mediated inflammatory diseases. The PRTX-100-103 Study demonstrated that PRTX-100 was generally safe and well tolerated at all dose levels, and at the higher doses, more patients showed improvement in their CDAI scores for RA than did patients at the lower dose or placebo cohorts.

Animal Studies

Protalex's lead candidate, PRTX-100, has demonstrated positive results in several standard mouse models of autoimmunity, including the following:

Collagen-Induced Arthritis **-** PRTX-100 has demonstrated reproducible efficacy in this well-established animal model of RA. Mice received two injections of collagen in order to stimulate an inflammatory response. One group was treated with various doses of PRTX-100, a second group received Enbrel®, a leading commercially available treatment for RA, and the control group was injected with vehicle saline solution. The mice were observed for clinical symptoms, joint size and loss of function. The results showed that low doses of PRTX-100 and standard doses of Enbrel® suppressed clinical symptoms including joint swelling over the first two to three weeks of treatment, and slowed disease progression as compared with the control group. Thereafter, the PRTX-100-treated mice continued to remain disease-free whereas the mice treated with Enbrel® showed a resumption of joint inflammation and tissue damage. This response to Enbrel® was expected because the mice developed immune response to it because it is a foreign protein. Overall, these results indicate that PRTX-100 is a potential treatment for RA in humans. The data from these studies has served as a rationale for conducting clinical trials in human patients.

BXSB Mice **-** These animals are genetically predisposed to autoimmune diseases. This model is used to evaluate drugs for autoimmune diseases such as Lupus and other autoimmune diseases. This genetic model more closely approximates the human condition in that it is complex, multi-factorial and usually treated by multiple drug regimens. In these studies, mice were treated with PRTX-100 and sacrificed at regular intervals. Their organs were weighed and sectioned for histological analysis and their spleens were used for immunological assays. Spleen enlargement, or splenomegaly, was significantly reduced in treated animals compared with the controls at almost every time point, demonstrating the ability of PRTX-100 to delay the onset and severity of this disease.

Completed pre-clinical safety studies in animals showed no drug-related toxicity at doses up to 5-fold the highest currently planned clinical trial dose. These studies were conducted on New Zealand white rabbits and on cynomolgus monkeys. No differences were observed in body weight gain or food consumption, nor in hematology, clinical chemistry, urinalysis, or organ weight data in animals treated with PRTX-100 compared with controls treated with vehicle. These study results represent a necessary component of our IND application with the FDA.

Additional studies in monkeys have further characterized the PK, toxicity, and pharmacodynamics of PRTX-100 with up to 12 weekly doses.

Clinical Trials

Favorable pre-clinical safety and efficacy studies for our lead compound, PRTX-100, laid the foundation for the IND for treating RA. We submitted the IND to the FDA in March 2005 and later in March 2005 the FDA verbally disclosed to us that it had placed our IND on clinical hold, pending additional product characterization. In August 2005, we formally replied to the FDA and in September 2005, the FDA notified us that it had lifted the clinical hold on our IND and that our proposed study could proceed. We have completed three clinical trials and are in the process of completing a fourth clinical trial under this IND. Our first Phase I single-dose clinical trial commenced in December 2005 and was completed in March 2006. This trial was performed in healthy volunteers and was designed primarily to assess the safety and tolerability of a single intravenous dose of PRTX-100. This study demonstrated that PRTX-100 appears safe and well-tolerated at the doses administered. There were no deaths or serious adverse events. The PK profile was determined and found consistent with that projected from pre-clinical models.

In May 2007, we filed an amendment to the IND with the FDA. This amendment included the final Phase I safety study report from the 2006 trial, changes to our techniques for purification and characterization of PRTX-100, a Chemistry, Manufacturing and Controls (CMC) update, and a protocol for a second single-dose Phase I clinical trial. In July and August 2007 a second Phase I study was performed under the IND, to further characterize the safety, PK, and pharmacodynamic profile of a single-dose of PRTX-100 in healthy volunteers at doses in the projected therapeutic range. Final results indicated that the drug appears safe and well-tolerated. In August 2009, a Phase 1b randomized, double-blind, placebo-controlled, multiple dose, dose-escalation and tolerability study of PRTX-100 in combination with methotrexate or leflunomide in patients with active RA, (the "PRTX 100-103 Study") was approved by the South African Medicines Control Agency. The PRTX-100-103 Study commenced in August 2010 at three sites in South Africa and was completed in January 2012 as detailed below.

In November 2012, we commenced enrollment and dosing of patients at a total of nine sites in the United States for the PRTX-100-104 Study, a second multicenter Phase 1b randomized, multiple-dose, dose-escalation study of PRTX-100 in combination with methotrexate or leflunomide in adults with active RA which is still in progress as detailed below. The PRTX-100-104 Study sequentially escalated the weekly dose of PRTX-100 from 1.5 micrograms/kg, the highest dose in the prior RA patient study, to doses of 3.0, 6.0, and 12.0 micrograms/kg. of PRTX-100. In July 2014, the last patient in the PRTX-100-104 Study received their last dose in the fifth and final cohort.

Idiopathic Thrombocytopenic Purpura (ITP) - ITP is an uncommon autoimmune bleeding disorder characterized by insufficient platelets in the blood. The affected individuals make antibodies against their own platelets leading to the platelets' destruction, which in turn leads to the abnormal bleeding. A small clinical trial in adult patients with chronic ITP was designed to provide safety data on repeated weekly dosing with PRTX-100 (the "PRTX-100b-103 Study"). This clinical study was to be conducted under the Australian and New Zealand Clinical Trial Notification procedure, not under a U.S. IND, and was initiated, but not completed. A leading Australian clinical research organization was contracted to manage and monitor this clinical trial. After the approval of the clinical protocol by ethics committees at six sites in Australia and one in New Zealand, the PRTX-100b-103 Study began enrolling patients in the second quarter of 2008. The PRTX-100b-103 Study was designed to evaluate the safety and PK of up to four doses of PRTX-100, starting at the lowest dose, and escalating upwards after safety review of the prior dose.

The PRTX-100b-103 Study proved difficult to enroll due to other on-going ITP Phase III studies and subsequent availability of two new and effective medicines for ITP. Nine patients were dosed at the first two dose levels by the end of the first quarter of 2009. At this point further recruitment of patients was suspended. No side effects or toxicities were noted with repeated weekly doses of PRTX-100 at doses of 0.075 and 0.15 micrograms per kg that were not seen with single doses in healthy volunteer trials. This repeated-dose safety data from the PRTX-100b-103 Study was included in the clinical trial application to evaluate PRTX-100 in patients with RA.

We intend to seek regulatory approval from the FDA to initiate clinical studies in ITP and to apply for Orphan Drug Designation in 2014.

Rheumatoid arthritis - RA is a highly inflammatory polyarthritis often leading to joint destruction, deformity and loss of function. In addition to characteristic symmetric swelling of peripheral joints, systemic symptoms related to chronic inflammation can commonly occur. Chronic pain, disability and excess mortality are unfortunate sequelae. RA is the most common autoimmune disease, affecting 1% to 2% of the world's population, with prevalence rising with age to about 5% in women over 55.

PRTX-100 shows measurable activity in a standard mouse model of autoimmune arthritis. A substantial body of published literature and proprietary data delineate the immunomodulatory activities of PRTX-100, which are distinct from those of current major biologic treatments for rheumatoid arthritis. Accordingly, we believe that RA represents a potentially important clinical indication for treatment with PRTX-100. While recent advances in biologic treatments for RA have improved the prognosis for many patients, many others continue to live with debilitating RA disease activity due either to the cost, side-effects, or limited effectiveness of these newer therapies.

The PRTX-100-103 Study

In August 2010, we commenced a multi-center Phase 1b clinical trial of PRTX-100 in South Africa on adult patients with active RA on methotrexate or leflunomide. The PRTX-100-103 Study served to evaluate safety and potential efficacy of PRTX-100 in patients with active RA and was approved to enroll up to 40 patients in four dose-escalating cohorts. In January 2012, we completed patient dosing in the fourth cohort of the PRTX-100-103 Study. A total of 37 patients were enrolled in four cohorts ranging from 0.15 micrograms/kg to 1.50 micrograms/kg of PRTX-100 or placebo, administered weekly for four weeks. Measures of safety, PK, and disease activity were evaluated over 16 weeks following the first dose. The PRTX-100-103 Study results demonstrated that PRTX-100 was generally safe and well-tolerated in patients with active RA at all tested dose levels and at the higher doses, decreased RA activity as scored by the CDAI.

The number of patients with a DAS28-CRP < 3.2 (Disease Activity Score) at six weeks was the predefined disease activity endpoint of the study. The results showed that the patients receiving PRTX-100 were more likely to respond than those receiving placebo at all times, the number of responders increased over time during the 16 week study evaluation period, and that the maximum tolerated dose was not reached at the highest dose level.

Additionally, the results indicate that PRTX-100 did not change CRP (C-Reactive Protein) levels, even in those patients whose swollen and tender joint count and global VAS (Visual Analogue Scale) scores had decreased to low levels after treatment. Because of the influence of the CRP component on the DAS28-CRP score, a post-hoc analysis was performed examining changes in the CDAI scores in all patients. The CDAI score does not evaluate CRP as a component, but instead comprises physician and patient-assessed chemical markers of disease activity. In the placebo, 0.15 micrograms/kg, and 0.45 micrograms/kg dose groups, one out of eight patients in each group attained low disease activity (CDAI ≤ 10) on two or more consecutive visits. In the 0.90 micrograms/kg and 1.50 micrograms/kg dose groups, two of eight and two of five patients, respectively, attained this same endpoint, and maintained a CDAI < 10 until the week 16 final visit. Of the four apparent responders in the 1.50 micrograms/kg group, two attained a CDAI ≤ 6 (remission), one attained a CDAI ≤ 10 (low activity), and one achieved a CDAI of 10.1 at one or more visits. The mean time to peak response in this group occurred six weeks after their last dose.

The disease activity results from the PRTX-100-103 Study demonstrated an acceptable safety profile, and suggested treatment with PRTX-100 could affect disease activity, although these effects were not statistically significant. In November 2012 we commenced the PRTX-100-104 Study to provide a better understanding of safety and potential treatment effect on RA disease activity measurements as well as to help define the optimal dose.

The PRTX-100-104 Study

In November 2012, we commenced enrollment in the United States for a new multicenter Phase 1b randomized, multiple-dose, dose-escalation study (the "PRTX-100-104 Study") of PRTX-100 in combination with methotrexate or leflunomide in adult patients with active RA. The sequential dose-escalation phase of this study was expected to enroll up to 40 patients into five cohorts ranging from 1.50 micrograms/kg up to 18.0 micrograms/kg of PRTX-100 or placebo. At each dose, one quarter of patients would receive a placebo treatment. Similar to the PRTX-100-103 Study, the primary objective of the PRTX-100-104 Study was to assess the safety and tolerability of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate or leflunomide therapy. The secondary objectives included determining the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the PK parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety and PK.

In August 2013, following a planned interim safety review by our Independent Data Safety Monitoring Committee (SMC) and upon completion of the fourth cohort, we expanded the 3.0 microgram, 6.0 microgram, and 12.0 micrograms/kg dose cohorts of the PRTX-100-104 Study. An additional nine patients were enrolled in the expansion cohort that was completed in October 2013. In total, the first four dose-escalating cohorts of the PRTX-100-104 Study, which included these three expanded cohorts, enrolled 41 patients at five U.S. clinical centers with doses ranging from 1.5 micrograms/kg up to 12.0 micrograms/kg. Five patients withdrew from the study prior to their day 85 visit.

In November 2013, following completion of the Cohort 4 expansion cohorts, we initiated enrollment of the fifth and final cohort (Cohort 5) in the PRTX 100-104 Study. The Cohort 5 sub-study enrolled 20 patients who were to receive five weekly doses of PRTX-100 followed by up to four additional monthly maintenance doses of PRTX-100 in the 3.0 micrograms/kg to 6.0 micrograms/kg range. The primary objective of the Cohort 5 sub-study is to assess safety and tolerability of these doses administered on a modified schedule. Secondary objectives include determining the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the PK parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety, PK and efficacy parameters. In July 2014, the last patient in Cohort 5 received their last dose. In total, 11 out of 20 patients in Cohort 5 will have completed all study visits by August 2014.

In June 2014, we announced preliminary findings from an unblinded interim analysis of patients in Cohorts 1 through 4 of the PRTX-100-104 Study through day 85 which indicated that PRTX-100 was generally safe and well tolerated. The unblinded analysis of the 104 Study included 41 patients recruited at five U.S. clinical sites in the first four dosing cohorts of the five-cohort study through completion of the 25-week study protocol.

The preliminary results indicated that PRTX-100 was generally safe and well tolerated and the Adverse Event (AE) profile was consistent with prior trials results. There were no immediate hypersensitivity reactions, nor any treatment-related Serious Adverse Events (SAEs) evident and no expedited reports to the U.S. Food and Drug Administration (FDA) were required. Pharmacokinetic analyses indicated a roughly linear increase in plasma maximum concentrations with increasing doses of 1.5, 3.0, 6.0, and 12mcg/kg.

Moreover, the study revealed positive effects of PRTX-100 treatment on certain measures of disease activity, although these effects were not statistically significant. At the higher doses, PRTX-100 showed activity comparable to existing well known biologics with apparent onset of action occurring subsequent to the fifth and final dose. For example, four weeks following the last PRTX-100 dose (Day 57), 32% of active-treated and 13% of placebo-treated patients had attained an ACR50 response (that is, a 50% reduction in the American College of Rheumatology Core Data Set). At day 113, 29% of the active-treated patients who received 6 or 12 mcg/kg PRTX-100 plus methotrexate achieved DAS28-CRP scores less than 2.6 (remission), while the placebo-treated patients showed no remission. Notably, among all patients treated with PRTX-100, 43% had DAS28-CRP < 3.2 (low disease activity) on both Day 57 and Day 85, while only 14% of placebo-treated patients showed such a reduction in RA disease activity on these days.

A total of nine study sites in the United States were used in the PRTX-100-104 Study.

Manufacturing

We currently contract the manufacturing of our lead drug substance PRTX-100 to Eurogentec S.A. in Belgium where it is produced under Current Good Manufacturing Practice, or cGMP, conditions. In June 2012, we contracted with Eurogentec for the manufacture of additional bulk drug substance that we believe will be sufficient supply for completion of the PRTX-100-104 Study as well as initiating other planned future studies. We have also contracted with an FDA-approved facility in Europe for the formulation of new drug product at higher concentrations in anticipation of administering higher dosages in this study as well as in future studies. The stability testing and packaging of the final drug product for clinical supplies are conducted at several other FDA-approved facilities in the United States. These companies, in the aggregate, have provided the drug product for both toxicological testing and clinical supplies. We believe that this entire process is scaleable to commercial production but will require additional manufacturing resources. The original three clinical trials of PRTX-100 were conducted with a liquid formulation. The PRTX-100-103 Study and the PRTX-100-104 Study utilized a newer lyophilized formulation designed to achieve better stability and longer product shelf-life. Compared to therapeutic doses of other biologic products used to treat RA, we believe the overall costs for these proposed therapeutic doses of PRTX-100 are significantly less due to the low dose and the simplicity of drug substance manufacture.

Markets

RA is our most advanced primary indication. RA is a serious autoimmune disorder that causes the body's immune system to produce antibodies that attack the lining of the joints, resulting in inflammation and pain. RA can lead to joint deformity or destruction, organ damage, disability and premature death. According to both the Arthritis Foundation and the American College of Rheumatology websites during 2013, approximately 1.5 million people in the United States have RA, which is approximately 1% of the nation's adult population. There are nearly three times as many women as men with the disease. The disease occurs in all ethnic groups and in every part of the world.

RA was chosen as a target disease because it represents a well-defined, rapidly growing market for which there is no current uniformly effective treatment. Sixty percent of people with inadequately treated RA are unable to work 10 years after onset. It is estimated that despite treatment with current approved RA therapeutics, at least one-third of patients continue to have significant disability and limitations due to their disease. Current treatments are costly, some are associated with increased risk of cancer and opportunistic infections, and in most cases must be continued for decades. The market for the existing biologic RA drugs is primarily limited to those countries that have a high per capita income because treatment can cost tens of thousands of dollars per patient per year. Thus, a large portion of the world's patient population cannot afford the existing biologic RA drugs. In contrast, we believe that PRTX-100 could potentially provide patients with a therapy that is efficacious, cost-effective, and has a highly favorable benefit-risk ratio.

Once further developed and approved, we believe that PRTX-100 could be used to treat patients with moderate to severe cases of RA, and particularly those individuals for whom other treatments failed. Given the differences in the regulatory approval process in different parts of the world, it is reasonable to believe that PRTX-100 might first be used in the developing world and then in Europe and North America.

In addition, we believe ITP also represents a potential indication for PRTX-100. ITP or Idiopathic thrombocytopenic purpura is a bleeding disorder in which the immune system destroys platelets, which are necessary for normal blood clotting. Persons with the disease have too few platelets in the blood. ITP affects women more often than men, and it is more common in children than in adults. In children, the disease usually resolves without treatment. Adults are usually treated with an anti-inflammatory steroid medicine (prednisone). In some cases, surgery to remove the spleen (splenectomy) is recommended. This increases the platelet count in about half of patients.

ITP has no cure, and relapses may occur years after seemingly successful medical or surgical management. If the disease does not get better with prednisone, a corticosteroid drug that is the first line therapy for ITP, other treatments may include: danazol (Danocrine), a drug taken by mouth; infusions of high-dose gamma globulin (an immune factor); drugs that suppress the immune system; anti-RhD therapy for people with certain blood types; and newer agents like romiplostim (Nplate) and eltrombopag (Promacta) that stimulate the bone marrow to make more platelets. Global sales of Nplate and Promacta were approximately $400 million and $250 million, respectively, in 2013. Neither romiplostim or eltrombopag impact the principal pathological mechanism of ITP, namely immune-mediated plated destruction, and we believe that PRTX-100 may have a more direct impact on ITP disease processes. Thus, we believe that PRTX-100 may complement or reduce the use of thrombopoeitic agents in patients with ITP.

Preliminary information gained in the laboratory on the mechanism of action of PRTX-100 also suggests potential efficacy in a range of autoimmune diseases, including, but not limited to psoriasis, myasthenia gravis, chronic idiopathic demyelinating polyneuropathy, and pemphigus.

Our long-term strategy contemplates the pursuit of FDA approval to treat autoimmune diseases other than RA.

Competition

We believe, based on the pre-clinical trials and the results to date of our five Phase I clinical trials, that PRTX-100 has a potential competitive advantage as it may be safer and more efficacious than existing RA therapies, and may cost less to manufacture than competing biologic-based therapies. Current RA treatments are characterized by complex manufacturing methods and, in 2013, resulted in an average annual retail cost of approximately $15,000 to $30,000 per patient, if the newer disease-modifying anti-rheumatic drugs approved in the last 20 years were used. The cost can increase according to the size/weight of a patient and the number of doses required. Additionally, patients are faced with the cost of the infusion itself and blood tests which are often not included in those cost estimates. A number of pharmaceutical agents are currently being used, with varying degrees of success, to control the signs and symptoms of RA and slow its progression. Available treatment options include:

- Analgesic/anti-inflammatory preparations, ranging from simple aspirin to the COX-2 inhibitors;
- Immunosuppressive/antineoplastic drugs, including azathioprine and methotrexate;
- TNF (Tumor Necrosis Factor) inhibitors, also known as anti-TNF therapy, currently represented by etanercept (Enbrel®), infliximab (Remicade®), and adalimumab (Humira®) and the newer entries, certolizumab (Cimzia®) and golimumab (Simponi®);
- Soluble Interleukin-l (IL-I) Receptor Therapy, Anakinra (Kineret®) and (Il-6) tocilizumab (Actemra®);
- Costimulatory molecule inhibitor abatacept (Orencia®);
- Anti CD20 B-cell-directed therapy, rituximab (Rituxan®); and
- Janus Kinase (JAK) inhibitor, tofacitinib citrate (Xeljanz).

Many large and small pharmaceutical companies are active in this market, with Amgen Corporation (with Pfizer), Johnson & Johnson, Inc. (with Merck) and Abbott Laboratories dominating the market for biologic therapies with their respective products, Enbrel®, Remicade® and Humira®. According to each company's 2013 annual reports, Enbrel generated revenues of approximately $9.7 billion combined for Amgen and Pfizer, Remicade generated revenues of more than $8.9 billion combined for Johnson & Johnson and Merck, and Abbvie reported revenues of $10.7 billion for Humira. The final two TNF inhibitors, usually second line use, have also increased their revenues. Cimzia generated revenues of $803 million for UCB. Although approved in Japan in March 2013, Astellas did not list its Cimzia in its 2013 Annual Report. Simponi generated revenues of $1.4 billion for Johnson & Johnson and Merck, while Orencia generated revenues of $1.4 billion for Bristol Myers Squibb. Kineret generated revenues of $484.7 million in sales for SOBI, but Amgen did not list its Kineret sales in the company's 2013 Annual Report. Actemra generated revenues of $1.2 billion and Rituxan $7.7 billion for Roche. Xeljanz, approved in 2012, has earned Pfizer $114 million in 2013.. These revenues reflect the use of these drugs for RA, other indications and off label uses.

Post–marketing experience has indicated that current and newly-marketed disease modifying anti-rheumatic drugs (DMARDs) subject patients to an increased risk of certain serious adverse events (SAEs). Products which inhibit the action of TNF-alpha, being the longest on the market and the most studied, have demonstrated an increased incidence of certain SAEs. Due to suppression of the immune system by these products, these SAEs include serious and opportunistic infections such as tuberculosis, fungal infections, and listeria infection, and increased risk of lymphomas. Transient neutropenia and other blood dyscrasias have been reported. TNF inhibitors are also not recommended in patients with demyelinating disease or with congestive heart failure. Rituxan (anti-CD20) use increases the potential for Hep B reactivation and multifocal leukoencephalopathy, a fatal viral disease. Kineret (IL-1) also shows an increased the risk of infection. Actemra (IL-6) use has led to increased liver enzyme levels, hypertension, transient neutropenia, and an increase in cholesterol levels. Orencia (T cell inhibition) also works by weakening the immune system, therefore can increase the risk of infections. Patients using Orencia have developed lymphoma and lung cancer. Xeljanz (JAK) is the newest RA treatment to enter the market. It has demonstrated similar side effects to TNF inhibitors, including invasive and opportunistic infections and the reactivation of tuberculosis. Lymphomas and other malignancies have been observed in patients treated with Xeljanz. In a study by a Swedish research group published in November 2012 by the American College of Rheumatology entitled, "Mortality Rates in Patients with Rheumatoid Arthritis Treated with Tumor Necrosis Factor Inhibitors", following treatment of RA with either of the TNF inhibitors Enbrel, Humira or Remicade, mortality rates were on average approximately one death per 30 patients treated in the first three years of treatment. Findings such as these and the long list of serious adverse events for all of the currently marketed treatments indicate that new and safer treatments for autoimmune diseases such as RA are needed.

Government Regulation and Product Approval

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the testing (preclinical and clinical), manufacturing, labeling, storage, recordkeeping, advertising, promotion, import, export, marketing and distribution, among other things, of drugs and drug product candidates. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. We and our manufacturers may also be subject to regulations under other U.S. federal, state, local and foreign laws.

In the United States, the FDA regulates drugs under the Food Drug and Cosmetic Act, or FDCA, and implementing regulations. The process required by the FDA before our drug candidates may be marketed in the United States generally involves the following (although the FDA is given wide discretion to impose different or more stringent requirements on a case-by-case basis):

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice or GLP regulations and other regulations;
- submission to the FDA of an IND application which must become effective before clinical trials may begin;
- performance of multiple adequate and well-controlled clinical trials meeting FDA requirements to establish the safety and efficacy of the product candidate for each proposed indication;
- submission of a Biological License Application or BLA to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product candidate is produced, and potentially other involved facilities as well, to assess compliance with cGMP, regulations and other applicable regulations; and
- the FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all. Risks to us related to these regulations are described in the Risk Factors in Item 1A of this Annual Report.

A separate submission to the FDA, under an existing IND must also be made for each successive clinical trial conducted during product development. The FDA must also approve changes to an existing IND. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice or GCP requirements and regulations for informed consent.

Clinical Trials

For purposes of BLA submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap (although additional or different trials may be required by the FDA as well):

- *Phase I clinical trials* are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. In some cases, particularly in cancer trials, a sponsor may decide to conduct what is referred to as a "Phase 1b" evaluation, which is a second safety-focused Phase I clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently FDA-approved drugs.

- *Phase II clinical trials* are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine an optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some cases, a sponsor may decide to conduct what is referred to as a "Phase IIb" evaluation, which is a second, confirmatory Phase II clinical trial that could, if positive and accepted by the FDA, serve as a pivotal clinical trial in the approval of a drug candidate.

- *Phase III clinical trials* are commonly referred to as pivotal trials. When Phase II clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In some cases, the FDA may condition continued approval of a BLA on the sponsor's agreement to conduct additional clinical trials with due diligence. In other cases, the sponsor and the FDA may agree that additional safety and/or efficacy data should be provided; however, continued approval of the BLA may not always depend on timely submission of such information. Such post-approval studies are typically referred to as Phase IV studies.

Biological License Application

The results of drug candidate development, preclinical testing and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, and the payment of a user fee, are submitted to the FDA as part of a BLA. The FDA reviews all BLAs submitted before it accepts them for filing and may request additional information rather than accepting a BLA for filing. Once a BLA is accepted for filing, the FDA begins an in-depth review of the application.

During its review of a BLA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA may refuse to approve a BLA and issue a not approvable letter if the applicable regulatory criteria are not satisfied, or it may require additional clinical or other data, including one or more additional pivotal Phase III clinical trials. Even if such data are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaboration partners interpret data. If the FDA's evaluations of the BLA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the BLA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. The FDA may withdraw drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the FDA-approved indications and in accordance with the FDA-approved label. Further, if there are any modifications to the drug, including changes in indications, other labeling changes, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

Fast Track Designation

The FDA's fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, applicants may seek traditional approval for a product based on data demonstrating an effect on a clinically meaningful endpoint, or approval based on a well-established surrogate endpoint. The sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of a marketing application. The FDA will determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

If the FDA grants fast track designation, it may initiate review of sections of a BLA before the application is complete. This so-called "rolling review" is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant has paid applicable user fees. The FDA's Prescription Drug User Fee Act or PDUFA review clock for both a standard and priority BLA for a fast track product does not begin until the complete application is submitted. Additionally, fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by emerging data, or if the designated drug development program is no longer being pursued.

In some cases, a fast track designated drug candidate may also qualify for one or more of the following programs:

- *Priority Review.* As explained above, a drug candidate may be eligible for a six-month priority review. The FDA assigns priority review status to an application if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track drug would ordinarily meet the FDA's criteria for priority review, but may also be assigned a standard review. We do not know whether any of our drug candidates will be assigned priority review status or, if priority review status is assigned, whether that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately approve the drug.

- *Accelerated Approval.* Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and efficacy in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival or irreversible morbidity. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies with due diligence, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, may cause the FDA to seek to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA

When appropriate, we intend to seek fast track designation, accelerated approval or priority review for our drug candidates. We cannot predict whether any of our drug candidates will obtain fast track, accelerated approval, or priority review designation, or the ultimate impact, if any, of these expedited review mechanisms on the timing or likelihood of the FDA approval of any of our drug candidates.

Satisfaction of the FDA regulations and approval requirements or similar requirements of foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a drug candidate is intended to treat a chronic disease, as is the case with the drug candidate we are developing, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for changes in dosage form or new indications for our drug candidates on a timely basis, or at all. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for our drug candidate would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Regulatory Requirements

Any drugs manufactured or distributed by us or any potential collaboration partners pursuant to future FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, sales or use, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the BLA for that drug.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning and/or untitled letters, corrective advertising and potential civil and criminal penalties.

Orphan Drug Designation in the United States, the European Union and other foreign jurisdictions

We will seek approval for Orphan Drug Designation in the United States as well as certain foreign jurisdictions for ITP. Based upon study data to date, we believe that PRTX-100 may be effective in the treatment of ITP, as well as other orphan immunological diseases.

Under the U.S. Orphan Drug Act, Orphan drug designation is granted by the FDA to drugs intended to treat a rare disease or condition, which for this program is defined as having a prevalence of fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a marketing application. After the FDA grants an orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

Orphan drug designation does not shorten the regulatory review and approval process, nor does it provide any advantage in the regulatory review and approval process. However, if a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to an orphan exclusivity period, in which the FDA may not approve any other applications to market the same drug for the same indication for seven years in the United States, except in limited circumstances.

In addition, outside of the U.S. medicinal products used to treat life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in European Union and medicinal products which, for economic reasons, would be unlikely to be developed without incentives may be granted orphan designation in the European Union. The application for orphan designation is submitted to the EMA before an application is made for marketing authorization. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity. During this ten year period, with a limited number of exceptions, neither the competent authorities of the European Union member states nor the EMA are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same orphan indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is safer, more effective or otherwise clinically superior to the original orphan medicinal product.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future products.

Patents, Trademarks, and Proprietary Technology

Patents and other proprietary rights are important to our business. Our practice is to file patent applications to protect technology, inventions and improvements to our technologies that are considered important to the development of our business. We have filed several U.S. patent applications and international counterparts of certain of these applications. We also rely upon our trade secrets, know-how, and continuing technological innovations, as well as patents that we may license from other parties, to develop and maintain our competitive position.

Our success will depend on our ability to maintain our trade secrets and proprietary technology in the United States and in other countries. We filed an initial therapeutic use patent application with the U.S. Patent and Trademark Office, or PTO, which issued in May 2007, as U.S. 7,211,258. The 258 patent has claims relating to the treatment of acute inflammation as well as rheumatoid arthritis (RA) and systemic lupus erythematosis (SLE) using protein A. A second patent claiming the use of protein A to treat idiopathic thrombocytopenia or autoimmune thrombocytic purpura issued as U.S. 7,425,331 in September, 2008. A further patent for the use of protein A issued as U.S. 7,807,170 in October, 2010. The 170 patent claims the use of protein A to reduce an acute inflammatory response or inflammation, including when these symptoms are associated with myasthenia gravis, ulcerative colitis, Crohn's Disease, psoriatic arthritis or pemphigus vulgaris. A further patent claiming the use of protein A to treat psoriasis and scleroderma issued as U.S. 8,168,189 in May, 2012. In December 2013, a patent with claims to the use of protein A to treat multiple sclerosis issued as U.S. 8,603,486. We have also filed for foreign patent protection in Canada, Japan and the European Union. Japanese patent JP 4598404 issued in October, 2010 with claims relating to use of protein A to treat rheumatoid arthritis, SLE, idiopathic thrombocytopenia, and autoimmune thrombocytopenia purpura. In April 2014, we received a notice of allowance in Japan for psoriasis, scleroderma and Crohn's Disease.

It is our policy to require our employees, consultants, and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or collaborations with us. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us is to be kept confidential and not to be disclosed to third parties except in specific circumstances.

Employees

We have three part-time employees, our president, our chief financial officer and an administrative person. In addition, we also have a Scientific Advisory Board which is staffed by highly qualified consultants with the background and scientific expertise we need to carry out our long-term business objectives. We believe that our relationship with all of our employees and our Scientific Advisory Board is generally good.

Properties

Our principal offices are located at 131 Columbia Turnpike, Suite 1, Florham Park, New Jersey in facilities we occupy on a month to month basis. We do not own or intend to invest in any real property. We currently have no policy with respect to investments or interests in real estate, real estate mortgages or securities of, or interests in, persons primarily engaged in real estate activities.

Legal Proceedings

We are not involved in any pending legal proceedings and are not aware of any threatened legal proceedings against us.

ITEM 1A. RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below, in addition to the other information set forth in this Annual Report, because they could materially and adversely affect our business, operating results, financial condition, cash flows and prospects, as well as adversely affect the value of an investment in our Common Stock. Also, you should be aware that the risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in and incorporated by reference into this Annual Report, including our consolidated financial statements and the related notes.

There are numerous and varied risks that may prevent us from achieving our goals. We believe that the following are the material risks that we face. If any of the following risks actually occurs, our business, financial condition or results of operation may be materially adversely affected. In such case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.

Risks relating to our Business

If we are unable to enroll enough patients to complete our clinical trials, our applications before regulatory agencies may never be submitted or approved, which may result in increased costs and harm our ability to develop products.

If we are not able to enroll enough patients to complete the RA or other planned clinical trials for PRTX-100, regulatory agencies may delay reviewing our applications for approval, or may reject them, based on our inability to enroll enough patients to complete our clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. Delays in planned patient enrollment may result in increased costs and delays, which could have a harmful effect on our ability to develop products. We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a drug or the period required for review of any application for regulatory agency approval of a particular compound. We also may encounter delays if we are unable to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for our planned clinical trials. In addition, we rely on a number of third-parties, such as clinical research organizations, to help support the clinical trials by performing independent clinical monitoring, data acquisition and data evaluations. Any failure on the part of these third-parties could delay the regulatory approval process.

Clinical trials are expensive, time consuming and difficult to design and implement. If clinical trials for PRTX-100 don't provide positive results, we may be required to abandon or repeat such clinical trials.

Human clinical trials are expensive and difficult to design and to implement, in part because they are subject to rigorous requirements. The clinical trial process is also time-consuming. Even with adequate financing, we estimate that our clinical trials for PRTX-100 will take up to several additional years to complete. Furthermore, poor results or failure can occur at any stage of the trials, and we can encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- slow enrollment of qualified patients;
- 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 or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the U.S. Food and Drug Administration ("FDA") and/or foreign regulatory agencies may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA and/or foreign regulatory agencies find deficiencies in our Investigational New Drug Application ("IND") and/or country specific regulatory submissions or in the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for future clinical trials.

If we fail to obtain regulatory approvals for PRTX-100 or any other drug we develop, we will not be able to generate revenues from the commercialization or sale of those drugs.

We must receive regulatory approval of each of our drugs before we can commercialize or sell that product. The pre-clinical laboratory testing, formulation development, manufacturing and clinical trials of any product we develop, as well as the distribution and marketing of these products, are regulated by numerous federal, state and local governmental authorities in the United States, principally the FDA, and by similar regulatory authorities in other countries. The development and regulatory approval process takes many years, requires the expenditure of substantial resources, is uncertain and subject to delays, and will thus delay our receipt of revenues, if any, from PRTX-100 or any other drug we develop. We cannot assure you that our clinical trials will demonstrate the safety and efficacy of PRTX-100 or any other drug we develop or will result in a marketable product.

No product can receive FDA approval unless human clinical trials show both safety and efficacy for each target indication in accordance with FDA and foreign country standards. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in early stage development. We therefore cannot assure you that the results from our clinical trials will be successful or that the results from our pre-clinical trials for PRTX-100 or any other drug we develop will be predictive of results obtained in future clinical trials.

Further, data obtained from pre-clinical and clinical trial activities are subject to varying interpretations that could delay, limit or prevent regulatory agency approval. We cannot assure you that our clinical trials will establish the safety and efficacy of PRTX-100 or any other drug we develop sufficiently for us to obtain regulatory approval.

Our products, if approved, may fail to achieve market acceptance.

There can be no assurance that any products we successfully develop, if approved for marketing, will achieve market acceptance or generate significant revenues. We intend for our products, including PRTX-100, to replace or alter existing therapies or procedures, and hospitals, physicians or patients may conclude that these products are less safe or effective or otherwise less attractive than existing therapies or procedures. If our products do not receive market acceptance for any reason, it would adversely affect our business, financial condition and results of operations.

Further, our competitors may develop new technologies or products that are more effective or less costly, or that seem more cost-effective, than our products. We can give no assurance that hospitals, physicians, patients or the medical community in general will accept and use any products that we may develop.

We may never obtain orphan drug status and market exclusivity for any disease indication, and if approved, we could lose orphan market exclusivity if another drug is approved first using the same method of action or demonstrates clinical superiority.

There is no assurance that if we file for an Orphan Drug Designation for any indication, that the FDA, the European Medicinal Agency ("EMA") or any other regulatory body will ever approve it. In addition, if an application is filed and approved, Orphan drug exclusive marketing rights may be lost if the FDA, EMA or other regulatory body later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Although obtaining approval to market a product with Orphan drug exclusivity may be advantageous, we cannot be certain that:

- we will be the first to obtain approval for any drug for which we obtain Orphan Drug Designation;
- Orphan Drug Designation will result in any commercial advantage or reduce competition; or
- limited exceptions to this exclusivity will not be invoked by the relevant regulatory authority.

If we are unable to obtain, to protect, and to maintain our proprietary rights in intellectual property, we may not be able to compete effectively or operate profitably.

Our commercial success also depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology covering our product candidates and avoiding infringement of the proprietary technology of others. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our industry are still evolving. However, we will be able to protect our proprietary rights from unauthorized use by third-parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively protected and maintained as trade secrets.

We have tried to protect our proprietary position by filing U.S. and international patent applications related to PRTX-100. We filed an initial therapeutic use patent application with the U.S. Patent and Trademark Office, or PTO, (issued as U.S. 7,211,258) which issued the 258 Patent in May 2007. The 258 Patent has claims relating to the treatment of acute inflammation as well as rheumatoid arthritis (RA) and systemic lupus erythematosis (SLE) using protein A. A second patent claiming the use of protein A to treat idiopathic thrombocytopenia or autoimmune thrombocytic purpura issued as U.S. 7,425,331 in September, 2008. A further patent for the use of protein A issued as U.S. 7,808,170 in October, 2010. The 170 Patent claims the use of protein A to reduce an acute inflammatory response or inflammation, including when these symptoms are associated with myasthenia gravis, ulcerative colitis, Crohn's Disease, psoriatic arthritis or pemphigus vulgaris. A further patent claiming the use of protein A to treat psoriasis and scleroderma issued as U.S. 8,168,189 in May, 2012. In December 2013, a patent with claims to the use of protein A to treat multiple sclerosis issued as U.S. 8,603,486. We have also filed for foreign patent protection in Canada, Japan and the European Union. Japanese patent JP 4598404 issued in October, 2010 with claims relating to use of protein A to treat rheumatoid arthritis, systemic lupus erythematosis (SLE), idiopathic thrombocytopenia, and autoimmune thrombocytopenia purpura. In April 2014, we received a notice of allowance in Japan for psoriasis, scleroderma and Crohn's Disease. Because the patent position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own may not provide any protection against competitors. Patents that we may file in the future or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed, or designed around any patents we may have issued to us. Moreover, the laws of foreign countries do not protect intellectual property rights to the same extent as the laws of the United States.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We protect this information by entering into confidentiality agreements with parties that have access to it, such as potential investors, advisors, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information, or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent was to be disclosed to or independently developed by a competitor, our business and financial condition could be adversely affected.

If other companies claim that we infringe their proprietary technology, we may incur liability for damages or be forced to stop our development and commercialization efforts.

Competitors and other third-parties may initiate patent litigation against us in the United States or in foreign countries based on existing patents or patents that may be granted in the future. These lawsuits can be expensive and would consume time and other resources even if unsuccessful or brought without merit. Our competitors may have sought or may seek patents that cover aspects of our technology. We are aware that a third-party has a pending patent application for technologies generally related to ours, and more patents for similar technologies may be filed in the future. In the United States, patent applications may remain confidential after filing or published 18 months after filing.

Owners or licensees of patents may file one or more infringement actions against us. Any such infringement action could cause us to incur substantial costs defending the lawsuit and could distract our management from our business, even if the allegations of infringement or misappropriation are unwarranted. The defense of multiple claims could have a disproportionately greater impact. Furthermore, an adverse outcome from this type of claim could subject us to a judgment that requires us to pay substantial damages. A judgment could also include an injunction or other court order that could prevent us from making, using, selling, offering for sale or importing our products or prevent our customers from using our products.

Alternatively, we could be required to license disputed rights from the third party. If a court determines, or if we independently discover, that any of our products or manufacturing processes violates third-party proprietary rights, we might not be able to reengineer the product or processes to avoid those rights, or obtain a license under those rights on commercially reasonable terms, if at all.

We may become involved in lawsuits to protect or enforce our patents that would be expensive and time consuming.

In order to protect or enforce our patent rights, we may initiate patent litigation against third-parties. In addition, we may become subject to interference or opposition proceedings conducted in patent and trademark offices to determine the priority of inventions. The defense of intellectual property rights, including patent rights through lawsuits, interference or opposition proceedings, and other legal and administrative proceedings, would be costly and divert our technical and management personnel from their normal responsibilities. An adverse determination of any litigation or defense proceedings could put our patent application at risk of not issuing.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation, confidential information may be inadvertently disclosed in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. This disclosure could negatively affect our business and financial results.

We may not be able to manufacture our products in commercial quantities, which would prevent us from marketing our products.

If any of our potential products were approved by the FDA or foreign regulatory agencies for commercial sale, we would need to manufacture them in larger quantities. We have no manufacturing facilities at this time, and we have no experience in the commercial manufacturing of drugs. Thus, we would need to either develop the capability of manufacturing on a commercial scale or engage third-party manufacturers with this capability. Significant scale-up of manufacturing may require certain additional validation studies, which the FDA must review and approve. Moreover, contract manufacturers often encounter difficulties in achieving volume production, quality control and quality assurance, as well as shortages of qualified personnel. For these reasons, a third-party manufacturer might not be able to manufacture sufficient quantities of PRTX-100 to allow us to commercialize it. If we are unable to increase the manufacturing capacity for PRTX-100, or any other product we may develop, we may experience delays in or shortages in supply when launching them commercially.

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

If we receive regulatory approval to commence commercial sales of PRTX-100, we will face competition with respect to commercial sales, marketing and distribution. These are areas in which we currently have no experience due to a lack of management. To market our product directly, we must develop a direct marketing and sales force with technical expertise and supporting distribution capability. Alternatively, we may engage a pharmaceutical or other healthcare companies with an existing distribution system and direct sales force to assist us. There can be no assurance that we will successfully establish sales and distribution capabilities either on our own or in collaboration with third-parties or gain market acceptance for our product. To the extent we enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third-parties. Those efforts may not succeed.

Competition in the pharmaceutical industry is intense; if we fail to compete effectively, our financial results will suffer.

We engage in a business characterized by extensive research efforts, rapid developments and intense competition. We cannot assure you that our products will compete successfully or that research and development by others will not render our products obsolete or uneconomical. Our failure to compete effectively would negatively affect our business, financial condition and results of operations. We expect that successful competition will depend, among other things, on product efficacy, safety, reliability, availability, timing and scope of regulatory approval and price. Specifically, other factors we expect will impact our ability to compete include the relative speed with which we can develop products, complete the clinical, development and laboratory testing and regulatory approval processes and supply commercial quantities of the product to the market.

We expect competition to increase as technological advances are made and commercial applications broaden. In commercializing PRTX-100 and any additional products we develop using our technology, we will face substantial competition from large pharmaceutical, biotechnology and other companies, universities and research institutions.

Substantially all of our competitors have substantially greater capital resources, research and development personnel, facilities and experience in conducting clinical trials and obtaining regulatory approvals than us. As well, most of our competitors have advantages over us in manufacturing and marketing pharmaceutical products. We are thus at a competitive disadvantage to those competitors who have greater capital resources and we may not be able to compete effectively.

If we are unable to hire additional qualified scientific, sales and marketing, and other personnel, we will not be able to achieve our goals.

We depend on the members of our management staff, Scientific Advisory Board and a small number of third-party consultants to provide the expertise needed to carry out our business objectives. The loss of any of these individuals' services may significantly delay or prevent the achievement of research, development or business objectives and could negatively affect our business, financial condition and results of operations if their replacements are not promptly retained. We face intense competition for such personnel and consultants. Such replacements are predicated, among other conditions, on our ability to raise additional funding. We cannot assure you that we will attract and retain qualified management and scientific personnel in the future, with or without adequate additional financing. We do not maintain key person life insurance on any of these individuals.

Further, we expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, contract manufacturing and marketing, will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise. The failure to attract and retain such personnel or to develop such expertise would impact prospects for our success.

Even if we obtain marketing approval, PRTX-100 will be subject to ongoing regulatory review.

If regulatory approval of PRTX-100 is granted, that approval may be subject to limitations on the indicated uses for which it may be marketed or contain requirements for costly post-marketing follow-up studies. As to products for which marketing approval is obtained, the manufacturer of the product and the manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other regulatory authorities. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or the manufacturer, including withdrawal of the product from the market. We may be slow to adapt, or we may never adapt, to changes in existing requirements or adoption of new requirements or policies.

If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Market acceptance of PRTX-100 will be limited if users are unable to obtain adequate reimbursement from third-party payors.

Government health administration authorities, private health insurers and other organizations generally provide reimbursement for products like PRTX-100, and our commercial success will depend in part on these third-party payors agreeing to reimburse patients for the costs of our product. Even if we succeed in bringing our proposed products to market, we cannot assure you that third-party payors will consider it cost-effective or provide reimbursement in whole or in part for its use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. PRTX-100 is intended to replace or alter existing therapies or procedures. These third-party payors may conclude that our product is less safe, effective or cost-effective than existing therapies or procedures. Therefore, third-party payors may not approve our product for reimbursement.

If third-party payors do not approve our product for reimbursement or fail to reimburse them adequately, sales will suffer as some physicians or their patients will opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payors make reimbursement available, these payors' reimbursement policies may adversely affect our ability to sell our product on a profitable basis.

Moreover, legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our product, which could adversely affect our business, financial condition and results of operations.

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after the FDA or other regulatory agencies approve PRTX-100 for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals they could negatively affect our business, financial condition and results of operations.

We may be required to defend lawsuits or pay damages in connection with the alleged or actual harm caused by our products.

We face an inherent business risk of exposure to product liability claims in the event that the use of any of our products is alleged to have resulted in harm to others. This risk exists in clinical trials as well as in commercial distribution. In addition, the pharmaceutical and biotechnology industries in general have been subject to significant medical malpractice litigation. We may incur significant liability if product liability or malpractice lawsuits against us are successful. Furthermore, product liabilities claims, regardless of their merits, could be costly and divert our management's attention from other business concerns, or adversely affect our reputation and the demand for our product. We currently maintain a $2,000,000 general liability insurance policy, a global $5,000,000 clinical liability insurance policy and as required, country specific clinical liability insurance will be procured. We intend to expand our liability insurance coverage for any products for which we obtain marketing approval, however, such insurance may be unavailable, prohibitively expensive or may not fully cover our potential liabilities. If we are unable to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims or field actions, we may be unable to continue to market our products and develop new markets.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Should we obtain regulatory approval for PRTX-100, we will have to compete with existing therapies, some of which have been marketed for years. In addition, a significant number of companies are pursuing the development of products that target the same indications that we are targeting. We face competition from both domestic and international companies. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, long drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other strategic collaborations.

The loss of one or more key members of our management team or Scientific Advisory Board could adversely affect our business.

Our performance is substantially dependent on the continued service and performance of our management team, and Scientific Advisory Board members, who have experience and specialized expertise in our business. In particular, the loss of Arnold P. Kling, our president, could adversely affect our business and operating results. We do not have "key person" life insurance policies for any members of our management team or Scientific Advisory Board, or employment agreements with any members of our management team.

Many of our business practices are subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the United States are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug, and Cosmetic Act, the False Claims Act and the Anti-Kickback Law and the Public Health Service Act, and any regulations promulgated under their authority, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid and the Department of Health and Human Services and other regulatory authorities as well as by the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Law, and similar state laws and regulations, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose products for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from the Medicare and Medicaid programs, and arrangements with referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Under the Patient Protection and Affordable Care Act and the companion Health Care and Education Reconciliation Act, which together are referred to as the healthcare reform law, such payments by pharmaceutical manufacturers to U.S. healthcare practitioners and academic medical centers must be publicly disclosed. A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where such practices have been found to be improper incentives to use such products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct.

Failure to satisfy requirements under the Federal Food, Drug, and Cosmetic Act can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct.

In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the United States, Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities (e.g., FDA in the United States), nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products.

Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the Federal Food, Drug, and Cosmetic Act and subjects us to civil and criminal sanctions. Furthermore, sanctions under the Federal False Claims Act have recently been brought against companies accused of promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud. The healthcare reform law significantly strengthened provisions of the Federal False Claims Act, Medicare and Medicaid Anti-Kickback provisions, and other health care fraud provisions, leading to the possibility of greatly increased qui tam suits by relators for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business.

We may be required to report detailed pricing information, net of included discounts, rebates and other concessions, to the Centers for Medicare & Medicaid Services, or CMS, for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations. We will need to establish systems for collecting and reporting this data accurately to CMS and institute a compliance program to assure that the information collected is complete in all respects. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business.

If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which would preclude us from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of their product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected. Also, under the United States Foreign Corrupt Practices Act, or FCPA, the United States has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business.

To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the United States Health and Human Services Department Office of Inspector General, or OIG, have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the United States Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. In the future, we may need to adopt healthcare compliance and ethics programs that would incorporate the OIG's recommendations, and train our applicable employees in such compliance. Such a program may be expensive and may not assure that we will avoid compliance issues.

The implementation of the healthcare reform law in the United States may adversely affect our business.

Through the March 2010 adoption of the healthcare reform law in the United States, substantial changes are being made to the current system for paying for healthcare in the United States, including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. The changes contemplated by the healthcare reform law are subject to rule-making and implementation timelines that extend for several years, and this uncertainty limits our ability to forecast changes that may occur in the future. However, implementation has already begun with respect to certain significant cost-saving measures under the healthcare reform law, for example with respect to several government healthcare programs that may cover the cost of our future products, including Medicaid, Medicare Parts B and D, and these efforts could have a materially adverse impact on our future financial prospects and performance.

For example, with respect to Medicaid, in order for a manufacturer's products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of the United States Department of Health and Human Services, and pay certain rebates to the states based on utilization data provided by each state to the manufacturer and to CMS, and pricing data provided by the manufacturer to the federal government. The states share this savings with the federal government, and sometimes implement their own additional supplemental rebate programs. Under the Medicaid drug rebate program, the rebate amount for most branded drug products was previously equal to a minimum of 15.1% of the Average Manufacturer Price, or AMP, or the AMP less Best Price, whichever is greater. Effective January 1, 2010, the healthcare reform law generally increases the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug product from a minimum of 15.1% to a minimum of 23.1% of the AMP, subject to certain exceptions, for example, for certain clotting factors, the increase is limited to a minimum of 17.1% of the AMP. For non-innovator multiple source (generic) products, the rebate percentage is increased from a minimum of 11.0% to a minimum of 13.0% of AMP. In 2010, the healthcare reform law also newly extended this rebate obligation to prescription drugs covered by Medicaid managed care organizations. These increases in required rebates may adversely affect our future financial prospects and performance.

The healthcare reform law also creates new rebate obligations for our products under Medicare Part D, a partial, voluntary prescription drug benefit created by the United States federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011, the healthcare reform law generally requires that in order for a drug manufacturer's products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of the United States Department of Health and Human Services, and reimburse each Medicare Part D plan sponsor an amount equal to 50% savings for the manufacturer's brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the "donut hole" (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS's contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation.

The healthcare reform law also introduced a biosimilar pathway that will permit companies to obtain FDA approval of generic versions of existing biologics based upon reduced documentation and data requirements deemed sufficient to demonstrate safety and efficacy than are required for the pioneer biologics. The new law provides that a biosimilar application may be submitted as soon as four years after the reference product is first licensed, and that the FDA may not make approval of an application effective until 12 years after the reference product was first licensed. With the likely introduction of biosimilars in the United States, we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges. The FDA has reported meeting with sponsors who are interested in developing biosimilar products, and is developing regulations to implement the abbreviated regulatory review pathway.

Regarding access to our products, the healthcare reform law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research, or CER. While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be determined to be less cost-effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results.

Risks Related to Our Dependence on Third Parties

If third-party manufacturers of our products fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may rise.

We have relied on, and intend to rely in the future, on third-party contract manufacturers to supply, store, test and distribute PRTX-100 and other potential products. Any products we develop may be in competition with other product candidates and products for access to these facilities. Thus, we may not be successful in contracting with third-party manufacturers, or they may not be able to manufacture these candidates and products in a cost-effective or timely manner. Additionally, our reliance on third-party manufacturers exposes us to the following risks, any of which could delay or prevent the completion of (x) our clinical trials, (y) the approval of our products by the FDA or (z) the commercialization of our products, resulting in higher costs or depriving us of potential product revenues:

- Contract manufacturers are obliged to operate in accordance with FDA-mandated cGMPs. Their failure to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the availability of material for clinical study and may delay or prevent filing or approval of marketing applications for our products. Additionally, failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

- It may be difficult or impossible for us to find replacement manufacturers quickly on acceptable terms, or at all. For example, we have initially relied on a single contract drug substance manufacturer, Eurogentec S.A., to produce PRTX-100. Changing this manufacturer, or changing the manufacturer for any other products we develop, may be difficult, time consuming and expensive. The number of potential manufacturers is limited, and changing manufacturers may require confirmation of the analytical methods of the manufacturing processes and procedures in accordance with FDA-mandated cGMPs. Such confirmation of the analytical methods may be costly and time-consuming.

- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store, test and distribute our products successfully.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Agency, and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit the performance of third-party contractors, we do not have control over our third-party manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

We believe Eurogentec S.A. has the capacity to produce a sufficient inventory of PRTX-100 to conduct our current planned clinical trials. If these inventories are lost or damaged, or if Eurogentec S.A. cannot or will not produce additional inventory to complete the remaining phases of clinical trials, the clinical development of our product candidate or its submission for regulatory approval could be significantly delayed and our ability to commercialize this product could be impaired.

If we do not have adequate clinical trial material available to complete our clinical trials, which could also lead to a significant delay in continuing and /or commencing our clinical trial programs, we may be unable to obtain FDA approval and our ability to commercialize this product could be impaired or precluded.

We rely on third parties to conduct our PRTX-100 studies and intend to rely on third parties to conduct our clinical trials for other product candidates. Such third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We rely and expect to continue to rely on third parties, such as clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct clinical trials for our drug product candidates. Relying on these third parties for clinical development activities will reduce our control over these activities.

We will remain responsible for ensuring that our PRTX-100-104 Study and each of our future clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA will require us to comply with cGTPs with respect to any clinical trials conducted in connection with a submission to the FDA, including an IND, and will require that we record and report clinical trial results to assure that data and reported results are credible and accurate and that the rights and safety are protected. We will also be required to register ongoing FDA-regulated clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, and could devote more of their resources to such other entities at the expense of expending sufficient resources on our clinical development activities.

We expect to depend on collaborations with third parties to develop and commercialize our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these drug product candidates.

We currently intend to commercialize PRTX-100 and to collaborate with third parties to commercialize PRTX-100 and any future product candidates. In addition, we may seek partners for further development and commercialization of our other product candidates. These collaborations could take the form of license, distribution, sales representative, joint venture, sponsored research or other arrangements with pharmaceutical and biotechnology companies, other commercial entities and academic and other institutions.

If we do enter into any such arrangements with third parties, we will likely have limited control over the amount and timing of resources that such collaborators dedicate to the development or commercialization of our product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. Our ability to generate revenues from these arrangements will depend on, among other things, our collaborators' successful performance of the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and could devote fewer resources to our product candidates than we expect them to;

- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of our product or products;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate or repeat or conduct new clinical trials;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources; and

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may collaborate with pharmaceutical and biotechnology companies to develop and commercialize our product candidates. For example, we currently intend to seek to collaborate with third parties to commercialize PRTX-100 and other product candidates we successfully develop.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States of our product candidate, the potential market for such product candidate, the costs and complexities of manufacturing and delivering the product candidate to patients, the potential and relative cost of competing products, uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications or conditions that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of recent business combinations among pharmaceutical and biotechnology companies that have resulted in a reduced number of potential future collaborators. Collaborations are complex and time consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

If we cannot find a collaborator for a particular program, we may have to curtail the development of such program or of one or more of our other development programs, delay the potential commercialization of such program or reduce the scope of any sales or marketing activities for the program or increase our expenditures and undertake development or commercialization activities for the program at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring these product candidates to market and generate product revenue.

Risks Relating to our Finances, Capital Requirements and Other Financial Matters

Auditors have doubt as to our ability to continue in business.

In their report on our May 31, 2014 financial statements, our auditors expressed substantial doubt as to our ability to continue as a going concern. A going concern qualification could impair our ability to finance our operations through the sale of debt or equity securities. Our ability to continue as a going concern will depend, in large part, on our ability to obtain additional financing and generate positive cash flow from operations, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

We are a clinical stage company with a history of operating losses that are expected to continue and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability.

We are a clinical stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by similarly situated companies. We have generated net losses in all periods since our inception in September 1999 including losses of approximately $ 11.9 million and $6.3 million for the years ended May 31, 2014 and 2013, respectively and as of May 31, 2014 we had an accumulated deficit of approximately $73.6 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. During the years ended May 31, 2014 and 2013, we incurred research and development expenses of approximately $3.2 million and $3.8 million, respectively. As of May 31, 2014, we had cash and cash equivalents of approximately $1.6 million and net working capital of approximately $1.2 million. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers.

Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. We currently have no agreements relating to any of these types of transactions and we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

Risks Associated with our Capital Stock

The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility as a result of a number of factors, including:

Our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our Common Stock;
- the actual number of shares of our Common Stock that trade;
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

Our Common Stock is quoted on the OTC Bulletin Board, which may have an unfavorable impact on our stock price and liquidity. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

Almost all of our outstanding shares of common stock, subject to volume limitations, are available for sale in the public market, either pursuant to Rule 144 under the Act or an effective registration statement. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

We have never paid and do not intend to pay cash dividends. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our affiliates control the majority of our shares of common stock and one shareholder holds a controlling interest.

As of July 18, 2014, our directors and executive officers and their Affiliates beneficially own approximately 80% of the outstanding shares of our Common Stock, with one such Affiliate, Niobe Ventures LLC, beneficially owns approximately 78% of our outstanding Common Stock. As a result, this stockholder is able to exercise control over matters requiring stockholder approval, including the election of directors, and the approval of mergers, consolidations and sales of all or substantially all of our assets.

Our affiliates control the majority of our shares of common stock. Provisions in our certificate of incorporation, our by-laws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and

- the ability of our Board to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board.

The classification of our board of directors and limitation on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company .

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the forgoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Our directors and executive officers and their affiliates beneficially own approximately 80% of the outstanding shares of common stock.

If our common stock becomes subject to the penny stock rules, this may make it more difficult to sell our shares

The Securities and Exchange Commission has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). If the price of our common stock drops below $5.00, our securities will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore security holders may have difficulty selling their shares.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal offices are located at 131 Columbia Turnpike, Suite 1, Florham Park NJ 07932. We occupy our principal offices on a month to month basis. We do not own or intend to invest in any real property. We currently have no policy with respect to investments or interests in real estate, real estate mortgages or securities of, or interests in, persons primarily engaged in real estate activities.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

(a) *Market Information*. Our Common Stock is traded on the OTCQB under the symbol "PRTX". The following table sets forth, for the periods indicated and as reported on the OTCQB, the high and low bid prices for our Common Stock, as adjusted for the one-for-five reverse stock split effected December 8, 2010. Such quotations reflect inter-dealer prices, without retail mark-up, markdown or commission and may not necessarily represent actual transactions.

	High	Low
2014*		
First Quarter	$ 4.00	$ 1.31
Second Quarter	10.00	3.11
Third Quarter	9.50	7.78
Fourth Quarter	9.05	3.76
2013*		
First Quarter	$ 1.50	$ 0.40
Second Quarter	1.66	0.51
Third Quarter	1.39	0.85
Fourth Quarter	2.40	0.79

* The prices for the fiscal years ended May 31, 2014 and 2013 are actual sale prices because the bid price information was not available.

(b) *Holders*. As of August 1, 2014, there were approximately 100 holders of record of our Common Stock. This does not reflect beneficial stockholders who hold their stock in nominee or "street" name through various brokerage firms.

(c) *Dividends*. We have never declared or paid cash dividends on our capital stock, and we do not intend to pay cash dividends in the foreseeable future. We plan to retain any earnings for use in the operation of our business and to fund future growth.

Unregistered Sale of Equity Securities

In June 2014 we issued non-qualified stock options for an aggregate of 200,000 shares of our Common Stock with an exercise price of $8.22 per share to two consultants. The option expires 5 years from the date of grant.

In May 2014 we issued a non-qualified stock option for 250,000 shares of our Common Stock with an exercise price of $8.20 per share to a consultant. The option expires 5 years from the date of grant.

In April 2014 we issued a non-qualified stock option for 250,000 shares of our Common Stock with an exercise price of $8.40 per share to a consultant. The option expires 5 years from the date of grant.

All of the foregoing options are subject to vesting and forfeiture and were issued in reliance upon the exemptions from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act.

ITEM 6. SELECTED FINANCIAL DATA

As a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information required by this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion, which refers to the historical results of Protalex, should be read in conjunction with the other sections of this Annual Report, including "Risk Factors," "Business" and the consolidated financial statements and other consolidated financial information included in this Annual Report. The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this Annual Report. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially. You should read this Management's Discussion and Analysis of Financial Condition and Results of Operations in conjunction with our 2014 Financial Statements and accompanying Notes. The matters addressed in this Management's Discussion and Analysis of Financial Condition and Results of Operations, may contain certain forward-looking statements involving risks and uncertainties.

Overview

We are focused on the development of a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases including rheumatoid arthritis (RA). Our lead product, PRTX-100, is a formulation of a proprietary, highly-purified form of staphylococcal protein A, which is an immunomodulatory protein produced by bacteria. PRTX-100 has demonstrated effectiveness in animal models of autoimmune diseases and has demonstrated activity on cultured human immune cells at very low concentrations, although the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we would see in future human clinical trials. The safety, tolerability and PK of PTRX-100 in humans have now been characterized in five clinical studies. We intend to seek regulatory approval to initiate clinical studies in an orphan indication and apply for an orphan drug designation in 2014.We do not anticipate generating operating revenue for the foreseeable future and do not currently have any products that are marketable.

In August 2010, we commenced a multi-center Phase 1b clinical trial of PRTX-100 in South Africa in adult patients with active RA on methotrexate or leflunomide (the "PRTX-100-103 Study"). The PRTX-100-103 Study served to evaluate safety and potential efficacy of PRTX-100 in patients with active RA and was approved to enroll up to 40 patients in four dose-escalating cohorts. In January 2012, we completed patient dosing in the PRTX-100-103 Study with a total of 37 patients enrolled in four cohorts ranging from 0.15 micrograms/kg to 1.50 micrograms/kg of PRTX-100 or placebo, administered weekly for four weeks. Measures of safety, PK and disease activity were evaluated over 16 weeks following the first dose. The PRTX-100-103 Study results demonstrated that PRTX-100 was generally safe and well-tolerated in patients with active RA at all tested dose levels. More patients in the 0.90 micrograms/kg and 1.50 micrograms/kg cohorts showed improvement in their CDAI than did patients in the lower dose or placebo cohorts.

In November 2012, we commenced enrollment in the United States for a new multicenter Phase 1b randomized, multiple-dose, dose-escalation study (the "PRTX-100-104 Study") of PRTX-100 in combination with methotrexate or leflunomide in adult patients with active RA. The sequential dose-escalation phase of this study was expected to enroll up to 40 patients into five cohorts ranging from 1.50 micrograms/kg up to 18.0 micrograms/kg of PRTX-100 or placebo. At each dose, one quarter of patients would receive a placebo treatment. Similar to the PRTX-100-103 Study, the primary objective of the PRTX-100-104 Study is to assess the safety and tolerability of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate or leflunomide therapy. The secondary objectives include determining the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the PK parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety and PK.

In August 2013, following a planned interim safety review by our Independent Data Safety Monitoring Committee (SMC) and upon completion of the fourth cohort, we expanded the 3.0 microgram, 6.0 microgram, and 12.0 micrograms/kg dose cohorts of the PRTX-100-104 Study. An additional nine patients were enrolled in the expansion cohort that was completed in October 2013. In total, the first four dose-escalating cohorts of the PRTX-100-104 Study, which included these three expanded cohorts, enrolled 41 patients with doses ranging from 1.5 micrograms/kg up to 12.0 micrograms/kg.

In November 2013, following completion of the Cohort 4 expansion cohorts, we initiated enrollment of the fifth and final cohort (Cohort 5) in the PRTX 100-104 Study. The Cohort 5 sub-study enrolled 20 patients who received five weekly doses of PRTX-100 followed by up to four additional monthly maintenance doses of PRTX-100 in the 3.0 micrograms/kg to 6.0 micrograms/ kg range. The objective of the Cohort 5 sub-study is to assess safety and tolerability of these doses administered on a modified schedule. Secondary objectives include determining the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the PK parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety, PK and efficacy parameters. In total, 11 out of 20 patients in Cohort 5 will have completed all study visits per protocol by August 2014.

In June 2014, we announced preliminary findings from an unblinded interim analysis of patients in Cohorts 1 through 4 of the PRTX-100-104 Study through day 85 which indicated that PRTX-100 was generally safe and well tolerated. The unblinded analysis of the 104 Study included 41 patients recruited at five U.S. clinical sites in the first four dosing cohorts of the five-cohort study through completion of the 25-week study protocol.

The preliminary results indicated that PRTX-100 was generally safe and well tolerated and the Adverse Event (AE) profile was consistent with prior trials results. There were no immediate hypersensitivity reactions, nor any treatment-related Serious Adverse Events (SAEs) evident and no expedited reports to the U.S. Food and Drug Administration (FDA) were required. Pharmacokinetic analyses indicated a roughly linear increase in plasma maximum concentrations with increasing doses of 1.5, 3.0, 6.0, and 12mcg/kg.

Moreover, the study revealed positive effects of PRTX-100 treatment on certain measures of disease activity, although these effects were not statistically significant. At the higher doses, PRTX-100 showed activity comparable to existing well known biologics with apparent onset of action occurring subsequent to the fifth and final dose. For example, four weeks following the last PRTX-100 dose (Day 57), 32% of active-treated and 13% of placebo-treated patients had attained an ACR50 response. At day 113, 29% of the active-treated patients who received 6 or 12 mcg/kg PRTX-100 plus methotrexate achieved DAS28-CRP scores less than 2.6 (remission), while the placebo-treated patients showed no remission. Notably, among all patients treated with PRTX-100, 43% had DAS28-CRP < 3.2 (low disease activity) on both Day 57 and Day 85, while only 14% of placebo-treated patients showed such a reduction in RA disease activity on these days.

A total of 61 patients enrolled across five cohorts in the PRTX 100-104 Study at nine study sites in the United States.

We maintain an administrative office in Florham Park, New Jersey and currently outsource all of our product development and regulatory activities, including clinical trial activities, manufacturing and laboratory operations, to third-party contract research organizations, consultants and facilities.

In April 2009, under prior management, we ceased all operations and terminated all employees in light of insufficient funds to continue our clinical trials and related product development. Our business was dormant until current management took control of our operations in November 2009 following the change in control transaction more fully described below. We are currently actively pursuing the commercial development of PRTX-100 for the treatment of RA.

On December 8, 2010, we effected a reverse stock split of the outstanding shares of our common stock, with par value of $0.00001 per share ("Common Stock"), on the basis of one new share of Common Stock for each five shares of Common Stock outstanding. All references in this Annual Report to number of shares, price per share and weighted average number of shares outstanding of Common Stock prior to this reverse stock split have been adjusted to reflect the reverse stock split on a retroactive basis unless otherwise noted.

Change in Control and Incremental Financing Transactions

On November 11, 2009 (the "Effective Date"), we consummated a financing transaction (the "Financing") in which we raised $3,000,000 of working capital pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with Niobe Ventures, LLC, a Delaware limited liability company ("Niobe"). Pursuant to the Purchase Agreement, we issued to Niobe (i) 8,695,652 restricted shares of our Common Stock at a purchase price of $0.23 per share (or $2 million in the aggregate) and (ii) a senior secured convertible promissory note in the principal amount of $1 million convertible into shares of our Common Stock at an initial conversion price equal to $0.23 per share (the "$1 Million Secured Note"). On February 11, 2011, Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of Common Stock.

As contemplated by the Purchase Agreement, all of our executive officers and all of the members of our Board of Directors (the "Board") prior to the closing of the Financing, with the exception of Frank M. Dougherty, resigned effective concurrently with the closing of the Financing. Mr. Dougherty resigned effective upon the expiration of the 10-day notice period required by Rule 14f-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In addition, effective upon the closing of the Financing, our Board appointed Arnold P. Kling as a director and then elected him as our president and elected Kirk M. Warshaw as our chief financial officer and secretary.

In addition, on the Effective Date, we terminated (i) the Investor Rights Agreement dated September 18, 2003 among us, vSpring SBIC L.P. ("vSpring") and certain of the investors set forth on Schedule A thereto and the Registration Rights Agreement dated May 25, 2005 among us, vSpring and certain of the investors set forth on Schedule I thereto in accordance with their respective terms and (ii) stock options exercisable for an aggregate of 246,714 shares of Common Stock (approximately 41% of our then outstanding stock options).

On February 11, 2011, for the purpose of providing us with additional working capital, pursuant to an existing Credit Facility Agreement dated as of December 2, 2009 (the "Facility") with Niobe, we issued to Niobe a senior secured convertible promissory note in the principal amount of $2 million (the "$2 Million Secured Convertible Note"). The $2 Million Secured Convertible Note provided for conversion into shares of our Common Stock at a conversion price of $0.23 per share, for an aggregate of 8,695,652 shares of our Common Stock (net of accrued interest thereon), bore interest at a rate of 3% per annum and matured on December 31, 2013. The original maturity was December 31, 2012 but in December 2012 Niobe agreed, for no consideration, to extend the maturity date to December 31, 2013.

The $2 Million Secured Convertible Note was convertible at any time, by the holder, subject only to the requirement that we have sufficient authorized shares of Common Stock after taking into account all outstanding shares of Common Stock and the maximum number of shares issuable under all issued and outstanding convertible securities. In addition, the $2 Million Secured Convertible Note would automatically be converted if we undertake certain Fundamental Transactions, as defined in the $2 Million Secured Convertible Note, (such as a merger, sale of all of our assets, exchange or tender offer, or reclassification of our stock or compulsory exchange). The $2 Million Secured Convertible Note also provided for the adjustment of the conversion price in the event of stock dividends and stock splits, and provides for acceleration of maturity, at the holder's option, upon an event of default, as defined in the $2 Million Secured Convertible Note. On August 27, 2013, Niobe elected to convert the principal and accrued interest of $2,155,000 under the $2 Million Secured Convertible Note into 9,369,565 shares of Common Stock.

On February 1, 2012, we raised $1,000,000 of working capital pursuant to a loan from Niobe. We issued to Niobe a secured promissory note in the principal amount of $1,000,000 (the "February 2012 Secured Note"). The February 2012 Secured Note bore interest at a rate of 3% per annum and had a maturity date of February 1, 2014.

On June 5, 2012, we raised an additional $1,000,000 of working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 31, 2014 (the "June 2012 Secured Note").

On October 1, 2012, we raised $800,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $800,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "October 2012 Secured Note").

On December 3, 2012, we raised $700,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $700,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "December 2012 Secured Note").

Collectively, the February 2012 Secured Note, the June 2012 Secured Note, the October 2012 Secured Note and the December 2012 Secured Note are hereinafter referred to as the "2012 Secured Notes."

On January 18, 2013, we raised $2,500,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,500,000, which bore interest at a rate of 3% per annum and had a maturity date of January 15, 2015 (the "January 2013 Secured Note").

On May 13, 2013, we raised $2,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 13, 2015 (the "May 2013 Secured Note").

On August 27, 2013, the Company raised $1,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bears interest at a rate of 3% per annum and matures on August 27, 2015 (the "August 2013 Secured Note").

Collectively, the January 2013 Secured Note, the May 2013 Secured Note, and the August 2013 Secured Note are hereinafter referred to as the "2013 Secured Notes."

Collectively, the 2012 Secured Notes and the 2013 Secured Notes represent a total of $9,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

On October 11, 2013, we issued a Consolidated, Amended and Restated Promissory Note to Niobe in the principal amount of $9,219,366 (the "Consolidated Note"). The face amount of the Consolidated Note reflects the $9.0 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on each note from its respective date of issuance. The terms of the Consolidated Note are identical to the Secured Notes except that: (a) the maturity date is September 1, 2015, which is after the latest maturity date of any of the Secured Notes; and (b) it provides for partial mandatory repayment in the event that the Company receives aggregate gross proceeds in excess of $7.5 million from a single or multiple "Liquidity Events" in an amount equal to twenty-five (25%) percent of such gross proceeds. A "Liquidity Event" means (a) the sale of any of our equity, or equity-linked, securities, and (b) the receipt of proceeds, directly or indirectly related to a development and/or commercialization relationship entered into with an unaffiliated third party. In the Secured Notes, the entire principal amount of each note was due, at Niobe's election, upon the consummation of an equity financing of $7.5 million or greater. Consistent with the terms of the Secured Notes and related security agreements entered into, our obligations under the Consolidated Note are secured by a first priority perfected security interest in all of our assets pursuant to a Consolidated, Amended and Restated Security Agreement dated October 11, 2013 with Niobe.

On January 23, 2014, we consummated a private placement financing to accredited investors of 471,334 shares of Common Stock at $6.00 per share, yielding gross proceeds of $2,828,000. No commissions were payable in connection with the financing transaction. Proceeds of the financing will be used for working capital purposes, principally to fund ongoing clinical trials and studies and related activities. The investors in the offering were granted piggy-back registration rights in connection with certain registration statements filed by the company, subject to certain exceptions, including a registration statement filed in connection with a primary offering by the company.

The securities issued in the aforementioned financings were issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Act") pursuant to Section 4(a)(5) and Rule 506 of Regulation D thereof. The offer, sale and issuance of such securities were made without general solicitation or advertising. The securities were offered and issued only to "accredited investors" as such term is defined in Rule 501 under the Act.

Critical Accounting Policies

Our financial statements are prepared in conformity with accounting principles generally accepted in the United States of America. Note 4 to the financial statements describes the significant accounting policies and methods used in the preparation of our financial statements.

We have identified the policies below as some of the more critical to our business and the understanding of our financial position and results of operations. These policies may involve a high degree of judgment and complexity in their application and represent the critical accounting policies used in the preparation of our financial statements. Although we believe our judgments and estimates are appropriate and correct, actual future results may differ from estimates. If different assumptions or conditions were to prevail, the results could be materially different from these reported results. The impact and any associated risks related to these policies on our business operations are discussed throughout this Annual Report where such policies affect our reported and expected financial results.

The preparation of our financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and equity and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. These estimates have a material impact on our financial statements and are discussed in detail throughout this Annual Report.

As part of the process of preparing our financial statements, we are required to estimate income taxes in each of the jurisdictions in which we operate. This process involves estimating actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within the balance sheet. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and to the extent we believe that recovery is not likely, we must establish a valuation allowance. In the event that we determine that we would be able to realize deferred tax assets in the future in excess of the net recorded amount, an adjustment to the deferred tax asset valuation allowance would increase income in the period such determination was made.

We account for our stock option grants under the provisions of the accounting guidance for Share-Based Payments. Such guidance requires the recognition of the fair value of share-based compensation in the statements of operations. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections in adopting and implementing this guidance, including expected stock price volatility and the estimated life of each award. The fair value of share-based awards is amortized over the vesting period of the award and we have elected to use the straight-line method for awards granted after the adoption of this guidance.

Results of Operations

Fiscal year ended May 31, 2014 compared to fiscal year ended May 31, 2013

Research and Development Expenses – Research and Development expenses decreased from $3,833,401 in our 2013 fiscal year to $3,232,321 in our 2014 fiscal year. The decrease of $601,000, or 16%, was the result of increased activity associated with our clinical study in the United States, as disclosed above but a significant decline in the expenses associated with the formulation and production of our bulk drug substance, drug product, and placebo. During such period, we engaged more consultants and incurred other clinical study-related expenses as we enrolled patients and analyzed study data.

Administrative Expenses - Administrative expenses increased to $7,750,587 in our 2014 fiscal year from $1,345,152 in our 2013 fiscal year. The increase of $6.4 million was related to an increase in non-cash stock compensation.

Professional Fees - Professional fees increased from $440,751 in fiscal year 2013 to $584,585 in fiscal year 2014. The increase of $143,000, or 33%, was due primarily to increases in consulting and legal expenses.

Interest Expense – Interest expense decreased from $663,866 in fiscal year 2013 to $283,720 in fiscal year 2014. The decrease was attributable to no longer having any interest expense computed from the beneficial conversion feature of the $2 Million Secured Convertible Note and the conversion of said note into equity as described above.

Net Loss Outlook

We have not generated any product sales revenues, have incurred operating losses since inception and have not achieved profitable operations. Our accumulated deficit from inception through May 31, 2014 was $73,587,282 and we expect to continue to incur substantial losses in future periods. We expect that our operating losses in future periods will be the result of continued research and development expenses relating to PRTX-100, as well as costs incurred in preparation for the potential commercialization of PRTX-100.

In addition to additional financing, we are highly dependent on the success of our research and development efforts and, ultimately, upon regulatory approval and market acceptance of our products under development, particularly our lead product candidate, PRTX-100. We may never receive regulatory approval for any of our product candidates, generate product sales revenues, achieve profitable operations or generate positive cash flows from operations, and even if profitable operations are achieved, they may not be sustained on a continuing basis.

Liquidity and Capital Resources

Since 1999, we have incurred significant losses and we expect to experience operating losses and negative operating cash flow for the foreseeable future. Historically, our primary source of cash to meet short-term and long-term liquidity needs has been the sale of shares of our Common Stock and loans from our majority stockholder. We have issued shares in private placements at discounts to then current market price.

On September 18, 2003, we raised $12,657,599 through the sale of 1,489,129 shares of our Common Stock at $8.50 per share, with warrants to purchase an additional 632,879 shares of our Common Stock, at an exercise price of $12.00 per share. These warrants expired on September 19, 2008. Net of transaction costs of $1,301,536, our proceeds were $11,356,063.

On May 25, 2005, we raised $5,057,885 through the sale of 518,758 shares of our Common Stock at $9.75 per share, with warrants to purchase an additional 184,024 shares of our Common Stock, at an exercise price of $11.25 per share. All of these warrants expired on May 25, 2010. Net of transaction costs of $206,717, our proceeds were $4,851,168.

On December 30, 2005, we raised $5,839,059 through the sale of 519,026 shares of our Common Stock at $11.25 per share, with warrants to purchase an additional 129,757 shares of our Common Stock, at an exercise price of $14.95 per share. We also issued warrants to purchase 45,415 shares of our Common Stock, at an exercise price of $14.95 per share, to the placement agent. All of these warrants expired on December 30, 2010. Net of transaction costs of approximately $328,118, our proceeds were $5,510,941.

In the fourth fiscal quarter of 2006, existing investors exercised 70,320 warrants which resulted in $786,538 in cash proceeds.

On July 7, 2006, we raised $14,217,660, net of transaction costs of $959,874, through the sale of 1,214,203 shares of our Common Stock at $12.50 per share, with warrants to purchase an additional 303,551 shares of our Common Stock, at an exercise price of $19.25 per share. We also issued warrants to purchase 106,243 shares of our Common Stock, at an exercise price of $19.25 per share, to the placement agent. All of these warrants expired on July 7, 2011.

In the first fiscal quarter of 2007, existing investors and option holders exercised 26,700 warrants and 1,200 options which resulted in $315,574 in cash proceeds.

On November 11, 2009, we raised $3,000,000, $2,000,000 from the sale of 8,695,652 shares of our Common Stock at $.23 per share and $1,000,000 from the issuance of the $1 Million Secured Note to Niobe.

On December 2, 2009, we entered into the Facility with Niobe to provide us with up to $2,000,000 of additional working capital in the form of secured loans at any time prior to June 30, 2012 subject to our achievement of certain predetermined benchmarks. On February 11, 2011 we received $2,000,000 of additional working capital from Niobe under the Facility, and issued to Niobe the $2 million Secured Convertible Note. On the same date, Niobe converted the $1 Million Secured Note and accrued interest thereon, into 4,510,870 shares of our Common Stock.

On August 27, 2013, Niobe elected to convert the principal and accrued interest of $2,155,000 under the $2 Million Secured Convertible Note into 9,369,565 shares of Common Stock.

From February 1, 2012 through August 27, 2013 we raised an aggregate of $9,000,000 of working capital pursuant to seven loans from Niobe, in varying principal amounts and issued to Niobe the Secured Notes.

As described above, on October 11, 2013 we issued the Consolidated Note to Niobe. The face amount of the Consolidated Note reflects the $9.0 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on each note from its respective date of issuance. Our obligations under the Consolidated Note are secured by a first priority perfected security interest in all of our assets pursuant to a Consolidated, Amended and Restated Security Agreement dated October 11, 2013 with Niobe.

On January 23, 2014, we consummated a private placement financing to accredited investors of 471,334 shares of Common Stock at $6.00 per share, yielding gross proceeds of $2,828,000.

Net Cash Used In Operating Activities and Operating Cash Flow Requirements Outlook

Our operating cash outflows for the fiscal years ended May 31, 2014 and 2013 have resulted primarily from research and development expenditures associated for PRTX-100 and administrative purposes. We expect to continue to use cash resources to fund operating losses and expect to continue to incur operating losses in fiscal 2015 and beyond due to continuing research and development activities.

Net Cash Used In Investing Activities and Investing Requirements Outlook

We do not expect to be required to make any significant investments in information technology and laboratory equipment to support our future research and development activities. In August 2008, we sold laboratory equipment with net proceeds of $200,000.

We may never receive regulatory approval for any of our product candidates, generate product sales revenues, achieve profitable operations or generate positive cash flows from operations, and even if profitable operations are achieved, these may not be sustained on a continuing basis. We have invested a significant portion of our time and financial resources since our inception in the development of PRTX-100, and our potential to achieve revenues from product sales in the foreseeable future is dependent largely upon obtaining regulatory approval for and successfully commercializing PRTX-100, especially in the United States. We expect to continue to use our cash and investments resources to fund operating and investing activities.

Off-Balance Sheet Arrangements

As of May 31, 2013 and May 31, 2014 we had no off-balance sheet arrangements such as guarantees, retained or contingent interest in assets transferred, obligation under a derivative instrument and obligation arising out of or a variable interest in an unconsolidated entity.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the index to the Financial Statements below, beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our president and chief financial officer, carried out an evaluation of the effectiveness of our "disclosure controls and procedures" (as defined in the Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report (the "Evaluation Date"). Based upon that evaluation, the president and chief financial officer concluded that as of the Evaluation Date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) is accumulated and communicated to our management, including our president and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Our management, including our president and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable assurance that the objectives of the control system are met. Further, 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. Because of the inherent limitations in all control systems, management's evaluation of controls and procedures can only provide reasonable assurance that all control issues and instances of fraud, if any, within Protalex have been detected.

(b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of May 31, 2014. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Our management has concluded that, as of May 31, 2014, our internal control over financial reporting is effective based on these criteria.

(c) Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the last fiscal quarter covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth information concerning our officers and directors as of August 1, 2014:

Name	Age	Title
Arnold P. Kling	56	President and Director
Kirk M. Warshaw	56	Chief Financial Officer, Secretary and Director
Marco M. Elser	55	Director

Arnold P. Kling. Mr. Kling has served as our president and director since November 2009. For the past 15 years, Mr. Kling has been the senior managing partner for a group of private equity investment funds that invest and manage early stage companies whose technologies have the potential to disrupt their targeted markets. From 1993 to 1995 he was a senior executive and general counsel of a Nasdaq listed licensing and multimedia company. From 1990 through 1993, Mr. Kling was an associate and partner in the corporate and financial services department of Tannenbaum, Helpern, Syracuse & Hirschtritt LLP, a mid-size New York law firm. Mr. Kling received a Bachelor of Science degree from New York University in International Business in 1980 and a Juris Doctor degree from Benjamin Cardozo School of Law in 1983. Mr. Kling currently also serves as a Director and President of 24Holdings, Inc. (OTCBB:TWFH) and Newtown Lane Marketing, Incorporated (OTCBB: NTWN). Mr. Kling's professional experience and background with other companies and with us, as our president and director since 2009, have given him the expertise needed to serve as one of our directors.

Kirk M. Warshaw. Mr. Warshaw has served as our chief financial officer, secretary and director since November 2009. Mr. Warshaw is a financial professional who, since 1990, has provided clients in various industries with advice on accounting, corporate finance, and general business matters. Prior to starting his own consulting firm, from 1983 to 1990, he held the various titles of controller, Chief Financial Officer, President, and chief executive officer at three separate financial institutions in New Jersey. From 1980 through 1983, Mr. Warshaw was a Senior Accountant at the public accounting firm of Deloitte, Haskins & Sells. Mr. Warshaw is a 1980 graduate of Lehigh University and has been a CPA in New Jersey since 1982. Mr. Warshaw is currently the Chief Financial Officer of Newtown Lane Marketing, Incorporated (OTCBB: NTWN), and a Director and the Chief Financial Officer of 24Holdings Inc. (OTCBB: TWFH). Mr. Warshaw's professional experience and background with other companies and with us, as our chief financial officer and director since 2009, have given him the expertise needed to serve as one of our directors.

Marco M. Elser. has served as a director since February 2014. For over five years, Mr. Elser has been a partner with AdviCorp Plc, a London-based investment banking firm. From 1994 to 2001, Mr. Elser served as International Vice President of Northeast Securities, managing distressed funds for family offices and small institutions. Prior to that, from 1985 through 1994, he served as a First Vice President of Merrill Lynch Capital Markets in Rome and London. Mr. Elser served on the Board of Directors of Pine Brook Capital, a Shelton, CT-based engineering company from 2007 to 2012 and was its Chairman from 2009 through 2012. He is presently a director (since 2002) of North Hills Signal Processing Corporation, a technology company and a director (since 2012) of Trans-Lux Corporation, a designer and manufacturer of digital signage display solutions. From 2002 to 2014, Mr. Elser was also the president of the Harvard Club of Italy, an association he founded with other alumni in Italy where he has been living since 1984. He received his BA in Economics from Harvard College in 1981 Mr. Elser's extensive knowledge of international finance and commerce allows him to make valuable contributions as one of our directors.

Scientific Advisory Board

Our Scientific Advisory Board (SAB) members work with our management team in the planning, development and execution of scientific and business strategies. It reviews, and advises management on our progress in research and clinical development as well as new scientific perspectives. The SAB is composed of well-respected, experienced academic and industry leaders with diverse expertise and knowledge in a variety of areas, including drug discovery, translational research, drug development, and business development.

Benjamin Bowen, Ph.D. serves as Chairman of our SAB. Dr. Bowen has 25 years of healthcare-specific experience as a research scientist, research manager, investment banker, and advisor. Since 2004, he has been an investment banker at Rodman & Renshaw, LLC, The Benchmark Company, LLC, and Northland Capital Markets. Starting in 2012, Mr. Bowen has been President of Owatonna Advisors, Inc., a consultancy that provides scientific and business advice to early stage life science companies. Between 1988 and 2003, he worked as a scientist and research manager at Genentech, CIBA-Geigy, and Novartis, last serving as Executive Director in the Cardiovascular and Metabolic Disease Therapeutic Area at Novartis. Mr. Bowen received a Bachelor of Arts degree in chemistry from Hamline University in 1983 and a Ph.D. degree in organic chemistry from MIT in 1988.

Edward Bernton, M.D. has a background in pharmacology, clinical immunology, and experimental medicine. Prior to December 2009, Dr. Bernton served as our medical director and worked as a consultant in clinical pharmacology and early-phase drug development. His medical sub-specialties include internal medicine, allergy/immunology, and diagnostic laboratory immunology. He has served as protocol author or investigator on over thirty Phase I clinical trials including many first-in-man studies for novel small molecules, biopharmaceutics, and vaccines. Dr. Bernton spent 12 years in both basic and clinical research in pharmacology, immunology, infectious diseases, and vaccinology at Walter Reed Army Institute of Research while serving 20 years as a medical officer in the US Army.

Michelle Catalina, Ph.D. has a background in immunology, molecular biology and biochemistry. Dr. Catalina has served as an instructor at the University of Massachusetts Medical Center where she directed production of tetrameric molecules for detection of antigen specific T cells and projects to study the generation and maintenance of antigen specific T cells. Dr. Catalina has also conducted research investigating the role of homing receptors on inflammatory and antigen specific processes. She received a Bachelor of Science degree in biochemistry from the University of Illinois in 1991 and a Ph.D. degree in immunology from the University of Texas Southwestern Medical Center in 1996.

James W. Dowe III serves as Vice Chairman of our SAB and has over thirty years of experience in the various stages of a company's development. His corporate experience ranges from being an active investor, CEO and/or Chairman of startups to public companies. His primary focus has been in biotechnology, computer software and investment management companies. In 1980, Mr. Dowe founded and later became the CEO and Chairman of Excalibur Technologies Corporation whose search engine is recognized for its ability to index and retrieve mixed data types including digital images, signals and multilingual text. Excalibur was merged with the Media Systems Division of the Intel Corporation to form Convera Corporation (CNVR). Mr. Dowe was co-founder and a director of AZUR Environmental, a private company (acquired by Strategic Diagnostics Inc. (Nasdaq: SDIX)). Mr. Dowe graduated from New Mexico State University with a Bachelor of Science degree in 1965 and served as an U.S. Naval officer during the Vietnam War.

Richard Francovitch, Ph.D. received his academic training in pharmacology and has an extensive background in developing and commercializing pharmaceutical products on a global scale. Dr. Francovitch has over 25 years of experience in the pharmaceutical industry. For the last 15 years prior to joining the Company he held various senior level positions, including Vice President, Head of the Hematology Franchise at GlaxoSmithKline Pharmaceuticals (LSE/NYSE: GSK), one of the world's leading research-based pharmaceutical and healthcare companies. Dr. Francovitch received a Bachelor of Science degree in biology from the University of Maryland in 1979 and a Ph.D. degree in Pharmacology from Tulane University in 1985.

William E. Gannon, Jr., M.D. serves as our Chief Medical Officer. He also serves as Chief Scientific Officer & Medical Director for Capital City Technical Consulting (CCTC) in Washington, DC. In addition to receiving his medical training and clinical work at Ross University, Case Western Reserve and George Washington University, Dr. Gannon obtained an M.B.A. from George Washington University in 1988 and has since built a wealth of experience in the management of clinical trials including designing the trials and building operational teams to ensure their successful completion. Dr. Gannon's primary focus has been on oncology therapeutic and diagnostic applications, but possesses a broad range of experience across therapeutic categories. Dr. Gannon has managed clinical trials and operations as well as the design, corporate and regulatory strategies, regulatory submissions and execution of Phase I through Phase IV clinical trials in the United States, Europe and Asia. Additionally, Dr. Gannon is involved in philanthropy in the Washington, DC area and currently serves on the Board of Directors for Emerging World Health and The Foundation for Sickle Cell Research.

John Bruce Lundy McClain, M.D. , has a background in clinical research, clinical product development, product safety, and product quality. Dr. McClain served 20 years in the United States Army in clinical and academic positions. He devoted 14 years in both basic and clinical research in infectious diseases and vaccinology at Walter Reed Army Institute of Research and Walter Reed Army Medical Center. For the last 19 years he has developed pharmaceutical products in industry, lastly as chief medical officer. Dr. McClain currently provides independent pharmaceutical expertise on clinical development, product quality and product safety to biopharmaceutical firms. Dr. McClain received a Bachelor of Science degree in biology from Spring Hill College in 1970 and his M.D. from the University of Alabama in 1974.

Third-Party Consultants

We engage a number of third-party consultants from time-to-time that provide various services supporting our clinical development program and trials.

Family Relationships

None of our directors or executive officers is related by blood, marriage or adoption.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who beneficially own more than ten percent of our Common Stock (collectively, the "Reporting Persons") to report their ownership of and transactions in our Common Stock to the SEC. Copies of these reports are also required to be supplied to us. To our knowledge, during the fiscal year ended May 31, 2014 the Reporting Persons complied with all applicable Section 16(a) reporting requirements.

Code of Ethics

Our Board adopted a code of ethics that applies to its directors, officers and employees as well as those of our subsidiaries. Copies of our codes of ethics are publicly available on our website at www.protalex.com. Requests for copies of our codes of ethics should be sent in writing to Protalex, Inc., 131 Columbia Turnpike, Suite 1, Florham Park, NJ 07932.

Board Composition and Election of Directors

Our Board consists of three directors. Each director is elected to a one year term and serves until his successor is duly elected and qualified. We intend to expand our Board to five directors a majority of who will be independent under the NASDAQ Rules.

Board Committees

Our Board has the authority to appoint committees to perform certain management and administrative functions. As of the date of this Annual Report, given the limited number of directors, our Board has not yet re-established any committees. However, we expect that our Board will appoint new directors in the future and once the Board has been expanded, we anticipate that the Board will again establish separate audit, compensation and nominating and corporate governance committees and may, from time to time, establish other committees it deems appropriate.

Audit Committee Financial Expert

Our entire Board will act as our audit committee until such time it decides to re-establish a separate audit committee. The Board has determined that Mr. Warshaw qualifies as our “audit committee financial expert,” as that term is defined in Item 407(d)(5) of Regulation S-K. Mr. Warshaw is not independent for audit committee purposes under the definition contained in Section 10A(m)(3) of the Exchange Act.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The table below summarizes the total compensation paid to or earned by each of the named executive officers for the fiscal years ended May 31, 2014 and 2013:

Name and Principal Position	Year	Salary ($) (1)	Option Awards ($) (1)	Total ($)
Arnold P. Kling,	2014	$ 72,000	0	$ 72,000
President	2013	$ 72,000	0	$ 72,000
Kirk M. Warshaw,	2014	$ 72,000	$ 164,500	$ 236,520
Chief Financial Officer	2013	$ 72,000	$ 164,500	$ 236,520

(1) Reflects the value of stock options that was charged to income as reported in our financial statements and calculated using the provisions of FASB ASC 718 "Share-based Payments." The assumptions underlying the valuation of equity awards are set forth in Note 7 of our financial statements, included elsewhere in this report.

Employment Contracts

There are no employment contracts between us and either Mr. Kling or Mr. Warshaw.

Indemnification Agreements

As of the date of this Annual Report, we have entered into indemnification agreements with each of our current directors and executive officers, each member of our SAB and each of our former executive officers and directors who resigned in November 2009 in connection with the closing of the Financing. It is anticipated that future directors, officers and members of our SAB will enter into an Indemnification Agreement with us in substantially similar form. The Indemnification Agreement provides, among other things, that we will indemnify and hold harmless each person subject to an Indemnification Agreement (each, an "Indemnified Party") to the fullest extent permitted by applicable law from and against all losses, costs, liabilities, judgments, penalties, fines, expenses and other matters that may result or arise in connection with such Indemnified Party serving in his or her capacity as a director of ours or serving at our direction as a director, officer, employee, fiduciary or agent of another entity. The Indemnification Agreement further provides that, upon an Indemnified Party's request, we will advance expenses to the Indemnified Party to the fullest extent permitted by applicable law. Pursuant to the Indemnification Agreement, an Indemnified Party is presumed to be entitled to indemnification and we have the burden of proving otherwise. The Indemnification Agreement also requires us to maintain in full force and effect directors' liability insurance on the terms described in the Indemnification Agreement. If indemnification under the Indemnification Agreement is unavailable to an Indemnified Party for any reason, we, in lieu of indemnifying the Indemnified Party, will contribute to any amounts incurred by the Indemnified Party in connection with any claim relating to an indemnifiable event in such proportion as is deemed fair and reasonable in light of all of the circumstances to reflect the relative benefits received or relative fault of the parties in connection with such event.

Outstanding Equity Awards at Fiscal Year End

The table below summaries the outstanding equity awards to our named executive officers as of the fiscal year ended May 31, 2014:

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Kirk M Warshaw, Chief Financial Officer	750,543	0	$ 0.25	12/29/2019
	250,000	0	$ 1.01	10/31/2021
	350,000	0	$ 1.05	05/22/2023

Compensation of Directors

The table below summaries the compensation paid to our independent director for the fiscal year ended May 31, 2014:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Marco M. Elser	$ 0	$ 896,887	$ 0	$ 896,887

(1) Reflects the value of stock options that was charged to income as reported in our financial statements and calculated using the provisions of FASB ASC 718 “Share-based Payments.” The assumptions underlying the valuation of equity awards are set forth in Note 7 of our financial statements, included elsewhere in this report. At May 31, 2014, Mr. Elser held options exercisable for an aggregate of 250,000 shares at an exercise price of $9.00 per share. The number of shares to be acquired upon exercise assumes that the options are fully-vested.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information regarding the beneficial ownership (as such term is defined in Rule 13d-3 under the Exchange Act) of our Common Stock as of August 1, 2014, except as noted below, by:

- each of our directors;
- each of our Named Executive Officers (as defined in Item 402(m) of Regulation S-K);
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of Common Stock; and
- all of our directors and executive officers as a group.

Except as indicated in the footnotes below, each holder listed below possesses sole voting and investment power with respect to their shares and such holder’s address is c/o Protalex, Inc., at 131 Columbia Turnpike, Suite 1, Florham Park, NJ 07932. An asterisk (*) denotes less than 1%. The information is not necessarily indicative of beneficial ownership for any other purpose. Percentage ownership calculations for beneficial ownership are based on 28,767,582 shares of Common Stock outstanding as of August 1, 2014.

Name and Title	Shares Beneficially Owned(1) Number	Percent
Arnold P. Kling, president and director (2)	22,581,159	78.5%
Kirk M. Warshaw, CFO, secretary and director (3)	1,350,543	4.5%
Marco M. Elser, director (4)	117,333	*
Officers and Directors as a group (3 persons) (5)	24,049,025	79.6%
5% Beneficial Owners		
Niobe Ventures LLC		
410 Park Avenue – Suite 1710		
New York, NY 10022	22,576,097	78.5%

(1) Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all shares of the Common Stock beneficially owned by them. A person is deemed to be the beneficial owner of securities which may be acquired by such person within 60 days from the date indicated above upon the exercise of options, warrants or convertible securities. Each beneficial owner's percentage ownership is determined by assuming that options, warrants or convertible securities that are held by such person (but not those held by any other person) and which are exercisable within 60 days of the date indicated above, have been exercised.

(2) Arnold P. Kling, our president and a director, possesses sole voting and dispositive control over the securities owned by Niobe Ventures, LLC and therefore is deemed to be the beneficial owner of the securities held by that entity.

(3) Consists of options to purchase 750,543 shares of Common Stock at an exercise price of $0.25 per share, 250,000 shares of Common Stock at an exercise price of $1.01 per share, and 300,000 shares of Common Stock at an exercise price of $1.05 per share.

(4) Includes options to purchase 83,333 shares of Common Stock at an exercise price of $9.00 per share.

(5) Includes 1,433,876 shares of Common Stock underlying options to purchase shares of Common Stock beneficially owned.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders – 2003 Stock Option Plan	**37,000**	**$ 13.86**	**651,616**
Equity compensation plans not approved by security holders – Stand Alone Option Grants	**4,280,543**	**$ 3.17**	**Not applicable**
Total	**4,317,543**	**$ 3.26**	**651,616**

During the fiscal year ended May 31, 2014, options for an aggregate of 1,300,000 shares of our Common Stock were granted under Equity Compensation Plans Not Approved by Security Holders as compensation for consulting services. These options include five and ten year options with exercise prices ranging from $8.20 to $9.00 per share, they vest from the first anniversary to the third anniversary from the date of grant and some are subject to earlier vesting upon the achievement of each of three milestones including, upon commencement of the drug test trial, upon demonstrated efficacy of the drug trial and finally, upon the execution of a licensing or financing transaction. 40,000 options under the 2003 Stock Option Plan expired unexercised.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

As described herein above, during the years ended May 31, 2013 and May 31, 2014, we raised an aggregate of $9,000,000 of working capital from six separate loans, in varying principal amounts, from Niobe and issued to Niobe the Secured Notes.

On February 11, 2011, for the purpose of providing us with additional working capital, pursuant to the Facility, we issued to Niobe the $2 Million Secured Convertible Note. On August 27, 2013, Niobe elected to convert the principal and accrued interest of $2,155,000 under the $2 Million Secured Convertible Note into 9,369,565 shares of Common Stock.

On November 11, 2009, we raised $3,000,000 of working capital from Niobe in the Financing transaction pursuant to which we issued to Niobe: (i) 8,695,652 restricted shares of our Common Stock at a purchase price of $0.23 per share (or $2 million in the aggregate); and (ii) the $1 Million Secured Note. On February 11, 2011, Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of our Common Stock.

Currently, we do not have written policies and procedures for the review, approval or ratification of related person transactions. However, given our small size, senior management and the audit committee (or full Board) are able to review all transactions consistent with applicable securities rules governing our transactions and proposed transactions exceeding the lesser of $120,000 or one percent of the average of our total assets as of May 31, 2014 and 2013 in which a related person has a direct or indirect material interest. Our Board reviews related person transactions and has approval authority with respect to whether a related person transaction is within our best interest.

Director Independence

We are not currently a “listed company” under SEC rules and are therefore not required to have a board comprised of a majority of independent directors or separate committees comprised of independent directors. We use the definition of “independence” under the NASDAQ Rules, as applicable and as may be modified or supplemented from time to time and the interpretations thereunder, to determine if the members of our Board are independent. In making this determination, our Board considers, among other things, transactions and relationships between each director and his immediate family and us, including those reported in this Annual Report under the caption “Certain Relationships and Related Transactions.” The purpose of this review is to determine whether any such relationships or transactions are material and, therefore, inconsistent with a determination that the directors are independent. On the basis of such review and its understanding of such relationships and transactions, our Board has determined that one of our Board members, Marco M. Elser, is an independent director.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The aggregate fees billed by our principal accounting firm, Liggett, Vogt & Webb P.A in the fiscal years ended May 31, 2013 and 2014 are as follows:

	2013	2014
Audit fees*	$ 33,500	$ 33,500
Audit related fees	0	0
Tax fees	4,500	4,500
All other fees**	0	9,500
Total fees	$ 38,000	$ 47,500

*Includes fees for professional services rendered for the audit of our annual financial statements and the review of financial statements included in our report on Form 10-Qs or services that are normally provided in connection with statutory and regulatory filings.
**Includes fees for professional services rendered in connection with the preparation and filing of our Registration Statement on Form S-1 filed on February 20, 2014.

Pre-Approval of Audit and Permissible Non-Audit Services

Our Board pre-approves all audit and permissible non-audit services provided by the independent auditors. The services may include audit services, audit-related services, tax services and other services. The independent auditors and management are required to periodically report to the Board regarding the extent of services provided by the independent auditors in accordance with this pre-approval, and the fees for the services performed to date. The Board may also pre-approve particular services on a case-by-case basis.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements

Reference is made to the Index to Financial Statements on page F-1 of this Annual Report which is filed as part of this Annual Report and incorporated by reference herein.

2. Financial Statement Schedules

None.

(b) Exhibits

The following exhibits are filed a part of, or incorporated by reference into this Annual Report.

EXHIBIT INDEX

3.1	Certificate of Incorporation of the Company	Incorporated by reference, to Exhibit 3.1 to the Company's 8-K filing on December 6, 2004.
3.2	Bylaws of the Company	Incorporated by reference, to Exhibit 3.2 to the Company's 8-K filing on December 6, 2004.
3.3	State of Delaware, Certificate of Amendment of Certificate of Incorporation	Incorporated by reference, to Exhibit 3.3 to the Company 10-QSB filed on January 13, 2006.
4.1	Consolidated, Amended and Restated Promissory Note in the principal amount of $9,219,366, dated October 11, 2013	Incorporated by reference, to Exhibit 4.1 to the Company's Quarterly Report on Form 10Q filed on October 11, 2013.
4.2	Final form of Securities Purchase Agreement dated as of January 22, 2014 between the Company and certain accredited investors pursuant to which such investors were granted piggy back registration rights	Filed herewith.
10.1	Frame Contract between the Company and Eurogentec S.A.	Incorporated by reference, to Exhibit 10.5 to the Company's 10-KSB/A filed on September 24, 2003.
10.2	Assignment of Intellectual Property from Alex LLC to the Company	Incorporated by reference, to Exhibit 10.8 to the Company's 10-KSB/A filed on September 24, 2003.
10.3	Assignment of Intellectual Property from Dr. Paul Mann to the Company	Incorporated by reference, to Exhibit 10.8 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.4	Protalex, Inc. 2003 Stock Option Plan Amended and Restated as of July 29, 2005	Incorporated by reference to Appendix B to the Company's Proxy Statement filed on September 23, 2005.
10.5†	Service Contract with AAIPharma Inc., dated January 29, 2007	Incorporated by reference to Exhibit 10.18 to the Company's Quarterly Report on Form 10-QSB filed on April 13, 2007.
10.6	Indemnification Agreement with Directors and Executive Officers dated August 28, 2009	Incorporated by reference, to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on August 28, 2009.
10.7**	Final Form of Indemnification Agreement with current Directors, Executive Officers and the members of the Scientific Advisory Board	Incorporated by reference, to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 13, 2010.
10.8**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw December 29, 2009	Incorporate by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10Q filed on January 8, 2010.
10.9**	Form of Non-Qualified Stock Option Agreement with each of William Gannon, Edward Bernton and Valerie Jackson	Incorporated by reference, to Exhibit 4.9 to the Company's Annual Report on Form 10-K filed on August 27, 2010.
10.10**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw dated November 1, 2011	Incorporated by reference, to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed on August 29, 2012.
10.11**	Form of Non-Qualified Stock Option Agreement with each of Edward Bernton and Valerie Jackson, dated November 1, 2011	Incorporated by reference, to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed on August 29, 2012.

10.12**	Form of Non-Qualified Stock Option Agreement with Marco M. Elser dated February 4, 2014	Incorporate by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on February 20, 2014.
10.13**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw dated May 22, 2013	Incorporated by reference, to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on February 20, 2014.
10.14	Consolidated, Amended and Restated Security Agreement dated October 11, 2013, between the Company and Niobe Ventures, LLC	Incorporated by reference, to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on February 20, 2014.
23.1	Consent of Liggett, Vogt & Webb, P.A.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act	Filed herewith.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith.
101.INS	*XBRL Instance Document*	Filed herewith.
101.SCH	*XBRL Taxonomy Extension Schema Document*	Filed herewith.
101.CAL	*XBRL Taxonomy Extension Calculation Linkbase Document*	Filed herewith.
101.LAB	*XBRL Taxonomy Extension Label Linkbase Document*	Filed herewith.
101.PRE	*XBRL Taxonomy Extension Presentation Linkbase Document*	Filed herewith.
101.DEF	*XBRL Taxonomy Extension Definition Linkbase Document*	Filed herewith.

†Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

***This exhibit is a management contract or compensatory plan or arrangement.*

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Protalex Inc.

Date: August 4, 2014

By:/s/ Arnold P. Kling
Arnold P. Kling, President

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: August 4, 2014

/s/ Arnold P. Kling
Arnold P. Kling, President and Director
(Principal Executive Officer)

Date: August 4, 2014

/s/ Kirk M. Warshaw
Kirk M. Warshaw, Chief Financial Officer and Director
(Principal Financial and Accounting Officer)

Date: August 4, 2014

/s/ Marco M. Elser
Marco M. Elser, Director

PROTALEX, INC.

INDEX TO FINANCIAL STATEMENTS

The following Financial Statements, and the related Notes thereto, of Protalex, Inc. and the Report of Independent Registered Public Accounting Firm are filed as a part of this Annual Report on Form 10-K.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Directors
Protalex, Inc.
Florham Park, New Jersey

We have audited the accompanying balance sheets of Protalex, Inc. as of May 31, 2014 and 2013, and the related statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Protalex, Inc. as of May 31, 2014 and 2013 and the results of its operations and its cash flows for each of the years ended May 31, 2014 and 2013, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that Protalex, Inc. will continue as a going concern. As more fully described in Note 3, the Company has incurred recurring operating losses and will have to obtain additional capital to sustain operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments to reflect the possible effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Liggett, Vogt & Webb, P.A.
Certified Public Accountants

New York, NY
August 4, 2014

PROTALEX, INC.
BALANCE SHEETS

	May 31, 2014	May 31, 2013
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,614,758	$ 2,457,046
Prepaid expenses	45,327	42,320
Total current assets	1,660,085	2,499,366
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $14,088 and $13,068 as of May 31, 2014 and May 31, 2013, respectively	5,447	6,467
Total other assets	5,447	6,467
Total Assets	$ 1,665,532	$ 2,505,833
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 412,718	$ 671,738
Accrued expenses	40,135	62,517
Current portion – long term debt– related party	0	4,210,833
Total current liabilities	452,853	4,945,088
LONG TERM LIABILITIES:		
Senior Secured Note – related party	9,000,000	6,000,000
Senior Secured Note Accrued Interest – related party	397,168	57,616
Total liabilities	9,850,021	11,002,704
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, par value $0.00001, 1,000,000 shares authorized; none issued and outstanding	0	0
Common stock, par value $0.00001, 100,000,000 shares authorized; 28,767,582 and 18,926,615 shares issued and outstanding, respectively	288	189
Additional paid in capital	65,402,505	53,237,993
Accumulated deficit	(73,587,282)	(61,735,053)
Total stockholders' equity (deficit)	(8,184,489)	(8,496,871)
Total liabilities and stockholders' equity (deficit)	$ 1,665,532	$ 2,505,833

The accompanying notes are an integral part of these financial statements.

PROTALEX, INC.

STATEMENTS OF OPERATIONS
Years Ended May 31,

	2014	2013
Revenues	$ 0	$ 0
Operating Expenses		
Research and development	3,232,321	3,833,401
Administrative	7,750,587	1,345,152
Professional fees	584,585	440,751
Depreciation and amortization	1,020	1,020
Operating loss	(11,568,513)	(5,620,324)
Other income (expense)		
Interest income	4	3,956
Interest expense	(283,720)	(663,866)
Loss before income taxes	(11,852,229)	(6,280,234)
Provision for income taxes	0	0
Net loss	$ (11,852,229)	$ (6,280,234)
Weighted average number of common shares outstanding	**26,222,563**	**18,926,615**
Loss per common share – basic and diluted	$ (0.45)	$ (0.33)

The accompanying notes are an integral part of these financial statements.

PROTALEX, INC.

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

For the Years Ended May 31, 2013 and May 31, 2014

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, May 31, 2012	18,926,683	$ 189	$52,331,016	$ (55,454,819)	$ (3,123,614)
June 1, 2012 – May 31, 2013 – shared-based expense	0	0	906,977	0	906,977
Net loss for the year ended May31, 2013	0	0	0	(6,280,234)	(6,280,234)
Balance, May 31, 2013	18,926,683	189	53,237,993	(61,735,053)	(8,496,871)
June 1, 2013 – May 31, 2014 – shared-based expense	0	0	7,228,008	0	7,228,008
August 27, 2013 – issuance of 9,369,565 shares of common stock	9,369,565	94	2,154,906	0	2,155,000
January 23, 2014 – issuance of 471,334 shares of common stock	471,334	5	2,781,598	0	2,781,603
Net loss for the year ended May 31, 2014	0	0	0	(11,852,229)	(11,852,229)
Balance, May 31, 2014	28,767,582	$ 288	$65,402,505	$ (73,587,282)	$ (8,184,489)

The accompanying notes are an integral part of this financial statement.

PROTALEX, INC.

STATEMENTS OF CASH FLOWS
Years Ended May 31,

	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (11,852,229)	$ (6,280,234)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities		
(Gain) on disposal of equipment, net	0	0
Depreciation and amortization	1,020	1,020
Equity based expense	7,228,008	906,977
(Increase)/decrease in:		
Prepaid expenses and deposits	(3,008)	360
Increase/(decrease) in:		
Accounts payable and accrued expenses	(281,402)	638,528
Accrued interest payable	283,720	0
Net cash and cash equivalents used in operating activities	(4,623,891)	(4,733,349)
CASH FLOWS FROM INVESTING ACTIVITIES:	0	0
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from stock issuance, including options and warrants exercised	2,781,603	0
Issuance of note payable to individuals	1,000,000	7,000,000
Net cash and cash equivalents provided by financing activities	3,781,603	7,000,000
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(842,288)	2,266,651
Cash and cash equivalents, beginning	2,457,046	190,395
Cash and cash equivalents, ending	$ 1,614,758	$ 2,457,046
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:		
Interest paid	$ 0	$ 0
Taxes paid	$ 0	$ 0
NONCASH FINANCING ACTIVITIES:		
Conversion of debt to equity	$ 2,155,000	$ 0

The accompanying notes are an integral part of these financial statements.

1. ORGANIZATION AND BUSINESS ACTIVITIES

The Company is focused on the development of a class of biopharmaceutical drugs for treating autoimmune inflammatory diseases including rheumatoid arthritis (RA). Its lead product, PRTX-100, is a formulation of highly-purified form of staphylococcal protein A, which is an immune modulating protein produced by bacteria.

The Company maintains an administrative office in Florham Park, New Jersey and currently outsources all of its product development and regulatory activities, including clinical trial activities, manufacturing and laboratory operations to third-party contract research organizations and facilities.

In April 2009, the Company ceased all operations and terminated all employees in light of insufficient funds to continue its clinical trials and related product development. The Company's business was dormant until new management took control of its operations in November 2009 following the change in control transaction more fully described below. The Company is currently actively pursuing the commercial development of PRTX-100 for the treatment of RA.

On December 8, 2010, the Company effected a reverse stock split of the outstanding shares of its common stock, with par value of $0.00001 per share ("Common Stock"), on the basis of one share of Common Stock for each five shares of Common Stock outstanding. Unless otherwise noted, all references in these financial statements and notes to financial statements to number of shares, price per share and weighted average number of shares outstanding of Common Stock prior to this reverse stock split have been adjusted to reflect the reverse stock split on a retroactive basis.

PRTX-100 has demonstrated effectiveness in animal models of autoimmune diseases as well as demonstrated activity on cultured human immune cells at very low concentrations, although the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that the Company would see in future human clinical trials. The Company does not anticipate generating operating revenue for the foreseeable future and does not currently have any products that are marketable.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. The ability of the Company to continue as a going concern is dependent upon developing products that are regulatory approved and market accepted. There is no assurance that these plans will be realized in whole or in part. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

2. CHANGE OF OWNERSHIP TRANSACTION

On November 11, 2009 (the "Effective Date"), the Company consummated a financing transaction (the "Financing") in which it raised $3,000,000 of working capital pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with Niobe Ventures, LLC, a Delaware limited liability company ("Niobe"). Pursuant to the Purchase Agreement, the Company issued to Niobe (i) 8,695,652 restricted shares of Common Stock at a purchase price of $0.23 per share (or $2 million in the aggregate) and (ii) a senior secured convertible promissory note in the principal amount of $1 million convertible into shares of Common Stock at an initial conversion price equal to $0.23 per share (the "$1 Million Secured Note"). On February 11, 2011, Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of Common Stock.

As contemplated by the Purchase Agreement, all of the Company's executive officers and all of the members of its Board of Directors (the "Board") prior to the closing of the Financing, with the exception of Frank M. Dougherty, resigned effective concurrently with the closing of the Financing. Mr. Dougherty resigned effective upon the expiration of the 10-day notice period required by Rule 14f-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In addition, effective upon the closing of the Financing, the Board appointed Arnold P. Kling as a director and then elected him as the Company's president and elected Kirk M. Warshaw as the Company's chief financial officer and secretary.

In addition, on the Effective Date, the Company terminated (i) the Investor Rights Agreement dated September 18, 2003 among us, vSpring SBIC L.P. ("vSpring") and certain of the investors set forth on Schedule A thereto and the Registration Rights Agreement dated May 25, 2005 among the Company, vSpring and certain of the investors set forth on Schedule I thereto in accordance with their respective terms and (ii) stock options exercisable for an aggregate of 246,714 shares of Common Stock (approximately 41% of the Company's then outstanding stock options).

On February 11, 2011, for the purpose of providing the Company with additional working capital, pursuant to an existing Credit Facility Agreement dated as of December 2, 2009 (the "Facility") with Niobe, the Company issued to Niobe a senior secured convertible promissory note in the principal amount of $2 million (the "$2 Million Secured Convertible Note"). The $2 Million Secured Convertible Note was convertible into shares of Common Stock at a conversion price of $0.23 per share, for an aggregate of 8,695,652 shares of Common Stock (net of accrued interest thereon), bore interest at a rate of 3% per annum and had a maturity date of December 31, 2013. The original maturity was December 31, 2012 but in December 2012 Niobe agreed, for no consideration, to extend the maturity date to December 31, 2013.

The $2 Million Secured Convertible Note was convertible at any time, by the holder, subject only to the requirement that the Company have sufficient authorized shares of Common Stock after taking into account all outstanding shares of Common Stock and the maximum number of shares issuable under all issued and outstanding convertible securities. In addition, the $2 Million Secured Convertible Note would automatically be converted if the Company undertake certain Fundamental Transactions, as defined in the $2 Million Secured Convertible Note, (such as a merger, sale of all of the Company's assets, exchange or tender offer, or reclassification of its stock or compulsory exchange). The $2 Million Secured Convertible Note also provided for the adjustment of the conversion price in the event of stock dividends and stock splits, and provides for acceleration of maturity, at the holder's option, upon an event of default, as defined in the $2 Million Secured Convertible Note. On August 27, 2013, Niobe elected to convert the principal and accrued interest of $2,155,000 under the $2 Million Secured Convertible Note into 9,369,565 shares of Common Stock.

On February 1, 2012, the Company raised $1,000,000 of working capital pursuant to a loan from Niobe. The Company issued to Niobe a secured promissory note in the principal amount of $1,000,000 (the "February 2012 Secured Note"). The February 2012 Secured Note bore interest at a rate of 3% per annum and had a maturity date of February 1, 2014.

On June 5, 2012, the Company raised an additional $1,000,000 of working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 31, 2014 (the "June 2012 Secured Note").

On October 1, 2012, the Company raised $800,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $800,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "October 2012 Secured Note").

On December 3, 2012, the Company raised $700,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $700,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "December 2012 Secured Note").

Collectively, the February 2012 Secured Note, the June 2012 Secured Note, the October 2012 Secured Note and the December 2012 Secured Note are hereinafter referred to as the "2012 Secured Notes."

On January 18, 2013, the Company raised $2,500,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,500,000, which bore interest at a rate of 3% per annum and had a maturity date of January 15, 2015 (the "January 2013 Secured Note").

On May 13, 2013, the Company raised $2,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 13, 2015 (the "May 2013 Secured Note").

On August 27, 2013, the Company raised $1,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bore interest at a rate of 3% per annum and had a maturity date of August 27, 2015. (the "August 2013 Secured Note").

Collectively, the January 2013 Secured Note, the May 2013 Secured Note, and the August 2013 Secured Note are hereinafter referred to as the "2013 Secured Notes."

Collectively, the 2012 Secured Notes and the 2013 Secured Notes represent a total of $9,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

On October 11, 2013, the Company issued a Consolidated, Amended and Restated Promissory Note to Niobe in the principal amount of $9,219,366 (the "Consolidated Note"). The face amount of the Consolidated Note reflects the $9.0 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on each note from its respective date of issuance. The terms of the Consolidated Note are identical to the Secured Notes except that: (a) the maturity date is September 1, 2015, which is after the latest maturity date of any of the Secured Notes; and (b) it provides for partial mandatory repayment in the event that the Company receives aggregate gross proceeds in excess of $7.5 million from a single or multiple "Liquidity Events" in an amount equal to twenty-five (25%) percent of such gross proceeds. A "Liquidity Event" means (a) the sale of any of the Company's equity, or equity-linked, securities, and (b) the receipt of proceeds, directly or indirectly related to a development and/or commercialization relationship entered into with an unaffiliated third party. In the Secured Notes, the entire principal amount of each note was due, at Niobe's election, upon the consummation of an equity financing of $7.5 million or greater. Consistent with the terms of the Secured Notes and related security agreements entered into, the Company's obligations under the Consolidated Note are secured by a first priority perfected security interest in all of the Company's assets pursuant to a Consolidated, Amended and Restated Security Agreement dated October 11, 2013 with Niobe.

On January 23, 2014, the Company consummated a private placement financing to accredited investors of 471,334 shares of Common Stock at $6.00 per share, yielding gross proceeds of $2,828,000. No commissions were payable in connection with the financing transaction. Proceeds of the financing will be used for working capital purposes, principally to fund ongoing clinical trials and studies and related activities. The investors in the offering were granted piggy-back registration rights in connection with certain registration statements filed by the Company, subject to certain exceptions, including a registration statement filed in connection with a primary offering by the Company.

3. GOING CONCERN

Since inception, the Company has incurred an accumulated deficit of $73,587,282 through May 31, 2014. For the years ended May 31, 2014 and 2013, the Company had net losses of $11,852,229 and $6,280,234, respectively. The Company has used $4,623,891 and $4,733,349 of cash in operating activities for the years ended May 31 2014 and 2013, respectively. As of May 31, 2014, the Company had cash and cash equivalents of $1,614,758 and net working capital of $1,207,232. The Company has incurred negative cash flow from operating activities since its inception. The Company has spent, and subject to obtaining additional financing, expects to continue to spend, substantial amounts in connection with executing its business strategy, including continued development efforts relating to PRTX-100.

The Company has no significant payments due on long-term obligations. However, the Company anticipates entering into significant contracts to perform product manufacturing and clinical trials in the future and that it will need to raise additional capital to fund the ongoing FDA approval process. If the Company is unable to obtain approval of its future IND applications or otherwise advance in the FDA approval process, its ability to sustain its operations would be significantly jeopardized.

The most likely sources of additional financing include the private sale of the Company's equity or debt securities. Additional capital that is required by the Company may not be available on reasonable terms, or at all.

In February 2014, the Company filed a registration statement on Form S-1 with the U.S. Securities and Exchange Commission ("SEC") in connection with a prospective underwritten public offering of up to 3,000,000 shares of Common Stock. The Company does not presently have any commitment or understanding with any underwriter with respect to any offering. No assurance can be given that it will pursue or consummate an offering, or if it does, that it will be able to raise sufficient additional working capital to fund its operations and satisfy its debt obligations as they become due.

4. BASIS OF ACCOUNTING AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and assumptions affecting the reported amounts of assets, liabilities, and expense, and the disclosure of contingent assets and liabilities. Estimated amounts could differ from actual results.

Loss per Common Share

The Financial Accounting Standards Board (FASB) has issued accounting guidance "Earnings Per Share" that provides for the calculation of "Basic" and "Diluted" earnings per share. Basic earnings per share include no dilution and is computed by dividing the loss to common stockholders by the weighted average number of common shares outstanding for the period. All potentially dilutive securities have been excluded from the computations since they would be antidilutive. However, these dilutive securities could potentially dilute earnings per share in the future. As of May 31, 2014 and 2013, the Company had a total of 4,317,543 and 3,057,543, respectively, of potentially dilutive securities comprised solely of stock options.

Share-Based Compensation

The Company adopted the FASB accounting guidance for share based payment transactions. This standard requires the Company to measure the cost of employee services received in exchange for equity share options granted based on the grant-date fair value of the options. The cost is recognized as compensation expense over the vesting period of the options. The compensation cost included in operating expenses was $7,228,008 and $906,977 for the years ended May 31, 2014 and 2013, respectively and included both the compensation cost of stock options granted prior to but not yet vested as of June 1, 2006 and compensation cost for all options granted subsequent to May 31, 2006. No tax benefit was recorded as of May 31, 2014 in connection with these compensation costs due to the uncertainty regarding ultimate realization of certain net operating loss carry forwards.

The Board adopted and the stockholders approved the 2003 Stock Option Plan on October 2003 and it was amended in October 2005. The plan was adopted to recognize the contributions made by the Company's employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to the Company's future success, and to improve the Company's ability to attract, retain and motivate individuals upon whom the Company's growth and financial success depends. Under the plan, stock options may be granted as approved by the Board or the Compensation Committee. There are 900,000 shares reserved for grants of options under the plan, of which 37,000 have been issued and 800 were exercised. The Company has issued 2,980,543 stock options as stand-alone grants, of which 400 were exercised. Stock options vest pursuant to individual stock option agreements. No options granted under the plan are exercisable after the expiration of ten years (or less in the discretion of the Board or the Compensation Committee) from the date of the grant. The plan will continue in effect until terminated or amended by the Board.

The accounting guidance requires the use of a valuation model to calculate the fair value of each stock-based award. The Company uses the Black-Scholes model to estimate the fair value of stock options granted based on the following assumptions:

Expected Term or Life. The expected term or life of stock options granted represents the expected weighted average period of time from the date of grant to the estimated date that the stock option would be fully exercised. The weighted average expected option term was determined using a combination of the "simplified method" for plain vanilla options as allowed by the accounting guidance. The "simplified method" calculates the expected term as the average of the vesting term and original contractual term of the options.

Expected Volatility. Expected volatility is a measure of the amount by which the Company's stock price is expected to fluctuate. Expected volatility is based on the historical daily volatility of the price of Common Stock. The Company estimated the expected volatility of the stock options at grant date.

Risk-Free Interest Rate. The risk-free interest rate is based on the implied yield on U.S. Treasury zero-coupon issues with remaining terms equivalent to the expected term of the Company's stock-based awards.

As of May 31, 2014, there were 4,317,543 stock options outstanding. At May 31, 2014, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model was approximately $3,830,307 (net of estimated forfeitures and exclusive of 275,000 options yet to be earned or valued) and will be recognized over a weighted average period of eighteen months. For the year ended May 31, 2014, the Company granted 1,300,000 stock options, with a fair value of $9,385,000 (net of estimated forfeitures and exclusive of 275,000 options yet to be earned or valued). 40,000 options expired and none were forfeited.

The fair value of the options is estimated on the date of the grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended May 31, 2014	Year Ended May 31, 2013
Dividends per year	0	0
Volatility percentage	418%-696%	418% - 426%
Risk free interest rate	4.00%	2.13%
Expected life (years)	5-10	7-10
Weighted Average Fair Value	$ 8.51	$ 1.22

Cash and Cash Equivalents

For the purposes of reporting cash flows, the Company considers all cash accounts which are not subject to withdrawal restrictions or penalties, and highly liquid investments with original maturities of 60 days or less to be cash and cash equivalents. The cash and cash equivalent deposits are not insured by The Federal Deposit Insurance Corporation ("FDIC").

Intellectual Technology Property, Amortization

The Company's intellectual technology property was originally licensed from a former related party. This intellectual technology property was then assigned to the Company upon the dissolution of the related party. The cost of the intellectual technology property is being amortized over a 20-year period. Amortization expense is $1,020 and $1,020 for the years ended May 31, 2014 and 2013, respectively. The Company reviews the intellectual property for impairment on at least an annual basis in accordance with the accounting guidance for "Goodwill and Other Intangible Assets"; no impairment charge was recorded as of May 31, 2014. Amortization expense for the intellectual property will be $1,020 for each of the next five years.

Income Taxes

Income taxes are recognized using enacted tax rates, and are composed of taxes on financial accounting income that is adjusted for the requirement of current tax law and deferred taxes. Deferred taxes are accounted for using the liability method. Under this method, deferred tax assets and liabilities are recognized based on the difference between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company does not expect to have current income taxes payable or deferred tax asset balances for the foreseeable future.

The FASB accounting guidance for income taxes establishes the criterion that an individual tax position has to meet for some or all of the benefits of that position to be recognized in the Company's financial statements. On initial application, ASC 740 must be applied to all tax positions for which the statute of limitations remains open. Only tax positions that meet the more-likely-than-not recognition threshold at the adoption date will be recognized or continue to be recognized. The cumulative effect of applying this accounting guidance is to be reported as an adjustment to retained earnings at the beginning of the period in which it is adopted.

Research and Development

Research and development costs are expensed as incurred and also include depreciation as reported above.

Financial Instruments

The Company adopted FASB ASC 820-Fair Value Measurements and Disclosure or ASC 820 for assets and liabilities measured at fair value on a recurring basis. ASC 820 establishes a common definition for fair value to be applied to existing generally accepted accounting principles that require the use of fair value measurements establishes a framework for measuring fair value and expands disclosure about such fair value measurements. The adoption of ASC 820 did not have an impact on the Company's financial position or operating results, but did expand certain disclosures.

ASC 820 defines fair value as the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Additionally, ASC 820 requires the use of valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs. These inputs are prioritized below:

Level 1: Observable inputs such as quoted market prices in active markets for identical assets or liabilities

Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data

Level 3: Unobservable inputs for which there is little or no market data, which require the use of the reporting entity's own assumptions.

The Company values its financial instruments as required by estimating their fair value. The estimated fair value amounts have been determined by the Company, using available market information or other appropriate valuation methodologies. However, considerable judgment is required in interpreting market data to develop estimates of fair value. Consequently, the estimates are not necessarily indicative of the amounts that could be realized or would be paid in a current market exchange.

The Company's financial instruments primarily consist of cash and cash equivalents, convertible debt, accounts payable and accruals.

Cash and cash equivalents include money market securities and commercial paper that are considered to be highly liquid and easily tradable. These securities are valued using inputs observable in active markets for identical securities and are therefore classified as Level 1 within the fair value hierarchy.

As of the balance sheet dates, the estimated fair values of the financial instruments were not materially different from their carrying values as presented due to the short maturities of these instruments and that the interest rates on the borrowings approximate those that would have been available for loans of similar remaining maturity and risk profile at respective year ends.

New Accounting Pronouncements

Except as set forth below, management does not believe that any other recently issued, but not yet effective, accounting standards could have a material effect on the accompanying consolidated financial statements. As new accounting pronouncements are issued, the Company will adopt those that are applicable under the circumstances.

In June 2014, FASB issued Accounting Standards Update ("ASU") No. 2014-10, "*Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*". The update removes all incremental financial reporting requirements from GAAP for development stage entities, including the removal of Topic 915 from the FASB Accounting Standards Codification. In addition, the update adds an example disclosure in Risks and Uncertainties (Topic 275) to illustrate one way that an entity that has not begun planned principal operations could provide information about the risks and uncertainties related to the company's current activities. Furthermore, the update removes an exception provided to development stage entities in Consolidations (Topic 810) for determining whether an entity is a variable interest entity—which may change the consolidation analysis, consolidation decision, and disclosure requirements for a company that has an interest in a company in the development stage. The update is effective for the annual reporting periods beginning after December 15, 2014, including interim periods within that reporting period. The Company has elected to adopt the provisions of this ASU early, accordingly all of the past disclosures and presentations on development stage accounting have been eliminated.

In June 2014, FASB issued ASU No. 2014-12, "*Compensation – Stock Compensation (Topic 718); Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*". The amendments in this ASU apply to all reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718 as it relates to awards with performance conditions that affect vesting to account for such awards. For all entities, the amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The effective date is the same for both public business entities and all other entities.

Entities may apply the amendments in this ASU either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying this Update as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. The Company is currently reviewing the provisions of this ASU to determine if there will be any impact on its results of operations, cash flows or financial condition.

5. INCOME TAXES

For the years ended May 31, 2014 and 2013, the components of income tax benefit (expense) consist of the following:

	Year Ended May 31, 2014	Year Ended May 31, 2013
Current:		
Federal	$ 0	$ 0
State	0	0
Deferred:		
Federal	4,028,000	2,135,000
State	711,000	377,000
Tax credits	185,000	249,000
Permanent timing difference	(2,999,000)	(467,000)
Increase in valuation allowance	(1,925,000)	(2,294,000)
Income tax benefit	$ 0	$ 0

Income tax as a percentage of income for the year ended May 31, 2014 and 2013 differ from statutory federal income tax rates due to the following:

	Year Ended May 31, 2014	Year Ended May 31, 2013
Statutory federal income tax rate	(34)%	(34)%
State income taxes, net of federal income tax impact	(6)%	(6)%
Change in valuation allowance	17%	37%
Permanent timing differences	25%	7%
General business credit/other	(2)%	(4)%
	0%	0%

The components of the net deferred tax asset as of May 31, 2014 and 2013 are as follows:

Assets:	May 31, 2014	May 31, 2013
Net operating losses	$ 21,550,000	$ 19,810,000
Severance accrual	0	0
General business credit	2,540,000	2,355,000
Deferred tax assets	24,090,000	22,165,000
Liability:		
Gross deferred tax asset	24,090,000	22,165,000
Less valuation allowance	(24,090,000)	(22,165,000)
Deferred tax asset, net of valuation allowance	$ 0	$ 0

The gross deferred tax assets have been fully offset by a valuation allowance and has no uncertain tax positions to be disclosed.

Internal Revenue Code Section 382 places a limitation on the amount of taxable income that can be offset by carryforwards after a change in control. As a result of these provisions, utilization of the NOL and tax credit carryforwards may be limited. Most of the deferred tax asset of net operating loss carryforwards and tax credits are subject to a Section 382 limitation on the amount to be utilized in a given year. The years May 31, 2010 through 2014 remain subject to examination by the relevant tax authorities.

The Company is subject to U.S. federal income tax as well as income taxes of state jurisdiction. The Company is not currently under examination by any Federal or state jurisdiction. The federal statute of limitations and state are opened from inception forward. Management believes that the accrual for tax liabilities is adequate for all open years. This assessment relies on estimates and assumptions and may involve a series of complex judgments about future events. On the basis of present information, it is the opinion of the Company's management that there are no pending assessments that will result in a material adverse effect on the Company's financial statements over the next twelve months. The Company recognizes any interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses for all periods presented. The Company has not recorded any material interest or penalties during any of the years presented.

6. RELATED PARTIES

On November 11, 2009 (the "Effective Date"), the Company consummated a financing transaction (the "Financing") in which it raised $3,000,000 of working capital pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with Niobe Ventures, LLC, a Delaware limited liability company ("Niobe"). Pursuant to the Purchase Agreement, the Company issued to Niobe (i) 8,695,652 restricted shares of Common Stock at a purchase price of $0.23 per share (or $2 million in the aggregate) and (ii) a senior secured convertible promissory note in the principal amount of $1 million convertible into shares of Common Stock at an initial conversion price equal to $0.23 per share (the "$1 Million Secured Note"). On February 11, 2011, Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of Common Stock.

On February 11, 2011, for the purpose of providing the Company with additional working capital, pursuant to an existing Credit Facility Agreement dated as of December 2, 2009 (the "Facility") with Niobe, the Company issued to Niobe a senior secured convertible promissory note in the principal amount of $2 million (the "$2 Million Secured Convertible Note"). The $2 Million Secured Convertible Note was convertible into shares of Common Stock at a conversion price of $0.23 per share, for an aggregate of 8,695,652 shares of Common Stock (net of accrued interest thereon), bore interest at a rate of 3% per annum and matured on December 31, 2013. The original maturity was December 31, 2012 but in December 2012 Niobe agreed, for no consideration, to extend the maturity date to December 31, 2013.

The $2 Million Secured Convertible Note was convertible at any time, by the holder, subject only to the requirement that the Company have sufficient authorized shares of Common Stock after taking into account all outstanding shares of Common Stock and the maximum number of shares issuable under all issued and outstanding convertible securities. In addition, the $2 Million Secured Convertible Note would automatically be converted if the Company undertake certain Fundamental Transactions, as defined in the $2 Million Secured Convertible Note, (such as a merger, sale of all of the Company's assets, exchange or tender offer, or reclassification of its stock or compulsory exchange). The $2 Million Secured Convertible Note also provided for the adjustment of the conversion price in the event of stock dividends and stock splits, and provides for acceleration of maturity, at the holder's option, upon an event of default, as defined in the $2 Million Secured Convertible Note. On August 27, 2013, Niobe elected to convert the principal and accrued interest of $2,155,000 under the $2 Million Secured Convertible Note into 9,369,565 shares of Common Stock.

On February 1, 2012, the Company raised $1,000,000 of working capital pursuant to a loan from Niobe. The Company issued to Niobe a secured promissory note in the principal amount of $1,000,000 (the "February 2012 Secured Note"). The February 2012 Secured Note bore interest at a rate of 3% per annum and had a maturity date of February 1, 2014.

On June 5, 2012, the Company raised an additional $1,000,000 of working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 31, 2014 (the "June 2012 Secured Note").

On October 1, 2012, the Company raised $800,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $800,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "October 2012 Secured Note").

On December 3, 2012, the Company raised $700,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $700,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "December 2012 Secured Note").

Collectively, the February 2012 Secured Note, the June 2012 Secured Note, the October 2012 Secured Note and the December 2012 Secured Note are hereinafter referred to as the "2012 Secured Notes."

On January 18, 2013, the Company raised $2,500,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,500,000, which bore interest at a rate of 3% per annum and had a maturity date of January 15, 2015 (the "January 2013 Secured Note").

On May 13, 2013, the Company raised $2,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 13, 2015 (the "May 2013 Secured Note").

On August 27, 2013, the Company raised $1,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bore interest at a rate of 3% per annum and had a maturity date of August 27, 2015. (the "August 2013 Secured Note").

Collectively, the January 2013 Secured Note, the May 2013 Secured Note, and the August 2013 Secured Note are hereinafter referred to as the "2013 Secured Notes."

Collectively, the 2012 Secured Notes and the 2013 Secured Notes represent a total of $9,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

On October 11, 2013, the Company issued a Consolidated, Amended and Restated Promissory Note to Niobe in the principal amount of $9,219,366 (the "Consolidated Note"). The face amount of the Consolidated Note reflects the $9.0 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on each note from its respective date of issuance. The terms of the Consolidated Note are identical to the Secured Notes except that: (a) the maturity date is September 1, 2015, which is after the latest maturity date of any of the Secured Notes; and (b) it provides for partial mandatory repayment in the event that the Company receives aggregate gross proceeds in excess of $7.5 million from a single or multiple "Liquidity Events" in an amount equal to twenty-five (25%) percent of such gross proceeds. A "Liquidity Event" means (a) the sale of any of the Company's equity, or equity-linked, securities, and (b) the receipt of proceeds, directly or indirectly related to a development and/or commercialization relationship entered into with an unaffiliated third party. In the Secured Notes, the entire principal amount of each note was due, at Niobe's election, upon the consummation of an equity financing of $7.5 million or greater. Consistent with the terms of the Secured Notes and related security agreements entered into, the Company's obligations under the Consolidated Note are secured by a first priority perfected security interest in all of the Company's assets pursuant to a Consolidated, Amended and Restated Security Agreement dated October 11, 2013 with Niobe.

All of the securities issued in the aforementioned financings were issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Act") pursuant to Section 4(a)(5) and Rule 506 of Regulation D thereof. The offer, sale and issuance of such securities were made without general solicitation or advertising. The securities were offered and issued only to "accredited investors" as such term is defined in Rule 501 under the Act.

Niobe, a majority stockholder of the Company and the holder of the Secured Notes, is controlled by the Company's President and Director, Arnold P. Kling.

During the fiscal year ended May 31, 2013, the Company issued an aggregate of 350,000 options to Mr. Warshaw. The 350,000 options issued during the fiscal year ended May 31, 2013 have a ten year life with an exercise price of $1.05. These options vested 50% upon issuance and the remainder will vest on May 22, 2014. The 350,000 options have been valued at $329,000 for which $164,500 of compensation expense has been recorded.

During the fiscal year ended May 31, 2014, the Company issued an aggregate of 250,000 options to Mr. Elser. The 250,000 options issued during the fiscal year ended May 31, 2014 have a ten year life with an exercise price of $9.00. These options vested 33.33% upon issuance, another 33.33% will vest on the 12 month anniversary of their issuance, and the remainder will vest on May 4, 2016. The 250,000 options have been valued at $2,018,000 for which $896,887 of compensation expense has been recorded.

7. STOCK OPTIONS

Prior to January 22, 2004, all options were issued as "stand alone" options. On January 22, 2004, the Board approved the Protalex, Inc. 2003 Stock Option Plan., and on October 25, 2005, the stockholders approved an amendment to the Protalex, Inc. 2003 Stock Option Plan to increase the authorized number of shares under the Plan from 300,000 to 900,000 which provides for incentive and non-qualified stock options to purchase a total of 900,000 shares of Common Stock. Under the terms of the plan, incentive options may not be granted at exercise prices less than the fair market value of the Common Stock at the date of the grant and non-qualified options shall not be granted at exercise prices equal to less than 85% of the fair market value of Common Stock at the date of the grant. Beginning January 1, 2005, all stock options are granted at fair market value. Vesting generally occurs ratably over forty eight months and is exercisable over a period no longer than ten years after the grant date. As of May 31, 2014, options to purchase 4,317,543 shares of Common Stock were outstanding, of which 37,000 were issued and 800 were exercised under the Company's 2003 Stock Option Plan and the remaining 4,280,543 were issued and 400 were exercised as standalone options. As of May 31, 2014, options to purchase 3,350,876 shares of Common Stock are exercisable.

The 1,000,000 options issued during the year ended May 31, 2013 are ten year options with exercise prices ranging from $1.05 to 1.39 per share. Some of these options vested 50% upon issuance and the remainder vest on their one year anniversary. Some options vest ratably over 2 years while some vest upon the achievement of certain benchmarks. The options issued during the year ended May 31, 2013 have been valued at $1,771,750 for which $735,667 of compensation expense has been recorded. The balance of the option expense recorded during the year ended May 31, 2013 is related to options issued in prior years.

The 1,300,000 options issued during the year ended May 31, 2014 consisted of five year and ten year options with exercise prices ranging from $8.40 to $9.00 per share. Some of these options vested 50% upon issuance and the remainder vest on their one year anniversary. Some options vest ratably over 2 years while some vest upon the achievement of certain benchmarks. The options issued during the year ended May 31, 2014 have been valued at $9,385,000 for which $5,789,996 of compensation expense has been recorded. The balance of the option expense recorded during the year ended May 31, 2014 is related to options issued in prior years.

A summary of the Common Stock option activity for employees, directors, officers and consultants as of May 31, 2014 and for the three years then ended is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at May 31, 2011	1,538,927	$ 1.99	3.70
Granted	750,000	$ 1.01	10
Exercised	0	0	0
Forfeited	0	0	0
Expired	(20,000)	0	0
Outstanding at May 31, 2012	2,268,927	$ 1.27	7.65
Granted	1,000,000	$ 1.22	10
Exercised	0	0	0
Forfeited	0	0	0
Expired	(211,385)	$ 7.52	0
Outstanding at May 31, 2013	3,057,542	$ 1.09	8.08
Granted	1,300,000	8.51	5.83
Exercised	0	0	0
Forfeited	0	0	0
Expired	(40,000)	7.50	0
Outstanding May 31, 2014	4,317,543	$ 3.26	6,67
Exercisable at May 31, 2014	3,350,876	$ 3.43	7.83

The outstanding and exercisable stock options as of May 31, 2014 and 2013 had an intrinsic value of $20,782,678 and $351,821, respectively.

The 1,300,000 options issued during the year were issued at an exercise price that was equal to the market price at the time the options were granted.

The following summarizes certain information regarding stock options at May 31, 2014:

Exercise Price Range	Number	Weighted Average Exercise Price	Weighted Average Remaining Life (years)	Number	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
$0.00 – 1.00	1,230,543	$ 0.44	6.07	1,230,543	$ 0.44	6.07
$1.01 – 5.00	1,750,000	$ 1.13	7.95	1,575,000	1.32	7.95
$5.01 – 10.00	1,300,,000	$ 8.51	5.83	508,333	$ 8.51	5.25
$10.01 – 15.00	37,000	$ 13.86	1.6	37,000	$ 13.86	1.6
	4,317,543	$ 3.26	6.67	3,350,876	$ 2.23	6.60

8. SENIOR SECURED NOTE – RELATED PARTY

On February 1, 2012, the Company raised $1,000,000 of working capital pursuant to a loan from Niobe. The Company issued to Niobe a secured promissory note in the principal amount of $1,000,000 (the "February 2012 Secured Note"). The February 2012 Secured Note bore interest at a rate of 3% per annum and had a maturity date of February 1, 2014.

On June 5, 2012, the Company raised an additional $1,000,000 of working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 31, 2014 (the "June 2012 Secured Note").

On October 1, 2012, the Company raised $800,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $800,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "October 2012 Secured Note").

On December 3, 2012, the Company raised $700,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $700,000, which bore interest at a rate of 3% per annum and had a maturity date of October 1, 2014 (the "December 2012 Secured Note").

Collectively, the February 2012 Secured Note, the June 2012 Secured Note, the October 2012 Secured Note and the December 2012 Secured Note are hereinafter referred to as the "2012 Secured Notes."

On January 18, 2013, the Company raised $2,500,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,500,000, which bore interest at a rate of 3% per annum and had a maturity date of January 15, 2015 (the "January 2013 Secured Note").

On May 13, 2013, the Company raised $2,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,000,000, which bore interest at a rate of 3% per annum and had a maturity date of May 13, 2015 (the "May 2013 Secured Note").

On August 27, 2013, the Company raised $1,000,000 of additional working capital pursuant to an incremental loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1,000,000, which bore interest at a rate of 3% per annum and had a maturity date of August 27, 2015. (the "August 2013 Secured Note").

Collectively, the January 2013 Secured Note, the May 2013 Secured Note, and the August 2013 Secured Note are hereinafter referred to as the "2013 Secured Notes."

Collectively, the 2012 Secured Notes and the 2013 Secured Notes represent a total of $9,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

On October 11, 2013, the Company issued a Consolidated, Amended and Restated Promissory Note to Niobe in the principal amount of $9,219,366 (the "Consolidated Note"). The face amount of the Consolidated Note reflects the $9.0 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on each note from its respective date of issuance. The terms of the Consolidated Note are identical to the Secured Notes except that: (a) the maturity date is September 1, 2015, which is after the latest maturity date of any of the Secured Notes; and (b) it provides for partial mandatory repayment in the event that the Company receives aggregate gross proceeds in excess of $7.5 million from a single or multiple "Liquidity Events" in an amount equal to twenty-five (25%) percent of such gross proceeds. A "Liquidity Event" means (a) the sale of any of the Company's equity, or equity-linked, securities, and (b) the receipt of proceeds, directly or indirectly related to a development and/or commercialization relationship entered into with an unaffiliated third party. In the Secured Notes, the entire principal amount of each note was due, at Niobe's election, upon the consummation of an equity financing of $7.5 million or greater. Consistent with the terms of the Secured Notes and related security agreements entered into, the Company's obligations under the Consolidated Note are secured by a first priority perfected security interest in all of the Company's assets pursuant to a Consolidated, Amended and Restated Security Agreement dated October 11, 2013 with Niobe.

9. STOCKHOLDERS EQUITY

On December 8, 2010, the Company effected a reverse stock split of the outstanding shares of its common stock, with par value of $0.00001 per share ("Common Stock"), on the basis of one (1) share of Common Stock for each five (5) shares of Common Stock outstanding. All references in these financial statements and notes to financial statements to number of shares, price per share and weighted average number of shares outstanding of Common Stock prior to this reverse stock split have been adjusted to reflect the reverse stock split on a retroactive basis unless otherwise noted,

On December 8, 2010, the Company authorized one (1) million shares of a "blank check" class of preferred stock.

On January 23, 2014, the Company consummated a private placement financing to accredited investors of 471,334 shares of Common Stock at $6.00 per share, yielding gross proceeds of $2,828,000. No commissions were payable in connection with the financing transaction. Proceeds of the financing will be used for working capital purposes, principally to fund ongoing clinical trials and studies and related activities. The investors in the offering were granted piggy-back registration rights in connection with certain registration statements filed by the Company, subject to certain exceptions, including a registration statement filed in connection with a primary offering by the Company.

10. SUBSEQUENT EVENTS

In June 2014 the Company issued non-qualified stock options for an aggregate of 200,000 shares of Common Stock with an exercise price of $8.22 per share to two consultants. The option expires five years from the date of grant.

The Company has evaluated subsequent events and has determined that there were no other subsequent events to recognize or disclose in these financial statements.

Exhibit 4.2

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this "Agreement") is dated as of January 22, 2014, between Protalex, Inc., a Delaware corporation (the "Company"), and each purchaser identified on the signature pages hereto (each, including its successors and assigns, a "Purchaser" and collectively, the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Rule 506 promulgated thereunder, the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(j).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Closing" means the closing of the purchase and sale of the Shares pursuant to Section 2.1.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) each Purchaser's obligations to pay its Subscription Amount and (ii) the Company's obligations to deliver the Shares, in each case, have been satisfied or waived, but in no event later than the third Trading Day following the date hereof.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.00001 per share, and any other class of securities into which such securities shall have been reclassified or changed.

"Common Stock Equivalents" means any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Company Counsel" means Morse Zelnick Rose & Lander, LLP, with offices located at 825 Third Avenue, New York, NY 10022.

"Effective Date" means the earliest of the date that (a) the initial Registration Statement has been declared effective by the Commission, (b) all of the Shares have been sold pursuant to Rule 144 or may be sold pursuant to Rule 144 without the requirement for the Company to be in compliance with the current public information required under Rule 144 and without volume or manner-of-sale restrictions or (c) following the six-month anniversary of the Closing Date provided that a holder of the Shares is not an Affiliate of the Company, all of the Shares may be sold pursuant to an exemption from registration under Section 4(1) of the Securities Act without volume or manner-of-sale restrictions and Company Counsel has delivered to such holders a standing written unqualified opinion that resales may then be made by such holders of the Shares pursuant to such exemption which opinion shall be in form and substance reasonably acceptable to such holders.

"Escrow Agent" shall have the meaning ascribed to such term in Section 2.4(a).

"Evaluation Date" shall have the meaning ascribed to such term in Section 3.1(q).

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended.

"GAAP" shall have the meaning ascribed to such term in Section 3.1(h).

"Gross Proceeds" shall have the meaning ascribed to such term in Section 4.4(e)(ii).

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3.1(n).

"IOLA Account" shall have the meaning ascribed to such term in Section 2.4(b).

"Legend Removal Date" shall have the meaning ascribed to such term in Section 4.1(c).

"Liens" means a lien, charge pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Mandatory Registration Termination Date" means the earliest to occur of (i) the first anniversary of the Closing Date, and (ii) such time as all the Shares held by Selling Purchasers can be sold pursuant to Rule 144.

"Material Adverse Effect" shall have the meaning assigned to such term in Section 3.1(b).

"Material Permits" shall have the meaning ascribed to such term in Section 3.1(l).

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

"Public Announcement" shall have the meaning ascribed to such term in Section 4.8.

"Purchaser Party" shall have the meaning ascribed to such term in Section 4.7.

"Registration Statement" means a registration statement described in and meeting the requirements set forth in Section 4.4 and covering the resale by the Selling Purchasers of their Shares.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 424" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(h).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Selling Purchasers" means the Purchasers who elect to have their Shares registered pursuant to Section 4.4.

"Shares" means the shares of Common Stock sold pursuant to this Agreement.

"Short Sales" means all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act.

"Subscription Amount" means, as to each Purchaser, the aggregate amount to be paid for the Shares purchased hereunder as specified below such Purchaser's name on the signature page of this Agreement and next to the heading "Subscription Amount," in United States dollars and in immediately available funds.

"Suspension" shall have the meaning ascribed to such term in Section 4.4(g)(ii).

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE AMEX, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange or the OTC Bulletin Board (or any successors to any of the foregoing).

"Transaction Documents" means this Agreement, including all schedules, exhibits and attachments hereto, including the Risk Factors included in Annex I hereto, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means American Stock Transfer & Trust Company, the current transfer agent of the Company, and any successor transfer agent of the Company.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, up to an aggregate minimum of $1,000,000 of Shares; provided, however, that the amount of the offering may be increased in the sole discretion of the Company. The purchase price per share shall be $6.00. Each Purchaser shall deliver to the Company, via wire transfer or a certified check, immediately available funds equal to such Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser, and the Company shall deliver to each Purchaser its certificates evidencing the Shares purchased by such Purchaser, and the Company and each Purchaser shall deliver the other items set forth in Section 2.2 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall occur at the offices of Company Counsel or such other location as the parties shall mutually agree.

2.2 Deliveries.

(a) On or prior to the Closing Date, the Company shall deliver or cause to be delivered to each Purchaser the following:

(i) this Agreement duly executed by the Company; and

(ii) a certificate evidencing the Shares purchased by Purchaser or a statement or advice from the Transfer Agent evidencing the book entry issuance of the Shares.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company the following:

(i) this Agreement duly executed by such Purchaser; and

(ii) such Purchaser's Subscription Amount by wire transfer to the account specified in writing by the Company.

2.3 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all respects on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed;

(iii) the Company shall have received, and shall close on, minimum Subscription Amounts of not less than $1,000,000 in the aggregate; and

(iv) the delivery by each Purchaser of the items set forth in Section 2.2(b) of this Agreement.

(b) The respective obligations of the Purchasers hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all respects when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.2(a) of this Agreement;

(iv) the Company shall have received, and shall close on, minimum Subscription Amounts of not less than $1,000,000 in the aggregate;

(v) there shall have been no Material Adverse Effect with respect to the Company since the date hereof; and

(vi) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Shares at the Closing.

2.4 Deposit and Escrow.

(a) The Company and each Purchaser hereby appoint Morse, Zelnick, Rose & Lander, LLP to act as escrow agent ("Escrow Agent") in connection with the transactions contemplated hereby upon the following terms and conditions:

(b) Simultaneously with the execution and delivery of this Agreement, Purchaser shall wire transfer such Purchaser's Subscription Amount to the Escrow Agent's Attorney Trust IOLA Account (the "IOLA Account"), a non-interest bearing account maintained at J.P. Morgan Chase Bank, in accordance with the following instructions:

JP Morgan Chase
500 Stanton Christiana Road
Newark, DE 19713
For credit to the account of:
Morse Zelnick Rose & Lander, LLP
Attorney Trust IOLA Account
Reference: Protalex, Inc. Private Placement
ABA#021000021
Account #967086639

(c) Escrow Agent shall hold such Subscription Amount in escrow in accordance with the terms hereof.

(d) At the Closing in accordance with the terms of this Agreement, Escrow Agent shall deliver the Subscription Amount to the Company.

(e) If the Closing does not take place on or before January 31, 2014 (unless extended by the Company in its sole discretion for up to 15 days upon notice to the Purchasers and the Escrow Agent), Escrow Agent shall return the Subscription Amount to Purchaser as soon as reasonably practicable thereafter but no later than February 10, 2014.

(f) It is agreed that:

(i) The duties of Escrow Agent are only as herein specifically provided, and, except for the provisions of Section 2.4(g) are purely ministerial in nature, and Escrow Agent shall incur no liability whatever, except for its own willful misconduct or gross negligence;

(ii) Escrow Agent shall not be liable or responsible for the collection of the proceeds of any checks used to pay the Subscription Amount;

(iii) In the performance of its duties hereunder, Escrow Agent shall be entitled to rely upon any document, instrument or signature believed by it to be genuine and signed by either of the other parties hereto or their successors;

(iv) Escrow Agent may assume that any person purporting to give any notice of instructions in accordance with the provisions hereof has been duly authorized to do so;

(v) Escrow Agent shall not be bound by any modification, cancellation or rescission of this Agreement unless in writing and signed by Escrow Agent, the Company and Purchaser;

(vi) Except as otherwise provided in Section 2.4(g), the Company shall reimburse and indemnify Escrow Agent for, and hold it harmless against, any and all loss, liability, costs or expenses in connection herewith, including reasonable attorneys' fees and disbursements, incurred without fraud, willful misconduct or gross negligence on the part of Escrow Agent, arising out of or in connection with its acceptance of, or the performance of its duties and obligations under, this Agreement, as well as the costs and expenses of defending against any claim or liability arising out of or relating to this Agreement (other than any claim or liability arising out of Escrow Agent's fraud, willful misconduct, gross negligence or breach of this Agreement);

(vii) Each of the Company and Purchaser hereby releases Escrow Agent from any act done or omitted to be done by Escrow Agent in good faith in the performance of its duties hereunder (other than any fraud, willful misconduct, gross negligence or breach of this Agreement by Escrow Agent); and

(viii) Escrow Agent may resign upon not less than ten (10) days written notice to the Company and Purchaser, provided that a successor Escrow Agent has then been appointed. If a successor Escrow Agent is not appointed by the Company and Purchasers within such ten (10) day period, Escrow Agent may petition a court of competent jurisdiction to name a successor.

(g) Escrow Agent is acting solely as a stakeholder with respect to the Subscription Amount. Escrow Agent, except as provided in paragraphs (d) and (e) of Section 2.4, shall not deliver the Subscription Amount to the Company or Purchaser, except on ten (10) days' prior written notice to the Company and Purchaser and only if neither such party shall object within such ten (10) day period. If there is any dispute as to whether Escrow Agent is obligated to deliver all or any portion of a Subscription Amount or as to whom Subscription Amount is to be delivered, Escrow Agent shall not make any delivery, but in such event Escrow Agent shall hold such Subscription Amount until receipt by Escrow Agent of an authorization in writing, signed by the Company and Purchaser, directing the disposition of the such Subscription Amount (together with all interest thereon, if any), or, in the absence of such authorization, Escrow Agent shall hold the Subscription Amount (together with all interest thereon, if any), until the final determination of the rights of the parties in an appropriate proceeding. If such written authorization is not given or proceedings for such determination are not begun within thirty (30) days after the date Escrow Agent shall have received written notice of such dispute, and thereafter diligently continued, Escrow Agent may, but is not required to, bring an appropriate action or proceeding for leave to deposit the Subscription Amount (together with all interest thereon, if any), in court pending such determination. Escrow Agent shall be reimbursed for all costs and expenses of such action or proceeding, including, without limitation, reasonable attorneys' fees and disbursements, by the party determined not to be entitled to the Subscription Amount, or if the Subscription Amount is split between the Company and Purchaser, such costs of Escrow Agent shall be split, pro rata, between the Company and Purchaser, in inverse proportion to the amount.

(h) Escrow Agent has executed this Agreement solely to confirm that the Subscription Amount has been deposited into the IOLA Account.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. Except as set forth in the SEC Reports or the schedules attached hereto, which SEC Reports and schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the SEC Reports or the corresponding section of the schedules, the Company hereby makes the following representations and warranties to each Purchaser:

(a) Subsidiaries. The Company has no subsidiaries.

(b) Organization and Qualification. The Company is duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. The Company is not in violation nor default of any of the provisions of its certificate of incorporation or bylaws. The Company is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of each of this Agreement and the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Shares and the consummation by it of the transactions contemplated hereby and thereby do not and will not: (i) conflict with or violate any provision of the Company's certificate of incorporation or bylaws, (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company debt or otherwise) or other understanding to which the Company is a party or by which any property or asset of the Company is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.2 of this Agreement, (ii) the notice and/or application(s) to each applicable Trading Market for the issuance and sale and listing of the Shares for trading thereon in the time and manner required thereby, and (iv) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").

(f) Issuance of the Shares. The Shares are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company other than restrictions on transfer provided for in the Transaction Documents.

(g) Capitalization. The capitalization of the Company is as set forth in the SEC Reports. The Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. There are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents. The issuance and sale of the Shares will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Purchasers) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Shares. Except as set forth in the SEC Reports, there are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(i) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in a subsequent SEC Report filed prior to the date hereof: (i) there has been no event, occurrence or development unrelated to general economic or market conditions that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Shares contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists, or is reasonably expected to occur or exist, with respect to the Company or its businesses, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made.

(j) Litigation. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, or any of its properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Shares or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company under the Exchange Act or the Securities Act.

(k) Compliance. The Company: (i) is not in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company under), nor has the Company received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree, or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(l) Regulatory Permits. The Company possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and the Company has not received any notice of proceedings relating to the revocation or modification of any Material Permit.

(m) Title to Assets. The Company has good and marketable title in all personal property owned by them that is material to the business of the Company, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company are held by it under valid, subsisting and enforceable leases with which the Company is in compliance.

(n) Intellectual Property. The Company has, or has rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as described in the SEC Reports as necessary, required or material for use in connection with their respective businesses and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). The Company has not received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. The Company has not received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company has taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(o) Insurance. The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company is engaged, including, but not limited to, directors and officers insurance coverage. The Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(p) Transactions With Affiliates and Employees. None of the officers or directors of the Company and, to the knowledge of the Company, none of the employees of the Company is presently a party to any transaction with the Company (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $120,000 other than for: (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(q) Sarbanes-Oxley; Internal Accounting Controls. The Company is in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company.

(r) Certain Fees. No brokerage or finder's fees or commissions are or will be payable by the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchasers shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(s) Private Placement. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, no registration under the Securities Act is required for the offer and sale of the Shares by the Company to the Purchasers as contemplated hereby. The issuance and sale of the Shares hereunder does not contravene the rules and regulations of the Trading Market.

(t) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Shares, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(u) Registration Rights. Except as otherwise provided in the Agreement, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.

(v) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration.

(w) Disclosure. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents (as defined below), the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes or might constitute material, non-public information. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company, their respective businesses and the transactions contemplated hereby, including the schedules to this Agreement, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(x) No Integrated Offering. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Shares to be integrated with prior offerings by the Company for purposes of (i) the Securities Act which would require the registration of any such securities under the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(y) No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising. The Company has offered the Shares for sale only to the Purchasers and certain other "accredited investors" within the meaning of Rule 501 under the Securities Act.

(z) Foreign Corrupt Practices. Neither the Company nor, to the knowledge of the Company, any agent or other person acting on behalf of the Company, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of FCPA.

(aa) Acknowledgment Regarding Purchasers' Purchase of Securities. The Company acknowledges and agrees that each of the Purchasers is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by any Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchasers' purchase of the Shares. The Company further represents to each Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(bb) Acknowledgment Regarding Purchaser's Trading Activity. Except as otherwise provided in this Agreement), it is understood and acknowledged by the Company that: (i) none of the Purchasers have been asked by the Company to agree, nor has any Purchaser agreed, to desist from purchasing or selling, long and/or short, securities of the Company, or "derivative" securities based on securities issued by the Company or to hold the Shares for any specified term, (ii) past or future open market or other transactions by any Purchaser, specifically including, without limitation, Short Sales or "derivative" transactions, before or after the closing of this or future private placement transactions, may negatively impact the market price of the Company's publicly-traded securities, (iii) any Purchaser, and counter-parties in "derivative" transactions to which any such Purchaser is a party, directly or indirectly, may presently have a "short" position in the Common Stock and (iv) each Purchaser shall not be deemed to have any affiliation with or control over any arm's length counter-party in any "derivative" transaction. The Company further understands and acknowledges that (y) one or more Purchasers may engage in hedging activities at various times during the period that the Shares are outstanding, and (z) such hedging activities (if any) could reduce the value of the existing stockholders' equity interests in the Company at and after the time that the hedging activities are being conducted. The Company acknowledges that such aforementioned hedging activities do not constitute a breach of any of the Transaction Documents.

(cc) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii) of this Section 3.1(cc), compensation paid to the Company's placement agent in connection with the placement of the Shares.

(dd) Office of Foreign Assets Control. Neither he Company, nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC").

(ee) Money Laundering. The operations of the Company are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(ff) No Undisclosed Events, Liabilities, Developments or Circumstances. No event, liability, development or circumstance has occurred or exists, or is reasonably expected to occur or exist with respect to the Company, or it businesses, properties, liabilities, prospects, operations (including results thereof) or condition (financial or otherwise), that (i) would be required to be disclosed by the Company under applicable securities laws on a registration statement on Form S-1 filed with the Commission relating to an issuance and sale by the Company of its Common Stock and which has not been publicly announced or (ii) could have a Material Adverse Effect.

3.2 Representations and Warranties of the Purchasers. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein):

(a) Organization; Authority. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Own Account. Such Purchaser understands that the Shares are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Shares as principal for its own account and not with a view to or for distributing or reselling such Shares or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Shares in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Shares in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Purchaser's right to sell the Shares otherwise in compliance with applicable federal and state securities laws). Such Purchaser is acquiring the Shares hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time such Purchaser was offered the Shares, it was, and as of the date hereof it is, either: (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act. Such Purchaser is not required to be registered as a broker-dealer under Section 15 of the Exchange Act.

(d) Experience of Such Purchaser. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment, including but not limited to the Risk Factors set forth on Annex I. Such Purchaser is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment.

(e) General Solicitation. Such Purchaser is not purchasing the Shares as a result of any advertisement, article, notice or other communication regarding the Shares published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other general solicitation or general advertisement.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, such Purchaser has not directly or indirectly, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, executed any purchases or sales, including Short Sales, of any securities of the Company during the period commencing as of the time that such Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof (it being understood and agreed that for all purposes of this Agreement, and without implication that the contrary would otherwise be true, neither transactions nor purchases nor sales shall include the location and/or reservation of borrowable shares of Common Stock). Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Shares covered by this Agreement. Other than to other Persons party to this Agreement (and such Purchaser's representatives and advisors), such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to the identification of the availability of, or securing of, available shares to borrow in order to affect Short Sales or similar transactions in the future.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Transfer Restrictions.

(a) The Shares may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Shares other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Shares under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

(b) The Purchasers agree to the imprinting, so long as is required by this Section 4.1, of a legend on any certificate evidencing the Shares in the following form:

THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED OR APPLICABLE STATE SECURITIES LAWS. THE SHARES MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED (I) IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THE SHARES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR (B) AN OPINION OF COUNSEL TO THE HOLDER (IF REQUESTED BY THE COMPANY), IN A FORM REASONABLY ACCEPTABLE TO THE COMPANY, THAT REGISTRATION IS NOT REQUIRED UNDER SAID ACT OR (II) UNLESS SOLD OR ELIGIBLE TO BE SOLD PURSUANT TO RULE 144 OR RULE 144A UNDER SAID ACT. NOTWITHSTANDING THE FOREGOING, THE SHARES MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN OR FINANCING ARRANGEMENT SECURED BY THE SHARES.

The Company acknowledges and agrees that a Purchaser may from time to time pledge pursuant to a bona fide margin agreement with a registered broker-dealer or grant a security interest in some or all of the Shares to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and who agrees to be bound by the provisions of this Agreement and, if required under the terms of such arrangement, such Purchaser may transfer pledged or secured Shares to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the appropriate Purchaser's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of Shares may reasonably request in connection with a pledge or transfer of the Shares, including, if the Shares are subject to registration pursuant to this Agreement, the preparation and filing of any required prospectus supplement under Rule 424(b)(3) under the Securities Act or other applicable provision of the Securities Act to appropriately amend the list of selling stockholders thereunder.

(c) Certificates evidencing the Shares shall not contain any legend (including the legend set forth in Section 4.1(b) hereof), (i) while a registration statement (including the Registration Statement) covering the resale of such security is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144, (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions, or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission). The Company shall cause its counsel to issue a legal opinion to the Transfer Agent promptly after the Effective Date if required by the Transfer Agent to effect the removal of the legend hereunder. The Company agrees that following the Effective Date or at such time as such legend is no longer required under this Section 4.1(c), it will, no later than three Trading Days following the delivery by a Purchaser to the Company or the Transfer Agent of a certificate representing Shares issued with a restrictive legend (such third Trading Day, the "Legend Removal Date"), deliver or cause to be delivered to such Purchaser a certificate representing such Shares that is free from all restrictive and other legends. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in this Section 4.

(d) Each Purchaser, severally and not jointly with the other Purchasers, agrees with the Company that such Purchaser will sell any Shares pursuant to either the registration requirements of the Securities Act, including any applicable prospectus delivery requirements, or an exemption therefrom, and that if Shares are sold pursuant to a Registration Statement, they will be sold in compliance with the plan of distribution set forth therein, and acknowledges that the removal of the restrictive legend from certificates representing Shares as set forth in this Section 4.1 is predicated upon the Company's reliance upon this understanding.

4.2 Furnishing of Information; Public Information. Until the earlier of one year from the Closing Date or no Purchaser owns any Shares, the Company covenants to maintain the registration of the Common Stock under Section 12(b) or 12(g) of the Exchange Act and to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act even if the Company is not then subject to the reporting requirements of the Exchange Act. As long as any Purchaser owns Shares, if the Company is not required to file reports pursuant to the Exchange Act, it will prepare and furnish to each of the Purchasers and make publicly available in accordance with Rule 144(c) such information as is required for each of the Purchasers to sell the Shares, including without limitation, under Rule 144. The Company further covenants that it will take such further action as any holder of Shares may reasonably request, to the extent required from time to time to enable such Person to sell such Shares without registration under the Securities Act, including without limitation, within the requirements of the exemption provided by Rule 144.

4.3 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Shares in a manner that would require the registration under the Securities Act of the sale of the Shares or that would be integrated with the offer or sale of the Shares for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.4 Registration Rights.

(a) Right to Include Shares. If at any time the Company proposes to register any of its equity securities under the Securities Act (other than (A) a registration statement on Form S-4 or Form S-8 or any similar or successor forms, (B) a registration of securities in a Rule 145 transaction, (C) with respect to a public offering by the Company of Common Stock or (D) with respect to an employee benefit plan), it will promptly give written notice to the Purchasers of its intention to do so. Upon the written request of any Purchaser made within ten (10) days after the receipt of any such notice (which request shall specify the Shares intended to be disposed of by such Purchaser and the intended method of disposition thereof), the Company will use its commercially reasonable efforts to effect the registration under the Securities Act of all Shares that the Company has been so requested to register by the Purchasers thereof, to the extent necessary to permit the disposition (in accordance with such intended methods thereof) of the Shares so to be registered; provided that if, at any time after giving written notice of its intention to register any securities pursuant to this Section 4.4 and prior to the effective date of the registration statement filed in connection with such registration, the Company shall determine for any reason not to register any securities the Company may, at its election, give written notice of such determination to each Purchaser and thereupon shall be relieved of its obligation to register any Shares in connection with such registration.

(b) Obligations of the Company. In connection with the Company's obligations under Section 4.4(a) above to file the Registration Statement with the Commission and to use its commercially reasonable efforts to cause the Registration Statement to become effective as soon as practicable after filing, the Company shall, as expeditiously and as reasonably as possible, subject to Section 4.4(g) hereof:

(i) Prepare and file with the Commission such amendments and supplements to the Registration Statement and the prospectus used in connection therewith as may be necessary to keep the Registration Statement effective until the Mandatory Registration Termination Date;

(ii) Furnish to the Selling Purchasers such reasonable number of copies of the Registration Statement, prospectus and preliminary prospectus, in conformity with the requirements of the Securities Act, and such other documents (including, without limitation, prospectus amendments and supplements as are prepared by the Company in accordance with Section 4.4(a) above) as the Selling Purchasers may reasonably request, in order to facilitate the disposition of such Selling Purchasers' Shares pursuant to the Registration Statement;

(iii) use its commercially reasonable efforts to register or qualify or cooperate with the Selling Purchasers in connection with the registration or qualification (or exemption from the registration or qualification) of such Shares for the resale by the Selling Purchaser under the securities or Blue Sky laws of such jurisdictions within the United States as any Selling Purchaser reasonably requests in writing, to keep each registration or qualification (or exemption therefrom) effective until the Mandatory Registration Termination Date and to do any and all other acts or things reasonably necessary to enable the disposition in such jurisdictions of the Shares covered by the Registration Statement; provided, that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified, subject the Company to any material tax in any such jurisdiction where it is not then so subject or file a general consent to service of process in any such jurisdiction; and

(iv) use commercially reasonable efforts to cause all the Shares registered hereunder to be listed on each trading venue on which securities of the same class issued by the Company are then listed.

(c) Furnish Information.

(i) It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 4.4 that the Selling Purchasers shall furnish to the Company such information regarding them and the Shares held by them as the Company shall reasonably request and as shall be required in order to effect any registration by the Company pursuant to this Section 4.4.

(ii) The Registration Statement will provide, at the request of the Selling Purchasers, for a plan of distribution with respect to the Shares covered thereby substantially as follows:

"The Shares may be sold from time to time by the Selling Purchasers. Such sales may be made on one or more exchanges or in the over-the-counter market, or otherwise at prices and at terms then prevailing or at prices related to the then-current market price, or in negotiated transactions. The Shares may be sold by the Selling Purchasers in one or more of the following types of transactions: (i) a block trade in which the broker or dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction; (ii) purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to the resale registration statement; (iii) an exchange distribution in accordance with the rules of such exchange; (iv) ordinary brokerage transactions and transactions in which the broker solicits purchasers; and (v) transactions between sellers and purchasers without a broker/dealer. In addition, any securities covered by the Registration Statement which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to the Registration Statement. From time to time the Selling Purchasers may engage in short sales, short sales versus the box, puts and calls and other transactions in securities of the issuer or derivatives thereof, and may sell and deliver the shares in connection therewith. In effecting sales, brokers or dealers engaged by the selling Investors may arrange for other brokers or dealers to participate. Brokers or dealers will receive commissions or discounts from selling Investors in amounts to be negotiated immediately prior to the sale."

(d) Expenses of Registration. All expenses incurred by the Company in connection with the registration of the Shares pursuant to this Section 4.4 (excluding underwriting, brokerage and other selling commissions and discounts) shall be borne by the Company. Such fees and expenses shall include, without limitation, all registration and qualification and filing fees, printing expenses, fees and disbursements of counsel for the Company.

(e) Indemnification.

(i) To the extent permitted by law, the Company will indemnify and hold harmless each Selling Purchaser (including the partners or officers, directors and stockholders of such Selling Purchaser), and each person, if any, who controls such Selling Purchaser within the meaning of the Securities Act, against any losses, claims, damages or liabilities, joint or several, to which they may become subject under the Securities Act, the Exchange Act, and other federal or state securities laws, or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) (A) arise out of or are based upon any untrue or alleged untrue statement of any material fact contained in the Registration Statement, in any preliminary prospectus or final prospectus relating thereto or in any amendments or supplements to the Registration Statement or any such preliminary prospectus or final prospectus, (B) arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading or (C) arise out of any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any other federal or state securities law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any other federal or state securities law; and the Company will reimburse such Selling Purchaser (including the partners, officers, directors and stockholders of such Selling Purchaser) or such controlling person for any legal or other expenses (but in no event for more than one law firm) reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this Section 4.4(e)(i) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the Company, nor shall the Company be liable in any such case for any such loss, damage, liability or action to the extent that it arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in connection with the Registration Statement, any preliminary prospectus or final prospectus relating thereto or any amendments or supplements to the Registration Statement or any such preliminary prospectus or final prospectus, (x) in reliance upon and in conformity with written information furnished expressly for use in connection with the Registration Statement or any such preliminary prospectus or final prospectus or any amendments or supplements to the Registration Statement, preliminary prospectus or final prospectus by the Selling Purchaser, any broker/dealer acting on their behalf or controlling person with respect to them or (y) the plan of distribution described in Section 4.4(c)(ii).

(ii) To the extent permitted by law, each Selling Purchaser will severally and not jointly indemnify and hold harmless the Company, its Affiliates, each of their respective directors, officers, partners, members and stockholders, each person, if any, who controls the Company within the meaning of the Securities Act, any broker/dealer, any underwriter and all other Selling Purchaser, against any losses, claims, damages or liabilities to which the Company or any such Affiliate, director, officer, partner, member, stockholder, controlling person, broker/dealer, underwriter or such other Selling Purchaser may become subject to, under the Securities Act, the Exchange Act, any other Federal securities laws, Blue Sky Laws, or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) (A) arise out of or are based upon any untrue or alleged untrue statement of any material fact contained in the Registration Statement or any preliminary prospectus or final prospectus relating thereto or in any amendments or supplements to the Registration Statement or any such preliminary prospectus or final prospectus, (B) arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (C) arise out of any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any other federal or state securities law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any other federal or state securities law, in each case to the extent and only to the extent (x) that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, in any preliminary prospectus or final prospectus relating thereto or in any amendments or supplements to the Registration Statement or any such preliminary prospectus or final prospectus, in reliance upon and in conformity with (I) written information furnished by the Selling Purchaser expressly for use in connection with the Registration Statement, or any preliminary prospectus or final prospectus or any such amendment or supplement, or (II) the plan of distribution described in Section 4.4(c)(ii), or (y) such Selling purchaser fails to comply with the prospectus delivery requirements of the Securities Act as applicable to it in connection with sales of Shares pursuant to the Registration Statement; and such Selling Purchaser will reimburse any legal or other expenses reasonably incurred by the Company or any such Affiliate, director, officer, partner, member, stockholder, controlling person, broker/dealer, underwriter or other Selling Purchaser in connection with investigating or defending any such loss, claim, damage, liability or action, provided, however, that the liability of each Selling Purchaser hereunder (when aggregated with amounts contributed, if any, pursuant to Section 4.4(e)(iv)) shall be limited to the proceeds received by such Selling Purchaser from the sale of the Shares pursuant to the Registration Statement (the "Gross Proceeds"), and provided further, however, that the indemnity agreement contained in this Section 4.4(e)(ii) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of those Selling Purchaser(s) against which the request for indemnity is being made (which consent shall not be unreasonably withheld or delayed).

(iii) Promptly after receipt by an indemnified party under this Section 4.4(e) of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 4.4(e), notify the indemnifying party in writing of the commencement thereof and the indemnifying party shall have the right to participate in and, to the extent the indemnifying party desires, jointly with any other indemnifying party similarly noticed, to assume at its expense the defense thereof with counsel mutually satisfactory to the indemnifying parties with the consent of the indemnified party which consent will not be unreasonably withheld, conditioned or delayed. In the event that the indemnifying party assumes any such defense, the indemnified party may participate in such defense with its own counsel and at its own expense; provided, however, that the counsel for the indemnifying party shall act as lead counsel in all matters pertaining to such defense or settlement of such claim and the indemnifying party shall only pay for such indemnified party's reasonable legal fees and expenses for the period prior to the date of its participation in such defense; provided further, however, that the indemnified party (together with all indemnified parties which may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if the representation of the indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual differing interests between the indemnified party and any other party represented by such counsel in such proceeding. Notwithstanding the foregoing, the indemnifying party shall not be obligated to pay the fees of more than one separate counsel. The failure to notify an indemnifying party of the commencement of any such action will not relieve such indemnifying party of any liability to the indemnified party under this Section 4.4 (except to the extent that such failure materially prejudiced the indemnifying party's ability to defend such action), nor shall the omission so to notify an indemnifying party relieve such indemnifying party of any liability which it may have to any indemnified party otherwise other than under this Section 4.4(e). No indemnifying party shall, without the consent of the indemnified party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a general release from all liability in respect to such claim or litigation and otherwise in form and substance reasonably satisfactory to the indemnified party.

(iv) If the indemnification provided in this Section 4.4(e) is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any loss, liability, claim, damage or expense referred to herein, then the indemnifying party, in lieu of indemnifying such indemnified party hereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such loss, liability, claim, damage or expense in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other in connection with the statements or omissions that shall have resulted in such loss, liability, claim, damage or expense, as well as any other relevant equitable considerations; provided that in no event shall any contribution by Selling Purchaser under this Section 4.4(e)(iv), when aggregated with amounts paid, if any, pursuant to Section 4.4(e)(ii), exceed the Gross Proceeds. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission.

(vi) The obligations of the Company and Purchasers under this Section 4.4(e) shall survive the completion of any offering of Shares pursuant to the Registration Statement.

(g) Selling Procedures. Any sale of Shares pursuant to the Registration Statement filed in accordance with Section 4.4(a) hereof shall be subject to the following conditions and procedures:

(i) Updating the Prospectus.

(A) If the Company informs the Selling Purchaser that the Registration Statement or final prospectus then on file with the Commission is not current or otherwise does not comply with the 1933 Act, the Company shall use commercially reasonable efforts to provide to the Selling Purchaser a current prospectus that complies with the 1933 Act as soon as practicable, but in no event later than ten (10) business days after delivery of such notice.

(B) If the Company requires more than ten (10) business days to update the prospectus under Section 4.4(g)(i)(A) above, the Company shall have the right to delay the preparation of a current prospectus that complies with the Securities Act without explanation to such Purchaser, subject to the limitations set forth in Section 4.4(g)(ii) below, for a period of not more than sixty (60) days (or two periods which total not more than ninety (90) days in the aggregate) during any twelve-month period.

(ii) General. Notwithstanding anything in this Agreement that may be to the contrary, upon (A) any request by the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement for amendments or supplements to the Registration Statement or related prospectus or for additional information relating to the Registration Statement, (B) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose, (C) the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose, (D) the happening of any event which makes any statement made in the Registration Statement or related prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or which requires the making of any changes in the Registration Statement or prospectus so that, in the case of the Registration Statement, it will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and that in the case of the prospectus, it will not contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading or (E) the determination of the Company's Board of Directors that it is advisable to suspend use of the prospectus for a discrete period of time due to pending corporate developments, public filings with the Commission or that there exists material nonpublic information about the Company that the Board of Directors, acting in good faith, determines not to disclose in a registration statement, the Company, in each such case, may suspend use of the related prospectus (each a "Suspension"), in which case the Company shall promptly so notify each Purchaser and each Purchaser shall not dispose of Shares covered by the Registration Statement or prospectus until copies of a supplemented or amended prospectus are distributed to the Selling Purchasers or until the Selling Purchasers are advised in writing by the Company that the use of the applicable prospectus may be resumed; provided, however, that, notwithstanding the foregoing, the Company may suspend use of the prospectus pursuant to Sections 4.4(f)(i)(B), 4(f)(ii)(D) and 4(f)(ii)(E), and a Selling Purchaser may be prohibited from selling or otherwise disposing of the Shares covered by the Registration Statement or prospectus, on not more than two occasions in total during any twelve-month period and for no more than ninety (90) days in the aggregate during any such twelve-month period. The Company shall use commercially reasonable efforts to ensure the use of the prospectus may be resumed as soon as practicable. The Company shall use commercially reasonable efforts to obtain the withdrawal of any order suspending the effectiveness of the Registration Statement, or the lifting of any suspension of the qualification (or exemption from qualification) of any of the securities for sale in any jurisdiction, at the earliest practicable moment. The Company shall, upon the occurrence of any event contemplated by clause (D), prepare a supplement or post-effective amendment to the Registration Statement or a supplement to the related prospectus or any document incorporated therein by reference or file any other required document so that, as thereafter delivered to the purchasers of the Shares being sold thereunder, such prospectus will not contain an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(iii) Each Selling Purchaser agrees that it will comply with the prospectus delivery requirements of the Securities Act as applicable to it in connection with sales of Shares pursuant to the Registration Statement. Each Selling Purchaser further agrees that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in Section 4.4(g)(i) or 4.4(g)(ii), such Purchaser will discontinue disposition of such Shares under the Registration Statement until such Purchaser's receipt of the copies of the supplemented prospectus or amended Registration Statement, or until it is advised in writing by the Company that the use of the applicable prospectus may be resumed, and, in either case, has received copies of any additional or supplemental filings that are incorporated or deemed to be incorporated by reference in such prospectus or Registration Statement. The Company may provide appropriate stop orders to enforce the provisions of this Section 4.4(g).

4.5 Non-Public Information. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company covenants and agrees that neither it, nor any other Person acting on its behalf, will provide any Purchaser or its agents or counsel with any information that the Company believes constitutes material non-public information, unless prior thereto such Purchaser shall have entered into a written agreement with the Company regarding the confidentiality and use of such information. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.6 Use of Proceeds. The Company shall use the net proceeds from the sale of the Shares hereunder for working capital and general corporate purposes.

4.7 Indemnification of Purchasers. Subject to the provisions of this Section 4.7, the Company will indemnify and hold each Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against any Purchaser Party in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of such Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is based upon a breach of such Purchaser Party's representations, warranties or covenants under the Transaction Documents or any agreements or understandings such Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by such Purchaser Party which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (y) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.7 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.8 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it, nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales, of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced (the "Public Announcement"). Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the Public Announcement, such Purchaser will maintain the confidentiality of the existence and terms of this transaction and the information included in the Transaction Documents and the schedules hereto. Notwithstanding the foregoing, and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time of the Public Announcement, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws and regulations from and after the time of the Public Announcement, and (iii) no Purchaser shall have any duty of confidentiality to the Company after the Public Announcement. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Shares covered by this Agreement.

4.9 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Shares as required under Regulation D and to provide a copy thereof, promptly upon request of any Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Shares for, sale to the Purchasers at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of any Purchaser.

ARTICLE V.
MISCELLANEOUS

5.1 Termination. This Agreement may be terminated by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before January 31, 2014 (unless extended by the Company in its sole discretion for up to 15 days upon notice to the Purchasers and the Escrow Agent); provided, however, that such termination will not affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. Each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser), stamp taxes and other taxes and duties levied in connection with the delivery of any Shares to the Purchasers.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2^{nd}) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Purchasers holding at least 67% of the Shares or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger or acquisition). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Shares, provided that such transferee agrees in writing to be bound, with respect to the transferred Shares, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 4.9.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law.

5.10 Survival. The representations, warranties and covenants contained herein shall survive the Closing and the delivery of the Shares.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Replacement of Shares. If any certificate or instrument evidencing any Shares is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Shares.

5.14 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.15 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereof or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights, including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. For reasons of administrative convenience only, each Purchaser and its respective counsel have chosen to communicate with the Company through Company Counsel. Company Counsel does not represent any of the Purchasers and only represents the Company. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

5.16 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.17 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.18 WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

5.19 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

(Signature Pages Follow)

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

PROTALEX, INC.

Address for Notice:

131 Columbia Turnpike, Suite 1,
Florham Park, NJ 07932
Attn: Kirk Warshaw, CFO
Fax: (212) 713-1818

By: _____
Name: Arnold P. Kling
Title: President

With a copy to (which shall not constitute notice):
Morse Zelnick Rose & Lander, LLP
825 Third Avenue
New York, NY 10022
Attn: Kenneth S. Rose, Esq.
Fax: (212) 208-6809

ESCROW AGENT (solely with respect to Section 2.4)**:**

Morse, Zelnick, Rose & Lander, LLP

By: _____
Name: Kenneth S. Rose
Title: Partner

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SIGNATURE PAGE FOR PURCHASER FOLLOWS]

[PURCHASER SIGNATURE PAGES TO PROTALEX, INC. SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: _____

Signature of Authorized Signatory of Purchaser: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Email Address of Authorized Signatory: _____

Facsimile Number of Authorized Signatory: _____

Address for Notice to Purchaser:

Address for Delivery of Securities to Purchaser (if not same as address for notice):

Shares: _____

Subscription Amount: $_____ ($6.00 per Share)

TIN/EIN Number: _____

ANNEX I

RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below, in addition to the other information set forth in this Annex I, because they could materially and adversely affect our business, operating results, financial condition, cash flows and prospects, as well as adversely affect the value of an investment in our Common Stock. Also, you should be aware that the risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in and incorporated by reference into the Securities Purchase Agreement of which this Annex I is a part and the various registration statements, current and periodic reports and other documents we file with the Commission, including our consolidated financial statements and the related notes.

Capitalized terms used in this Annex I have the same meaning as ascribed to them in Securities Purchase Agreement of which this Annex I is a part.

Risks relating to our Business

If we are unable to enroll enough patients to complete our clinical trials, regulatory agencies may delay their review of, or reject our applications, which may result in increased costs and harm our ability to develop products.

If we are not able to enroll enough patients to complete the RA or other planned clinical trials for PRTX-100, regulatory agencies may delay reviewing our applications for approval, or may reject them, based on our inability to enroll enough patients to complete our clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. Delays in planned patient enrollment may result in increased costs and delays, which could have a harmful effect on our ability to develop products. We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a drug or the period required for review of any application for regulatory agency approval of a particular compound. We also may encounter delays if we are unable to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for our planned clinical trials. In addition, we rely on a number of third-parties, such as clinical research organizations, to help support the clinical trials by performing independent clinical monitoring, data acquisition and data evaluations. Any failure on the part of these third-parties could delay the regulatory approval process.

Clinical trials are expensive, time consuming and difficult to design and implement. If clinical trials for PRTX-100 don't provide positive results, we may be required to abandon or repeat such clinical trials.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous requirements. The clinical trial process is also time-consuming. Even with adequate financing, we estimate that our clinical trials for PRTX-100 will take several years to complete. Furthermore, poor results or failure can occur at any stage of the trials, and we can encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- slow enrollment of qualified patients;
- 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 or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA and/or foreign regulatory agencies may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA and/or foreign regulatory agencies find deficiencies in our IND and/or country specific regulatory submissions or in the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for future clinical trials.

If we fail to obtain regulatory approvals for PRTX-100 or any other drug we develop, we will not be able to generate revenues from the commercialization or sale of those drugs.

We must receive regulatory approval of each of our drugs before we can commercialize or sell that product. The pre-clinical laboratory testing, formulation development, manufacturing and clinical trials of any product we develop, as well as the distribution and marketing of these products, are regulated by numerous federal, state and local governmental authorities in the United States, principally the U.S. Food and Drug Administration ("FDA"), and by similar agencies in other countries. The development and regulatory approval process takes many years, requires the expenditure of substantial resources, is uncertain and subject to delays, and will thus delay our receipt of revenues, if any, from PRTX-100 or any other drug we develop. We cannot assure you that our clinical trials will demonstrate the safety and efficacy of PRTX-100 or any other drug we develop or will result in a marketable product.

No product can receive FDA approval unless human clinical trials show both safety and efficacy for each target indication in accordance with FDA and foreign country standards. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in early stage development. We therefore cannot assure you that the results from our clinical trials will be successful or that the results from our pre-clinical trials for PRTX-100 or any other drug we develop will be predictive of results obtained in future clinical trials.

Further, data obtained from pre-clinical and clinical trial activities are subject to varying interpretations that could delay, limit or prevent regulatory agency approval. We cannot assure you that our clinical trials will establish the safety and efficacy of PRTX-100 or any other drug we develop sufficiently for us to obtain regulatory approval.

Our products, if approved, may fail to achieve market acceptance.

There can be no assurance that any products we successfully develop, if approved for marketing, will achieve market acceptance or generate significant revenues. We intend for our products, including PRTX-100, to replace or alter existing therapies or procedures, and hospitals, physicians or patients may conclude that these products are less safe or effective or otherwise less attractive than existing therapies or procedures. If our products do not receive market acceptance for any reason, it would adversely affect our business, financial condition and results of operations.

Further, our competitors may develop new technologies or products that are more effective or less costly, or that seem more cost-effective, than our products. We can give no assurance that hospitals, physicians, patients or the medical community in general will accept and use any products that we may develop.

We may never obtain orphan drug status and market exclusivity for any disease indication, and if approved, we could lose orphan market exclusivity if another drug is approved first using the same method of action or demonstrates clinical superiority.

There is no assurance that we will file for an Orphan Drug Designation for any indication, nor if such application is made, that the FDA, the European Medicines Agency ("EMA") or any other regulatory body will ever approve it. In addition, if an application is approved, Orphan drug exclusive marketing rights may be lost if the FDA, EMA or other regulatory body later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Although obtaining approval to market a product with Orphan drug exclusivity may be advantageous, we cannot be certain that:

- we will be the first to obtain approval for any drug for which we obtain Orphan Drug Designation;
- Orphan Drug Designation will result in any commercial advantage or reduce competition; or
- limited exceptions to this exclusivity will not be invoked by the relevant regulatory authority.

If we are unable to obtain, protect, and maintain our proprietary rights in intellectual property, we may not be able to compete effectively or operate profitably.

Our commercial success also depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology covering our product candidates and avoiding infringement of the proprietary technology of others. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our industry are still evolving. However, we will be able to protect our proprietary rights from unauthorized use by third-parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We have tried to protect our proprietary position by filing U.S. and international patent applications related to PRTX-100. We filed an initial therapeutic use patent application with the U.S. Patent and Trademark Office, or PTO, which issued the 258 Patent in May 2007. The 258 Patent has claims relating to the treatment of acute inflammation as well as rheumatoid arthritis (RA) and systemic lupus erythematosis (SLE) using protein A. A second patent claiming the use of protein A to treat idiopathic thrombocytopenia or autoimmune thrombocytic purpura issued as U.S. 7,425,331 in September, 2008. A further patent for the use of protein A the 170 Patent was issued in October, 2010. The 170 Patent claims the use of protein A to reduce an acute inflammatory response or inflammation, including when these symptoms are associated with myasthenia gravis, ulcerative colitis, Crohn's disease, psoriatic arthritis or pemphigus vulgaris. A further patent claiming the use of protein A to treat psoriasis and scleroderma issued as U.S. 8,168,189 in May, 2012. In December 2013, a patent with claims to the use of protein A to treat multiple sclerosis issued as U.S. 8,603,486. We have also filed for foreign patent protection in Canada, Japan and the European Union. Japanese patent JP 4598404 issued in October, 2010 with claims relating to use of protein A to treat rheumatoid arthritis, systemic lupus erythematosis (SLE), idiopathic thrombocytopenia, and autoimmune thrombocytopenia purpura. Because the patent position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own may not provide any protection against competitors. Patents that we may file in the future or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed, or designed around any patents we may have issued to us. Moreover, the laws of foreign countries do not protect intellectual property rights to the same extent as the laws of the United States.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We protect this information by entering into confidentiality agreements with parties that have access to it, such as potential investors, advisors, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information, or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent was to be disclosed to or independently developed by a competitor, our business and financial condition could be adversely affected.

If other companies claim that we infringe their proprietary technology, we may incur liability for damages or be forced to stop our development and commercialization efforts.

Competitors and other third-parties may initiate patent litigation against us in the U.S. or in foreign countries based on existing patents or patents that may be granted in the future. These lawsuits can be expensive and would consume time and other resources even if unsuccessful or brought without merit. Our competitors may have sought or may seek patents that cover aspects of our technology. We are aware that a third-party has a pending patent application for technologies generally related to ours, and more patents for similar technologies may be filed in the future. In the United States, patent applications may remain confidential after filing or published 18 months after filing.

Owners or licensees of patents may file one or more infringement actions against us. Any such infringement action could cause us to incur substantial costs defending the lawsuit and could distract our management from our business, even if the allegations of infringement or misappropriation are unwarranted. The defense of multiple claims could have a disproportionately greater impact. Furthermore, an adverse outcome from this type of claim could subject us to a judgment that requires us to pay substantial damages. A judgment could also include an injunction or other court order that could prevent us from making, using, selling, offering for sale or importing our products or prevent our customers from using our products.

Alternatively, we could be required to license disputed rights from the third party. If a court determines, or if we independently discover, that any of our products or manufacturing processes violates third-party proprietary rights, we might not be able to reengineer the product or processes to avoid those rights, or obtain a license under those rights on commercially reasonable terms, if at all.

We may become involved in lawsuits to protect or enforce our patents that would be expensive and time consuming.

In order to protect or enforce our patent rights, we may initiate patent litigation against third-parties. In addition, we may become subject to interference or opposition proceedings conducted in patent and trademark offices to determine the priority of inventions. The defense of intellectual property rights, including patent rights through lawsuits, interference or opposition proceedings, and other legal and administrative proceedings, would be costly and divert our technical and management personnel from their normal responsibilities. An adverse determination of any litigation or defense proceedings could put our patent application at risk of not issuing.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation, confidential information may be inadvertently disclosed in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. This disclosure could negatively affect our business and financial results.

If third-party manufacturers of our products fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may rise.

We have relied on, and intend to rely in the future, on third-party contract manufacturers to supply, store and distribute PRTX-100 and other potential products. Any products we develop may be in competition with other product candidates and products for access to these facilities. Thus, we may not be successful in contracting with third-party manufacturers, or they may not be able to manufacture these candidates and products in a cost-effective or timely manner. Additionally, our reliance on third-party manufacturers exposes us to the following risks, any of which could delay or prevent the completion of (x) our clinical trials, (y) the approval of our products by the FDA or (z) the commercialization of our products, resulting in higher costs or depriving us of potential product revenues:

- Contract manufacturers are obliged to operate in accordance with FDA-mandated cGMPs. Their failure to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the availability of material for clinical study and may delay or prevent filing or approval of marketing applications for our products. Additionally, failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

- It may be difficult or impossible for us to find replacement manufacturers quickly on acceptable terms, or at all. For example, we have initially relied on a single contract drug substance manufacturer, Eurogentec S.A., to produce PRTX-100. Changing this manufacturer, or changing the manufacturer for any other products we develop, may be difficult, time consuming and expensive. The number of potential manufacturers is limited, and changing manufacturers may require confirmation of the analytical methods of the manufacturing processes and procedures in accordance with FDA-mandated cGMPs. Such confirmation of the analytical methods may be costly and time-consuming.

- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Agency, and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit the performance of third-party contractors, we do not have control over our third-party manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

We believe Eurogentec S.A. has the capacity to produce a sufficient inventory of PRTX-100 to conduct our current planned clinical trials. If these inventories are lost or damaged, or if Eurogentec S.A. cannot or will not produce additional inventory to complete the remaining phases of clinical trials, the clinical development of our product candidate or its submission for regulatory approval could be significantly delayed and our ability to commercialize this product could be impaired.

If we do not have adequate clinical trial material available to complete our clinical trials, which could also lead to a significant delay in continuing and /or commencing our clinical trial programs, we may be unable to obtain FDA approval and our ability to commercialize this product could be impaired or precluded.

We may not be able to manufacture our products in commercial quantities, which would prevent us from marketing our products.

If any of our potential products were approved by the FDA or foreign regulatory agencies for commercial sale, we would need to manufacture them in larger quantities. We have no manufacturing facilities at this time, and we have no experience in the commercial manufacturing of drugs. Thus, we would need to either develop the capability of manufacturing on a commercial scale or engage third-party manufacturers with this capability. Significant scale-up of manufacturing may require certain additional validation studies, which the FDA must review and approve. Moreover, contract manufacturers often encounter difficulties in achieving volume production, quality control and quality assurance, as well as shortages of qualified personnel. For these reasons, a third-party manufacturer might not be able to manufacture sufficient quantities of PRTX-100 to allow us to commercialize it. If we are unable to increase the manufacturing capacity for PRTX-100, or any other product we may develop, we may experience delays in or shortages in supply when launching them commercially.

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

If we receive regulatory approval to commence commercial sales of PRTX-100, we will face competition with respect to commercial sales, marketing and distribution. These are areas in which we currently have no experience due to a lack of management. To market our product directly, we must develop a direct marketing and sales force with technical expertise and supporting distribution capability. Alternatively, we may engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. There can be no assurance that we will successfully establish sales and distribution capabilities either on our own or in collaboration with third-parties or gain market acceptance for our product. To the extent we enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third-parties. Those efforts may not succeed.

Competition in the pharmaceutical industry is intense; if we fail to compete effectively, our financial results will suffer.

We engage in a business characterized by extensive research efforts, rapid developments and intense competition. We cannot assure you that our products will compete successfully or that research and development by others will not render our products obsolete or uneconomical. Our failure to compete effectively would negatively affect our business, financial condition and results of operations. We expect that successful competition will depend, among other things, on product efficacy, safety, reliability, availability, timing and scope of regulatory approval and price. Specifically, other factors we expect will impact our ability to compete include the relative speed with which we can develop products, complete the clinical, development and laboratory testing and regulatory approval processes and supply commercial quantities of the product to the market.

We expect competition to increase as technological advances are made and commercial applications broaden. In commercializing PRTX-100 and any additional products we develop using our technology, we will face substantial competition from large pharmaceutical, biotechnology and other companies, universities and research institutions.

Substantially all of our competitors have substantially greater capital resources, research and development personnel, facilities and experience in conducting clinical trials and obtaining regulatory approvals than us. As well, most of our competitors have advantages over us in manufacturing and marketing pharmaceutical products. We are thus at a competitive disadvantage to those competitors who have greater capital resources and we may not be able to compete effectively.

If we are unable to hire additional qualified scientific, sales and marketing, and other personnel, we will not be able to achieve our goals.

We depend on the members of our management staff, Scientific Advisory Board and a small number of third-party consultants to provide the expertise needed to carry out our business objectives. The loss of any of these individuals' services may significantly delay or prevent the achievement of research, development or business objectives and could negatively affect our business, financial condition and results of operations if their replacements are not promptly retained. We face intense competition for such personnel and consultants. Such replacements are predicated, among other conditions, on our ability to raise additional funding. We cannot assure you that we will attract and retain qualified management and scientific personnel in the future, with or without adequate additional financing. We do not maintain key person life insurance on any of these individuals.

Further, we expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, contract manufacturing and marketing, will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise. The failure to attract and retain such personnel or to develop such expertise would impact prospects for our success.

Even if we obtain marketing approval, PRTX-100 will be subject to ongoing regulatory review.

If regulatory approval of PRTX-100 is granted, that approval may be subject to limitations on the indicated uses for which it may be marketed or contain requirements for costly post-marketing follow-up studies. As to products for which marketing approval is obtained, the manufacturer of the product and the manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other regulatory authorities. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or the manufacturer, including withdrawal of the product from the market. We may be slow to adapt, or we may never adapt, to changes in existing requirements or adoption of new requirements or policies.

If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Market acceptance of PRTX-100 will be limited if users are unable to obtain adequate reimbursement from third-party payors.

Government health administration authorities, private health insurers and other organizations generally provide reimbursement for products like PRTX-100, and our commercial success will depend in part on these third-party payors agreeing to reimburse patients for the costs of our product. Even if we succeed in bringing our proposed products to market, we cannot assure you that third-party payors will consider it cost-effective or provide reimbursement in whole or in part for its use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. PRTX-100 is intended to replace or alter existing therapies or procedures. These third-party payors may conclude that our product is less safe, effective or cost-effective than existing therapies or procedures. Therefore, third-party payors may not approve our product for reimbursement.

If third-party payors do not approve our product for reimbursement or fail to reimburse them adequately, sales will suffer as some physicians or their patients will opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payors make reimbursement available, these payors' reimbursement policies may adversely affect our ability to sell our product on a profitable basis.

Moreover, legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our product, which could adversely affect our business, financial condition and results of operations.

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after the FDA or other regulatory agencies approve PRTX-100 for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals they could negatively affect our business, financial condition and results of operations.

We may be required to defend lawsuits or pay damages in connection with the alleged or actual harm caused by our products.

We face an inherent business risk of exposure to product liability claims in the event that the use of any of our products is alleged to have resulted in harm to others. This risk exists in clinical trials as well as in commercial distribution. In addition, the pharmaceutical and biotechnology industries in general have been subject to significant medical malpractice litigation. We may incur significant liability if product liability or malpractice lawsuits against us are successful. Furthermore, product liabilities claims, regardless of their merits, could be costly and divert our management's attention from other business concerns, or adversely affect our reputation and the demand for our product. We currently maintain a $2,000,000 general liability insurance policy, a global $5,000,000 clinical liability insurance policy and as required, country specific clinical liability insurance will be procured. We intend to expand our liability insurance coverage for any products for which we obtain marketing approval, however, such insurance may be unavailable, prohibitively expensive or may not fully cover our potential liabilities. If we are unable to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims or field actions, we may be unable to continue to market our products and develop new markets.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. PRTX-100, should we obtain regulatory approval, will have to compete with existing therapies. In addition, a significant number of companies are pursuing the development of products that target the same indications that we are targeting. We face competition from both domestic and international companies. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, long drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other strategic collaborations.

The loss of one or more key members of our management team could adversely affect our business.

Our performance is substantially dependent on the continued service and performance of our management team, [who have extensive experience and specialized expertise] in our business. In particular, the loss of Arnold P. Kling, our president, could adversely affect our business and operating results. We do not have "key person" life insurance policies for any members of our management team or employment agreements with any members of our management team.

If we are unable to engage additional qualified personnel, our ability to grow our business may be harmed.

We will need to engage additional qualified personnel and consultants with expertise in clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We expect that the hiring of such additional personnel may increase our annual expenditures by approximately $2-$3 million or more. We will compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot assure you that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success and any failure to do so successfully may have a material adverse effect on us.

Many of our business practices are subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the United States are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug, and Cosmetic Act, the False Claims Act and the Anti-Kickback Law and the Public Health Service Act, and any regulations promulgated under their authority, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid and the Department of Health and Human Services and other regulatory authorities as well as by the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Law, and similar state laws and regulations, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose products for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from the Medicare and Medicaid programs, and arrangements with referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Under the Patient Protection and Affordable Care Act and the companion Health Care and Education Reconciliation Act, which together are referred to as the healthcare reform law, such payments by pharmaceutical manufacturers to U.S. healthcare practitioners and academic medical centers must be publicly disclosed. A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where such practices have been found to be improper incentives to use such products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct.

Failure to satisfy requirements under the Federal Food, Drug, and Cosmetic Act can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct.

In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the United States, Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities (e.g., FDA in the United States), nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products.

Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the Federal Food, Drug, and Cosmetic Act and subjects us to civil and criminal sanctions. Furthermore, sanctions under the Federal False Claims Act have recently been brought against companies accused of promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud. The healthcare reform law significantly strengthened provisions of the Federal False Claims Act, Medicare and Medicaid Anti-Kickback provisions, and other health care fraud provisions, leading to the possibility of greatly increased qui tam suits by relators for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business.

We may be required to report detailed pricing information, net of included discounts, rebates and other concessions, to the Centers for Medicare & Medicaid Services, or CMS, for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations. We will need to establish systems for collecting and reporting this data accurately to CMS and institute a compliance program to assure that the information collected is complete in all respects. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business.

If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which would preclude us from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of their product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected. Also, under the United States Foreign Corrupt Practices Act, or FCPA, the United States has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business.

To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the United States Health and Human Services Department Office of Inspector General, or OIG, have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the United States Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. In the future, we may need to adopt healthcare compliance and ethics programs that would incorporate the OIG's recommendations, and train our applicable employees in such compliance. Such a program may be expensive and may not assure that we will avoid compliance issues.

Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from government and health administration authorities, private health maintenance organizations and health insurers and other healthcare payers.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such product. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced.

Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products, such as plasma-derived products, are subject to price controls in several of the world's principal markets, including many countries within the European Union. In the United States, where pricing levels for our products are substantially established by third-party payors, if payors reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on financial results, particularly in cases where our products command a premium price in the marketplace, or where changes in reimbursement induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products could materially adversely affect our financial prospects and performance.

The implementation of the healthcare reform law in the United States may adversely affect our business.

Through the March 2010 adoption of the healthcare reform law in the United States, substantial changes are being made to the current system for paying for healthcare in the United States, including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. The changes contemplated by the healthcare reform law are subject to rule-making and implementation timelines that extend for several years, and this uncertainty limits our ability to forecast changes that may occur in the future. However, implementation has already begun with respect to certain significant cost-saving measures under the healthcare reform law, for example with respect to several government healthcare programs that may cover the cost of our future products, including Medicaid, Medicare Parts B and D, and these efforts could have a materially adverse impact on our future financial prospects and performance.

For example, with respect to Medicaid, in order for a manufacturer's products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of the United States Department of Health and Human Services, and pay certain rebates to the states based on utilization data provided by each state to the manufacturer and to CMS, and pricing data provided by the manufacturer to the federal government. The States share this savings with the federal government, and sometimes implement their own additional supplemental rebate programs. Under the Medicaid drug rebate program, the rebate amount for most branded drug products was previously equal to a minimum of 15.1% of the Average Manufacturer Price, or AMP, or the AMP less Best Price, whichever is greater. Effective January 1, 2010, the healthcare reform law generally increases the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug product from a minimum of 15.1% to a minimum of 23.1% of the AMP, subject to certain exceptions, for example, for certain clotting factors, the increase is limited to a minimum of 17.1% of the AMP. For non-innovator multiple source (generic) products, the rebate percentage is increased from a minimum of 11.0% to a minimum of 13.0% of AMP. In 2010, the healthcare reform law also newly extended this rebate obligation to prescription drugs covered by Medicaid managed care organizations. These increases in required rebates may adversely affect our future financial prospects and performance.

The healthcare reform law also creates new rebate obligations for our products under Medicare Part D, a partial, voluntary prescription drug benefit created by the United States federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011, the healthcare reform law generally requires that in order for a drug manufacturer's products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of the United States Department of Health and Human Services, and reimburse each Medicare Part D plan sponsor an amount equal to 50% savings for the manufacturer's brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the "donut hole" (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS's contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation.

The healthcare reform law also introduced a biosimilar pathway that will permit companies to obtain FDA approval of generic versions of existing biologics based upon reduced documentation and data requirements deemed sufficient to demonstrate safety and efficacy than are required for the pioneer biologics. The new law provides that a biosimilar application may be submitted as soon as 4 years after the reference product is first licensed, and that the FDA may not make approval of an application effective until 12 years after the reference product was first licensed. With the likely introduction of biosimilars in the United States, we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges. The FDA has reported meeting with sponsors who are interested in developing biosimilar products, and is developing regulations to implement the abbreviated regulatory review pathway.

Regarding access to our products, the healthcare reform law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research, or CER. While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be determined to be less cost-effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results.

Risks Relating to our Finances, Capital Requirements and Other Financial Matters

Auditors have doubt as to our ability to continue in business.

In their report on our May 31, 2013 financial statements, our auditors expressed substantial doubt as to our ability to continue as a going concern. A going concern qualification could impair our ability to finance our operations through the sale of debt or equity securities. Our ability to continue as a going concern will depend, in large part, on our ability to obtain additional financing and generate positive cash flow from operations, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

We are a clinical stage company with a history of operating losses that are expected to continue and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability.

We are a clinical stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by similarly situated companies. We have generated net losses in all periods since our inception in September 1999 including losses of approximately $4.4 million and $6.3 million for the years ended May 31, 2012 and 2013, respectively and approximately$2.8 million for the six months ended November 30, 2013. At November 30, 2013, we had an accumulated deficit of approximately $64.7 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. During the years ended May 31, 2012 and 2013, we incurred research and development expenses of approximately $1.9 million and $3.8 million, respectively, and approximately $1.6 million for the six months ended November 30, 2013. As of November 30, 2013, we had cash and cash equivalents of approximately $1.1 million and net working capital of approximately $550,000 compared to cash and cash equivalents of approximately $32,000 and negative net working capital of approximately $2.7 million as of November 30, 2012. We have suffered recurring losses from operations.

We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We anticipate that, based upon our projected expenditures, our current cash and cash equivalents will be sufficient to fund our operations into the 4th fiscal quarter of 2014. If we complete this offering, the expected net proceeds from the sale of the shares offered hereby, if added to our current cash and cash equivalents is anticipated to be sufficient to fund our operations into the 1st fiscal quarter of 2015. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. We currently have no agreements relating to any of these types of transactions and we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

If we fail to maintain proper and effective internal controls over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules, or SOX, beginning with the annual report for the year ended December 31, 2012, our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act we may need to further upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

Risks Associated with our Capital Stock

The market price of our Common Stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our Common Stock;
- the actual number of shares of our Common Stock that trade;
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our Common Stock, regardless of our actual operating performance.

We have never paid and do not intend to pay cash dividends. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

Provisions in our certificate of incorporation, our by-laws and Delaware law might discourage, delay or prevent a change in control of the Company or changes in our management and, therefore, depress the trading price of our Common Stock.

Provisions of our certificate of incorporation, our by-laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of the Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and

- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

The classification of our Board of Directors and limitation on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of the Company.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the forgoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our Common Stock. They could also deter potential acquirers of the Company, thereby reducing the likelihood that you could receive a premium for your Shares in an acquisition.

Our affiliates control the majority of our shares of common stock and one shareholder holds a controlling interest.

As of December 31, 2013, our directors and executive officers and their Affiliates beneficially own approximately 82% of the outstanding shares of our Common Stock, with one such Affiliate, Niobe Ventures LLC, beneficially owns approximately 79% of our outstanding Common Stock. As a result, this stockholder is able to exercise control over matters requiring stockholder approval, including the election of directors, and the approval of mergers, consolidations and sales of all or substantially all of our assets.

Our Common Stock is quoted on the OTC Bulletin Board, which may have an unfavorable impact on our stock price and liquidity.

Our Common Stock is not listed on any securities exchange. Rather, it is quoted on the OTC Bulletin Board. The OTC Bulletin Board is a significantly more limited market than the New York Stock Exchange, NYSE Amex or any of the securities exchanges that are part of the NASDAQ system. The quotation of our shares on the OTC Bulletin Board may result in a less liquid market available for existing and potential stockholders to trade shares of our Common Stock, which could have an adverse impact on the trading price of our Common Stock and could have a long-term adverse impact on our ability to raise capital in the future. In addition, we cannot assure that our Common Stock will continue to be quoted on the OTC Bulletin Board. For example, the current market makers in our Common Stock are under no obligations to continue to do so and if they should decide to terminate their market making activities in our Common Stock, you may not be able to trade your Shares.

If our Common Stock becomes subject to the penny stock rules, this may make it more difficult to sell the Shares.

The Commission has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTC Bulletin Board does not meet such requirements and if the price of our Common Stock is less than $5.00, our securities will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our Common Stock and, therefore, you may have difficulty selling the Shares.

Risks Associated with the Offering

The Shares are "restricted securities" and, as such, may not be sold except in limited circumstances.

None of the Shares have been registered under the Securities Act, or registered or qualified under any state securities laws. Rather, they will be sold and/or issued pursuant to exemptions contained in and under those laws. Accordingly, the Shares will be "restricted securities" as defined in Rule 144 and, therefore, may not be sold until they are registered under applicable federal and state securities laws, or an exemption from the registration requirements of those laws is available. (Rule 144 permits the resale, subject to various terms and conditions, of limited amounts of restricted securities after they have been held for six months.) The certificates representing the Shares will contain legends reflecting their restricted status or an appropriate notation will be made in the Company's stock register. Subject to the availability of an exemption from the registration requirements of the Securities Act, you will not be able to sell the Shares until the Registration Statement is filed and declared effective by the Commission. However, we are only obligated to register the Shares under limited circumstances. Moreover, even if we were to become obligated to register the Shares, there are many reasons, including some over which we have little or no control, which could delay the filing of the Registration Statement or which could keep the Registration Statement from being declared effective, including delays resulting from the regulatory review process and comments raised by the Commission during that process with respect to the Registration Statement.

Filing the Registration Statement could have an adverse impact on the market price of the Common Stock. Even if the Shares are covered by an effective registration statement covering their resale, there may be periods when you will be prevented from selling the Shares.

We are under no obligation to register the Shares unless and until we file a resale registration statement. We expect that if we ever file such a registration statement it will include the Shares as well as shares of Common Stock held by other shareholders. Following the effective date of the Registration Statement, all such shares would become available for sale in the public market, which could harm the market price of the Common Stock. Moreover, following the effective date of the Registration Statement, there may be periods when you still will be unable to publicly resell any the Shares that you hold. In particular, upon the occurrence of material developments, we may be required to update the information included in the Registration Statement as a result of such development. Examples of material developments that might require post-effective amendments to the Registration Statement or supplements to the prospectus included therein include, without limitation, the announcement of quarterly and annual operating results or material corporate events such as the licensing of a new product or the regulatory approval of one of our product candidates. During these "blackout" periods when a material development has occurred but the information included in the Registration Statement has not yet been amended or supplemented, you will be unable to resell any Shares pursuant to the prospectus. Accordingly, you may not always be able to resell your Shares publicly at times and prices that you feel are appropriate.

The purchase price of the Shares may not be indicative of our value.

The purchase price of the Shares may bear no relationship to our assets, book value, results of operations or any other established criterion of value. Therefore, we cannot assure you that you will be able to sell your Shares at or above the price you paid for them. Following effectiveness of the Registration Statement, the market price of the Common Stock may fluctuate significantly in response to factors, some of which are beyond our control, such as:

- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- quarterly variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts;
- our ability to license our products to a third-party pharmaceutical company;
- developments in the pharmaceutical industry; and
- general market conditions and other factors, including factors unrelated to operating performance.

Further, the stock market in general in recent years has experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of the Common Stock, which could cause a decline in value. You should also be aware that price volatility might be worse if the trading volume of the Common Stock is low.

You will experience immediate and substantial dilution with respect to the Shares you purchase in the offering.

Because we have negative book value and no tangible assets, you will experience immediate and substantial dilution in the net tangible book value per share of the Common Stock you purchase in the offering.

We have broad discretion in the use of the net proceeds of this offering and may not use them effectively.

We intend to use the net proceeds from this offering to continue clinical testing and commercialization of PRTX-100 and for working capital and other general corporate purposes. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our Common Stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our Common Stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We have not retained independent professionals for you.

We have not retained any independent professionals to protect your interests in connection with the offering and sale of the Shares. You must rely on the advice of your own professional advisors and legal counsel.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (SEC File No.s. 333-130998, 333-130997, 333-125919) of Protalex, Inc. of our report dated August 4, 2014, with respect to the financial statements as of and for the years ended May 31, 2014 and 2013, which appear in the Annual Report of Protalex, Inc. on Form 10-K for the year ended May 31, 2014.

/s/ Liggett, Vogt & Webb, P.A.
LIGGETT, VOGT & WEBB, P.A.

New York, NY
August 4, 2014

Exhibit 31.1

CERTIFICATION

I, Arnold P. Kling, certify that:

1. I have reviewed this annual report on Form 10-K of Protalex, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f))for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2014

/s/ Arnold P. Kling
Arnold P. Kling
President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Kirk M. Warshaw, certify that:

1. I have reviewed this annual report on Form 10-K of Protalex, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f))for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2014

/s/ Kirk M. Warshaw
Kirk M. Warshaw
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Protalex, Inc. (the "Company") on Form 10-K for the period ending May 31, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, Arnold P. Kling, President of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: August 4, 2014

/s/ Arnold P. Kling

Arnold P. Kling
President
(Principal Executive Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Protalex, Inc. (the "Company") on Form 10-K for the period ending May 31, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, Kirk M. Warshaw, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: August 4, 2014

/s/ Kirk M. Warshaw

Kirk M. Warshaw
Chief Financial Officer
(Principal Financial Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.