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, 2013

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.)**

133 Summit Ave – Suite 22
Summit, New Jersey 07901
(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 $7,416,405 as of November 30, 2012, 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 27, 2013 was 28,296,180

DOCUMENTS INCORPORATED BY REFERENCE

None.

PROTALEX, INC.

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NOTICE ABOUT 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 in the development stage, 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

Overview

We are a development stage company 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 highly-purified staphylococcal protein A, which is an immune modulating protein produced by bacteria. 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 we would see in future human clinical trials. 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 (the "PRTX-100-103 Study"). The PRTX-100-103 Study was a proof of concept study 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. Safety and disease 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 dose levels. More patients in the 0.90 micrograms/kg and 1.50 micrograms/kg cohorts showed improvement in their CDAI (Clinical Disease Activity Index for RA) than did patients in the lower dose or placebo cohorts. The safety, tolerability and pharmacokinetics (PK) of PTRX-100 in humans have now been characterized in four clinical studies.

In November 2012, we commenced enrollment and dosing of patients in the U.S. for our new multicenter Phase 1b randomized, multiple-dose, dose-escalation study (the "PRTX-100-104 Study") of PRTX-100 in combination with methotrexate and leflunomide in adults 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 was to assess the safety and tolerability of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate 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, PK and efficacy parameters.

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 elected to expand the 3.0 microgram, 6.0 microgram, and 12.0 microgram/kg dose cohorts of the PRTX-100-104 Study from 8 patients to 12 patients per group. With these three expansion cohorts, the dosing groups now each include nine active- and three placebo-treated patients. Accordingly, the sequential dose-escalation phase of the PRTX-100-104 Study, which includes these three expanded cohorts, will now enroll up to 44 patients, with doses ranging from 1.5 micrograms/kg up to 12.0 micrograms/kg.

We maintain an administrative office in Summit, 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 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 under the $2 Million Secured Convertible Note of $155,000 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bear interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on May 13, 2015 (the "May 2013 Secured Note").

Collectively, the January 2013 Secured Note and the May 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 $8,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

Payment of the principal and accrued interest on the Secured Notes will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Secured Notes.

Our obligations under the Secured Notes are secured by a security agreement granting Niobe a security interest in substantially all of our personal property and assets, including our intellectual property.

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(6) 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 immune modulating protein produced by bacteria. PRTX-100 has the ability, at very low concentrations, to bind to and to regulate activation of human B-lymphocytes and macrophages which mediate inflammation in certain autoimmune diseases. Laboratory studies indicate that the mechanism involves interaction with specific intracellular signaling pathways. Pre-clinical studies also demonstrate that very 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 up to 1.5 micrograms/kg, 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 proven effective in two standard mouse models of autoimmunity:

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 very 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 have shown 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 were an important component of our IND application with the FDA.

Additional studies in monkeys have further characterized the pharmacokinetics, 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 Investigational New Drug Application or IND for treating RA. We submitted the IND to the U.S. Food and Drug Administration (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 commenced our first Phase I single-dose clinical trial in December 2005 and completed the Phase I clinical trial 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 appeared 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, 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, pharmacokinetic, and pharmaco-dynamic profile of a single-dose of PRTX-100 in healthy volunteers at doses in the projected therapeutic range. Final results indicated that the drug was 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 in patients with active RA 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 in the U.S. 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 and 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.

Idiopathic Thrombocytopenic Purpura - ITP is an uncommon autoimmune bleeding disorder characterized by too few 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 conducted under the Australian and New Zealand Clinical Trial Notification procedure, not under a U.S. IND. 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. A leading Australian clinical research organization was contracted to manage and monitor this clinical trial. The PRTX-100b-103 Study was designed to evaluate the safety and pharmacokinetics 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 extremely 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 2009. At this point further recruitment of patients was suspended. No side effects or toxicities were noted with repeated weekly doses of PRTX-100 that were not seen with single doses in healthy volunteer trials. This repeated-dose safety data from the PRTX-100b-103 Study formed the basis for the clinical trial application to evaluate PRTX-100 in patients with RA.

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 percent 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 immune-modulatory 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 (with monoclonal antibodies) 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. The PRTX-100-103 Study was a proof of concept study 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. Safety and disease 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 dose levels and at the higher doses, decreased RA activity as scored by the CDAI.

The primary disease activity response endpoint was the number of patients with a DAS28-CRP < 3.2 at week six. The results showed that the PRTX-100 patients as a group had more responders than placebo at all times, that 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 indicated that PRTX-100 did not decrease 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 to remove the influence of changes in CRP. 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 4 apparent responders in the 1.50 micrograms/kg group, 2 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.

As the disease activity results from the PRTX-100-103 Study demonstrated an acceptable safety profile, we commenced the PRTX-100-104 Study in November 2012 to provide a better understanding of safety and treatment effect on RA disease activity measurements as well as help define the optimal dose.

The PRTX-100-104 Study

In November 2012, we commenced enrollment and dosing of patients in the U.S. for the PRTX-100-104 Study of PRTX-100 in combination with methotrexate or leflunimode in adults with active RA. Similar to the PRTX-100-103 Study, the primary objective of this study was to assess the safety and tolerability of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate 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, PK and efficacy parameters.

The sequential dose escalation phase of the PRTX-100-104 Study was expected to enroll up to 40 patients in the U.S. into five cohorts ranging from 1.50 micrograms/kg up to 18.0 micrograms/kg of PRTX-100 or placebo. The dose escalation phase could be followed by up to 12 additional patients for cohort expansion at the optimal dose. Following the enrollment and dosing of the fourth cohort, a planned interim safety review by the SMC took place in July 2013. As a result of the review, we elected to expand the 3.0 microgram, 6.0 microgram, and 12.0 microgram/kg dose cohorts of the PRTX-100-104 Study from 8 patients to 12 patients per group, following completion of the fourth cohort which occurred in August 2013. Each of these dose cohort now include nine active- and three placebo-treated patients per dose group. Accordingly, the sequential dose-escalation phase of the PRTX-100-104 Study with these three expanded cohorts will now enroll up to 44 patients, with doses ranging from 1.5 micrograms/kg up to 12.0 micrograms/kg.

In addition, the SMC indicated that our current plan to amend the PRTX 100-104 Study with respect to the fifth and final dosing cohort did not represent any safety concerns. The proposed amended fifth cohort sub-study, if approved, will include additional monthly maintenance doses of PRTX-100. The dose for infusions will be in the 3.0 micrograms/kg to 6.0 micrograms/kg range. Although patients in the fifth cohort may receive more doses of PRTX-100 than patients in prior cohorts, the cumulative dosage will not exceed that of the current 12.0 micrograms/kg cohort. This fifth cohort sub-study is expected to enroll up to 12 additional patients.

Enrollment in the PRTX-100-104 Study is currently taking place at five study sites in the U.S. which may be expanded by an additional two to five U.S. sites.

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 other 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 U.S. 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 current focus as a primary indication. RA is a serious autoimmune disorder that causes the body's immune system to mistakenly 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 2012, approximately 1.3 million people in the U.S. have Rheumatoid Arthritis 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. It is estimated that despite treatment with current approved RA therapeutics, at least a 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 the cost of treatment is about $30,000 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 these 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 our products could be used to treat patients with moderate to severe cases of RA, and particularly those individuals for whom other treatments have 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.

Preliminary information gained in the laboratory on the mechanism of action of PRTX-100 suggests potential efficacy in a range of autoimmune diseases, including, but not limited to psoriasis, myasthenia, ITP and pemphigus.
Our long-term strategy, should PRTX-100 demonstrate safety and clinical proof of concept in RA, contemplates the pursuit of FDA approval to treat other autoimmune diseases where the drug's ability to decrease the inflammatory response will abrogate the underlying disease processes.

Competition

We believe, based on the pre-clinical trials and the results to date of our four Phase I clinical trials, that PRTX-100 has a potential competitive advantage as it may be safer and more efficacious than existing therapies, and may cost less to manufacture than competing biologic-based therapies. Current RA treatments are characterized by complex manufacturing methods and, in 2012, resulted in an average annual retail cost of approximately $15,000 to $25,550 per patient. 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 2012 annual reports, Enbrel generated revenues of approximately $7.9 billion combined for Amgen and Pfizer, Remicade generated revenues of more than $8.2 billion combined for Johnson & Johnson and Merck, and Abbott reported revenues of $9.3 billion for Humira. The final two TNFa inhibitors, usually second line use, have also increased their revenues. Cimzia generated revenues of $619 million for UCB and Astellas, and Simponi generated revenues of $938 million for Johnson & Johnson and Merck. Orencia generated revenues of $1.2 billion for Bristol Myers Squibb. Kineret generated revenues of $74 million for Amgen, and Actemra generated revenues of $699 million for Roche. Rituxan generated revenues of $6.8 billion for Roche and Xeljanz which was approved in 2012 for Pfizer has not reported revenues to date. These revenues reflect the use of these drugs for RA, other indications and off label uses.

Post-marketing experience has indicated an enhanced risk for serious and opportunistic infections in patients treated with TNF inhibitors. Disseminated tuberculosis due to reactivation of latent disease was also seen commonly within clinical trials of TNF inhibitors. There is also a possibly increased risk of lymphoma in patients treated with TNF inhibitors. TNF inhibitors are not recommended in patients with demyelinating disease or with congestive heart failure. Transient neutropenia or other blood dyscrasias have been reported with Enbrel® and the other TNF inhibitors. There was also an increased risk of serious infections with rituximab therapy in clinical trials, and abatacept has also been associated with an increased risk of serious infections. In addition, according to 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 etanercept, infliximab, or adalimumad, mortality rates were on average approximately 1 death per 30 patients treated in the first three years of treatment. Findings such as these indicate that new and safer treatments for autoimmune diseases such as RA are needed.

As mentioned above, several companies have marketed or are developing thrombopoetin agonists for treatment of ITP. They include Amgen's Nplate and GSK's Promacta, both FDA approved.

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 U.S., 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 U.S. 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 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.

Other 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 are currently evaluating filing for Orphan Drug Designation in the U.S. as well as certain foreign jurisdictions from among several disease indications. Based upon study data to date, we believe that PRTX-100 may be effective in the treatment of ITP, as well as other orphan immune systems 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 U.S. Orphan drug designation must be requested before submitting a marketing application. After the FDA grants 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 U.S., 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 European Medicines Agency (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 U.S., 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 U.S., 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 U.S. 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"). 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"). 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. 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.

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.

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 on Form 10-K, 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 on Form 10-K, including our consolidated financial statements and the related notes.

Risks Related to Our Business

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 have a history of significant losses, and we may never achieve or sustain profitability.

We have been focused on product development and have not generated any revenues to date. We have incurred operating losses each year of our operations and if we continue to operate we expect to continue to incur operating losses for at least the next several years. We may never become profitable. The process of developing our products requires significant clinical development and laboratory testing and clinical trials, as well as regulatory approvals. In addition, commercialization of our targeted products will require the establishment of sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect our research and development and general and administrative expenses will increase over the next several years and, as a result, we expect our losses will increase. As of May 31, 2013, our cumulative net loss was $61,735,053. Our net loss was $6,280,234 for the fiscal year ended May 31, 2013. Our continued losses may adversely affect the value of our Common Stock and may jeopardize our ability to continue our operations.

If we cannot raise additional capital on acceptable terms, we will be unable to complete planned clinical trials, obtain regulatory approvals, commercialize our product candidate or sustain our operations.

We will require substantial future capital in order to continue to conduct the research and development, clinical and regulatory activities necessary to bring our products to market and to establish commercial manufacturing, marketing and sales capabilities. If we are unable to raise sufficient additional funds when required, we will likely be required to suspend or cease current operations until such financing is obtained, if ever. Our future capital requirements will depend on many factors, including:

- the progress of pre-clinical development and laboratory testing and clinical trials;
- time and costs involved in obtaining regulatory approvals;
- the number of indications we pursue;
- costs in filing and prosecuting patent applications and enforcing or defending patent claims; and
- the establishment of selected strategic alliances and activities required for product commercialization.

As of May 31, 2013, we had cash and cash equivalents of $2,457,046 and negative net working capital of $2,445,722 compared to cash and cash equivalents of $190,395 and negative net working capital of $2,121,018 as of May 31, 2012. We have suffered recurring losses from operations.

If in the future we raise additional funds through the issuance of equity, equity-related or debt securities, such securities may have rights, preferences or privileges senior to those of our Common Stock. Furthermore, because of the relatively low trading price of our Common Stock, the number of shares of the new equity or equity-related securities that may be required to be issued may cause stockholders to experience significant dilution. In addition, the issuance of debt securities could increase the liquidity risk or perceived liquidity risk faced by us. We cannot, however, be certain that additional financing will be available on acceptable terms or at all.

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, 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:

- 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 U.S., principally the 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 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. 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 U.S.

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 U.S., 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, in part, 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 or precluded.

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 and limited experience in designing drug manufacturing facilities. 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, some 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.

Risks Relating to Our Industry

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.

Risks Related to Our Common Stock

Our Common Stock has experienced in the past, and may experience in the future, significant price volatility, which substantially increases the risk of loss to persons owning our Common Stock.

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Factors that could cause this volatility in the market price of our Common Stock include:

- announcements of the introduction of new products by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- rumors relating to us or our competitors;
- litigation or public concern about the safety of our potential products;
- our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- FDA or international regulatory actions;
- depth and liquidity of the market for our Common Stock; and
- inability to raise adequate capital.

Because of the limited trading market for our Common Stock, and because of the significant price volatility, you may not be able to sell your shares of Common Stock when you desire to do so. During the fiscal year ended May 31, 2013, our stock price ranged from a high of $2.40 to a low of $0.40 per share. The inability to sell your shares in a rapidly declining market may substantially increase your risk of loss as a result of such illiquidity and because the price for our Common Stock may suffer greater declines due to its price volatility.

Future sales of Common Stock by our existing stockholders may cause our stock price to fall.

The market price of our Common Stock could decline as a result of sales by our existing stockholders of shares of Common Stock in the market or the perception that these sales could occur. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate and thus inhibit our ability to raise additional capital when it is needed.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on our capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude us from paying these dividends.

Control by single stockholder

Niobe 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 a "penny stock" which may restrict the ability of stockholders to sell our Common Stock in the secondary market.

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price, as defined, of less than $5.00 per share, or an exercise price of less than $5.00 per share, subject to certain exceptions, including an exception of an equity security that is quoted on a national securities exchange. Our Common Stock is not now quoted on a national exchange but is traded on QB tier of the OTC Markets Group, Inc. (“OTCQB”). Thus, they are subject to rules that impose additional sales practice requirements on broker-dealers who sell these securities. For example, the broker-dealer must make a special suitability determination for the purchaser of such securities and have received the purchaser's written consent to the transactions prior to the purchase. Additionally, the rules require the delivery, prior to the transaction, of a disclosure schedule prepared by the SEC relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered underwriter, and current quotations for the securities, and, if the broker-dealer is the sole market maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, among other requirements, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. The "penny stock" rules, may restrict the ability of our stockholders to sell our Common Stock and warrants in the secondary market.

Our Common Stock is quoted on the OTCQB which may have an unfavorable impact on our stock price and liquidity.

Our Common Stock is quoted on the OTCQB. The OTCQB is a significantly more limited market than the New York Stock Exchange or NASDAQ system. The quotation of our shares on the OTCQB may result in a less liquid market available for existing and potential stockholders to trade shares of our Common Stock, could depress the trading price of our Common Stock and could have a long-term adverse impact on our ability to raise capital in the future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal offices are located at 133 Summit Avenue, Suite 22, Summit, New Jersey which are owned by Kirk M. Warshaw, LLC (the "LLC"), an affiliated company of Kirk Warshaw, our chief financial officer and director. We occupy our principal offices on a month to month basis. We pay a monthly fee of $500 to the LLC for the use and occupancy and administrative services related to our principal offices. 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
2012*		
First Quarter	$ 1.75	$ 1.12
Second Quarter	2.50	0.52
Third Quarter	2.00	0.52
Fourth Quarter	1.88	0.61
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, 2012 and 2013 are actual sale prices because the bid price information was not available.

(b) *Holders*. As of August 21, 2013, there were approximately 63 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

During the fiscal year ended May 31, 2013, we issued non-qualified stock options exercisable for an aggregate of 1,000,000 shares of our Common Stock, at prices ranging from $1.01 per share to $1.39 per share, to two consultants and our CFO. All of these options expire 10 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

You should read this Management's Discussion and Analysis of Financial Condition and Results of Operations in conjunction with our 2013 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 a development stage company 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 highly-purified staphylococcal protein A, which is an immune modulating protein produced by bacteria. 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 we would see in future human clinical trials. 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 (the "PRTX-100-103 Study"). The PRTX-100-103 Study was a proof of concept study 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. Safety and disease 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 dose levels. More patients in the 0.90 micrograms/kg and 1.50 micrograms/kg cohorts showed improvement in their CDAI (Clinical Disease Activity Index for RA) than did patients in the lower dose or placebo cohorts. The safety, tolerability and pharmacokinetics (PK) of PTRX-100 in humans have now been characterized in four clinical studies.

In November 2012, we commenced enrollment and dosing of patients in the U.S. for our new multicenter Phase 1b randomized, multiple-dose, dose-escalation study (the "PRTX-100-104 Study") of PRTX-100 in combination with methotrexate and leflunomide in adults 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 was to assess the safety and tolerability of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate 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, PK and efficacy parameters.

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 elected to expand the 3.0 microgram, 6.0 microgram, and 12.0 microgram/kg dose cohorts of the PRTX-100-104 Study from eight patients to 12 patients per group. With these three expansion cohorts, the dosing groups now each include nine active- and three placebo-treated patients. Accordingly, the sequential dose-escalation phase of the PRTX-100-104 Study, which includes these three expanded cohorts, will now enroll up to 44 patients, with doses ranging from 1.5 micrograms/kg up to 12.0 micrograms/kg.

We maintain an administrative office in Summit, 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, 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 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 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 under the $2 Million Secured Convertible Note of $155,000 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bear interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on May 13, 2015 (the "May 2013 Secured Note").

Collectively, the January 2013 Secured Note and the May 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 $8,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

In addition, payment of the principal and accrued interest on the Secured Notes will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Secured Notes. Our obligations under the Secured Notes are secured by a security agreement granting Niobe a security interest in substantially all of our personal property and assets, including our intellectual property.

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(6) 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 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 U.S., 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 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, 2013 compared to fiscal year ended May 31, 2012

Research and Development Expenses – Research and Development expenses increased from $1,900,001 in our 2012 fiscal year to $3,833,401 in our 2013 fiscal year. The increase of $1,933,400, or 102%, was primarily the result of increased activity associated with our clinical study in the US, as disclosed above and the formulation and production of more 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 $1,345,152 in our 2013 fiscal year from $1,291,867 in our 2012 fiscal year. The increase, $53,000, was related to an increase in non-cash stock compensation offset by declines in many of the other general and administrative expenses that constitute this category.

Professional Fees - Professional fees increased from $309,696 in our 2012 fiscal year to $440,751 in fiscal year 2013. The increase of $131,000, or 42%, was due primarily to increases in consulting and advisory expenses.

Interest Expense – Interest expense decreased from $943,607 in fiscal year 2012 to $663,866 in fiscal year 2013. The decrease was attributable to no longer having any interest expense associated with the beneficial conversion feature of the $2 Million Secured Convertible Note offset by increases due to us having more significant amounts of debt outstanding during FY 2013 compared to FY 2012.

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, 2013 was $61,735,053 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.

From February 1, 2012 through May 31, 2013 we raised an aggregate of $8,000,000 of working capital pursuant to six loans from Niobe, in varying principal amounts and issued to Niobe the Secured Notes.

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

Our operating cash outflows for the fiscal years ended May 31, 2013 and 2012 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 2013 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 U.S. 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, 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, 2013. 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, 2013, 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 Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On August 27, 2013, we issued 9,369,565 shares of our common stock to Niobe upon the conversion of the $2 Million Secured Convertible Note, including $155,000 of accrued interest thereon. The shares were issued in reliance upon the exemption from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act.

On August 27, 2013, we 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").

Our obligations under the August 2013 Secured Note, and all prior borrowings from Niobe, are secured by a security agreement granting Niobe a security interest in substantially all of our personal property and assets, including its intellectual property. In addition, payment of the principal and accrued interest on the August 2013 Secured Note will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the August 2013 Secured Note.

The foregoing August 2013 Secured Note and the security agreement are filed as Exhibits 4.9 and 10.21, respectively, to this Report.

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, 2013:

Name	Age	Title
Arnold P. Kling	55	President and Director
Kirk M. Warshaw	55	Chief Financial Officer, Secretary and Director
John E. Doherty	59	Director

Arnold P. Kling. Mr. Kling has served as our president and director since November 2009. For the past 12 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.

John E. Doherty. Mr. Doherty is a co-founder and has served as a director and a member of our Scientific Advisory Board since November 2009. From September 2005 to present he has been a private investor. Prior to that, from September 1999 to September 2005 he was a member of our Board, and also our President and Chief Executive Officer from September 1999 to December 2002. Mr. Doherty's professional experience and background with us and other companies have given him the expertise needed to serve 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.

Edward Bernton, M.D., serves as Chairman of our SAB pursuant to a consulting agreement effective December 1, 2009, and as amended effective as of April 10, 2012, as well as our Chief Scientific Officer and has a background in pharmacology, clinical immunology, and experimental medicine. Dr. Bernton prior to this was Senior Director, Clinical Development, at Emergent Biosolutions (NYSE: EBS), a biopharmaceutical company focused on the development, manufacturing and commercialization of vaccines and therapeutic antibodies that assist the body's immune system to prevent or treat disease. He also served as our medical director and worked as a consultant in clinical pharmacology and early-phase drug development prior to December 2009. His medical subspecialties include internal medicine, allergy/immunology, and diagnostic laboratory immunology. He served five years as Scientific Director for PAREXEL International Corporation's (Nasdaq: PRXL) Clinical Pharmacology in North America. He has served as protocol author or investigator on over 30 Phase I clinical trials including many first-in-man studies for novel small molecules, biopharmaceutics, and vaccines. Other past experience includes, serving three years as a regulatory and product development consultant at Quintiles, a bio and pharmaceutical services provider offering clinical, commercial, consulting and capital solutions, serving three years as Chief Medical Officer or VP at various Biotech start-ups and serving 12 years in both basic and clinical research in pharmacology, immunology, infectious diseases, and vaccinology while on active duty at Walter Reed Army Institute of Research.

James W. Dowe III, serves as Vice Chairman of our SAB pursuant to a consulting agreement effective December 1, 2009, 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. Mr. Dowe started his career at the White Sands Missile Range as a mathematician and a programmer, and later he joined the Dikewood Corporation in New Mexico as a mathematician and analyst. Subsequently, he became the Associate Director of the Computing Center at the University of New Mexico. 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 is the inventor of the Adaptive Pattern Recognition Process (APRP) which is the basis of Convera's technology. Mr. Dowe was co-founder and a director of AZUR Environmental, a private company (acquired by Strategic Diagnostics Inc. (Nasdaq: SDIX)) with an expertise in providing cost-effective reliable solutions for monitoring water quality throughout the world. 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.

William E. Gannon, Jr., M.D., serves as our Chief Medical Officer pursuant to a consulting agreement effective December 1, 2009. 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. 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 has held positions in multinational Clinical Research Organizations, medical device, biotech and pharmaceutical firms. In his most recent position prior to CCTC, Inc., Dr, Gannon served as Vice President – Clinical & Medical Affairs in biotechnology arena. 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 U.S., Europe and Asia. Additionally, Dr. Gannon is involved in philanthropy in the Washington, DC area and currently serves on the Board of Directors for The Mautner Project – The National Lesbian Health organization.

Third-Party Consultants

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

Board Composition

Currently, our Board consists of three members; however, only John E. Doherty qualifies as "independent" under the rules and regulations of the SEC and the NASDAQ.

Family Relationships

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

Board Committees

Our Board has the authority to appoint committees to perform certain management and administrative functions. As of the date of this 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.

Director Independence

Our Board has determined that Mr. Doherty is "independent" in accordance with the NASDAQ's independence standards. In its application of such standards, the Board takes into consideration all transactions with independent directors and the impact of such transactions, if any, on any of its independent directors' ability to continue to serve on the Board. To that end, for the fiscal year ended May 31, 2013, the Board considered all the compensation paid to Mr. Doherty, as disclosed below in "Item 11 – Executive Compensation – Compensation of Directors," and determined that such compensation was within the limits of the independence standards set by the NASDAQ and did not impact his ability to continue to serve as an independent director.

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, 2013 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., 133 Summit Avenue, Suite 22, Summit, NJ 07901.

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, 2013 and 2012:

Name and Principal Position	Year	Salary ($) (1)	Option Awards ($) (1)	Total ($)
Arnold P. Kling,	2013	$ 72,000	0	$ 72,000
President	2012	$ 72,000	0	$ 72,000
Kirk M. Warshaw,	2013	$ 72,000	$ 164,500	$ 236,500
Chief Financial Officer	2012	$ 72,000	$ 211,850	$ 370,830

(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 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, 2013:

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		$ 0.25	12/29/2019
	250,000		$ 1.01	11/01/2021
	175,000	175,000(1)	$ 1.05	05/22/2023

(1) Granted on May 22, 2013 (the "Grant Date"), this option is exercisable to acquire 50% of the underlying shares on the Grant Date and 100% of the underlying shares on the 6 month anniversary of the Grant Date.

Compensation of Directors

The table below summaries the compensation paid to our independent director for the fiscal year ended May 31, 2013:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
John E. Doherty(2)	$ 24,000	$ -	$ 24,000(1)	$ 48,000

(1) Consulting fees paid to Mr. Doherty as a member of the SAB.

(2) At May 31, 2013, Mr. Doherty held options exercisable for an aggregate of 400,000 shares at exercise prices ranging from $0.50 to $1.01 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, as of August 27, 2013, the number of shares of our Common Stock beneficially owned by (i) each person or entity known to us to be the beneficial owner of more than 5% of our outstanding Common Stock; (ii) each of our named executive officers and directors; and (iii) all of our officers and directors as a group. On December 8, 2010, we effected a reverse stock split of the outstanding shares of our Common Stock on the basis of one new share of Common Stock for each five shares of Common Stock outstanding. Accordingly, the number of shares beneficially owned by (i) each person or entity known to us to be the beneficial owner of more than 5% of our outstanding Common Stock; (ii) each of our named executive officers and directors; and (iii) all of our officers and directors as a group have been adjusted to reflect the reverse stock split. Unless otherwise indicated, the address of each person listed below is in the care of Protalex, Inc., 133 Summit Avenue, Suite 22, Summit, New Jersey 07901.

	Shares Beneficially Owned(1)	
	Number	Percent
Name and Title		
Arnold P. Kling, president and director (2)(6)	22,418,105	79.2 %
Kirk M. Warshaw, CFO, secretary and director (3)	1,175,543	3.9 %
John E. Doherty, director (4)	942,532	3.2 %
Officers and Directors as a group (3 persons) (5)	24,262,993	82.1 %
5% Beneficial Owners		
Niobe Ventures LLC (6)		
410 Park Avenue – Suite 1710		
New York, NY 10022	22,413,043	79.2 %

(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 175,000 shares of Common Stock at an exercise price of $1.05 per share.

(4) Includes options to purchase 200,000 shares of Common Stock at an exercise price of $0.50 per share and 200,000 shares of Common Stock at an exercise price of $1.01 per share.

(5) Includes: (i) 9,369,565 shares of Common Stock issued upon conversion of the $2 Million Secured Convertible Note including accrued interest thereon as of August 27, 2013 deemed to be beneficially owned by Arnold P. Kling as the manager of Niobe Ventures, LLC; and (ii) options to purchase an aggregate of 2,118,075 shares of Common Stock beneficially owned by Messrs. Warshaw and Doherty.

(6) Includes 9,369,565 shares of Common Stock issued upon conversion of the $2 Million Secured Convertible Note including accrued interest thereon as of August 27, 2013.

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	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders – 2003 Stock Option Plan	**77,000**	**$ 10.56**	**611,616**
Equity compensation plans not approved by security holders – Stand Alone Option Grants	**2,980,543**	**$ 0.84**	**Not applicable**
Total	**3,057,543**	**$ 1.09**	**611,616**

During the fiscal year ended May 31, 2013, options for an aggregate of 1,000,000 shares of our Common Stock were granted under Equity Compensation Plans Not Approved by Security Holders as compensation to three professionals who provide us with services. These options are ten year options with exercise prices ranging from $1.05 to $1.39, 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.

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

As described herein above, during the years ended May 31, 2012 and May 31, 2013, we raised an aggregate of $8,000,000 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 under the $2 Million Secured Convertible Note of $155,000 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, 2013 and 2012 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.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The aggregate fees billed by our principal accounting firm, Liggett, Vogt & Webb P.A in the fiscal year ended May 31, 2013 and Sherb & Co., LLP, for the fiscal year ended May 31, 2012 are as follows:

	2013	2012
Audit fees*	$ 33,500	$ 30,500
Audit related fees	0	0
Tax fees	4,500	4,500
All other fees	0	0
Total fees	$ 38,000	$ 35,000

*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.

Pre-Approval of Audit and Permissible Non-Audit Services

As of the date of this Report, given the limited number of directors, our Board has not re-established any committees since the consummation of the Financing. As a result, 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	Secured Convertible Promissory Note dated November 11, 2009	Incorporated by reference, to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 13, 2010
4.2	$2 Million Senior Secured Convertible Promissory Note dated February 11, 2011	Incorporated by reference, to Exhibit 4.1 to the Company's Quarterly Report on Form 10Q filed on April 12, 2011
4.3	$1 Million Secured Convertible Promissory Note dated February 1, 2012	Incorporated by reference, to Exhibit 4.3 to the Company's Annual Report on Form 10-K filed on August 29, 2012.
4.4	$1 Million Secured Convertible Promissory Note dated June 5, 2012	Incorporated by reference, to Exhibit 4.4 to the Company's Annual Report on Form 10-K filed on August 29, 2012.
4.5	$800,000 Secured Promissory Note dated October 1, 2012	Incorporate by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10Q filed on January 1, 2013.
4.6	$700,000 Secured Promissory Note dated December 3, 2012	Incorporate by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10Q filed on January 1, 2013.
4.7	$2.5 Million Secured Promissory Note dated January 18, 2013	Incorporate by reference to Exhibit 4.1 to the Company's Current Report Form 8-K filed on January 22, 2013.
4.8	$2.0 Million Secured Promissory Note dated May 13, 2013.	Incorporate by reference to Exhibit 4.1 to the Company's Current Report Form 8-K filed on May 14, 2013.

4.9	$1 Million Secured Promissory Note dated August 27, 2013	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	Note and Common Stock Purchase Agreement dated November 11, 2009, between the Company and Niobe Ventures, LLC	Incorporated by reference, to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 13, 2010.
10.9	Final Form of Credit Facility Agreement dated as of December 2, 2009, between the Company and Niobe Ventures, LLC	Incorporate by reference to Exhibit 10.4 to the Company's Current Report Form 8-K filed on December 2, 2009.
10.10	Final Form of 3rd Amended and Restated Security Agreement dated as of June 5, 2012, between the Company and Niobe Ventures, LLC	Incorporated by reference, to Exhibit 10.10 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 Kirk M. Warshaw	Incorporate by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10Q filed on January 8, 2010 .
10.12**	Form of Non-Qualified Stock Option Agreement with John Doherty	Incorporate by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10Q filed on April 7, 2010.
10.13**	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.
10.14**	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.
10.15**	Form of Non-Qualified Stock Option Agreement with John Doherty, dated November 1, 2011.	Incorporated by reference, to Exhibit 10.15 to the Company's Annual Report on Form 10-K filed on August 29, 2012.
10.16**	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.
10.17	Final Form of 4th Amended and Restated Security Agreement dated as of October 1, 2012, between the Company and Niobe Ventures, LLC	Incorporate by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10Q filed on January 1, 2013.
10.18	Final Form of 5th Amended and Restated Security Agreement dated as of December 3, 2012, between the Company and Niobe Ventures, LLC	Incorporate by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10Q filed on January 1, 2013.
10.19	Sixth Amended and Restated Security Agreement dated as of January 18, 2013, between the Company and Niobe Ventures, LLC	Incorporate by reference to Exhibit 10.1 to the Company's Current Report Form 8-K filed on January 22, 2013.
10.20	Seventh Amended and Restated Security Agreement dated as of May 13, 2013, between the Company and Niobe Ventures, LLC	Incorporate by reference to Exhibit 10.1 to the Company's Current Report Form 8-K filed on May 14, 2013.
10.21	Eighth Amended and Restated Security Agreement dated as of August 27, 2013, between the Company and Niobe Ventures, LLC	Filed herewith.
23.1	Consent of Liggett, Vogt & Webb, P.A.	Filed herewith.
23.2	Consent of Sherb & Co, LLP	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*	*
101.SCH	*XBRL Taxonomy Extension Schema Document*	*
101.CAL	*XBRL Taxonomy Extension Calculation Linkbase Document*	*
101.LAB	*XBRL Taxonomy Extension Label Linkbase Document*	*
101.PRE	*XBRL Taxonomy Extension Presentation Linkbase Document*	*
101.DEF	*XBRL Taxonomy Extension Definition Linkbase Document*	*

†Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.
**Filed with this report in accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.*
***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 28, 2013

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 28, 2013

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

Date: August 28, 2013

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

Date: August 28, 2013

/s/John E. Doherty
John E. Doherty, Director

PROTALEX, INC.

(A Development Stage Company)

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.
(A Development Stage Company)
Summit, New Jersey

We have audited the accompanying balance sheet of Protalex, Inc. (A Development Stage Company) as of May 31, 2013 and the related statements of operations, changes in stockholders' equity (deficit) , and cash flows for the year then ended May 31, 2013. We have also audited the amounts presented for the period June 1, 2012 to May 31, 2013, included in the statements of stockholders' equity (deficit) and in the total amounts presented in the statements of operations and cash flows for the period from September 17, 1999 (inception) to May 31, 2013. We did not audit the period September 17, 1999 (inception) to May 31, 2012. 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, 2013 and the results of its operations and its cash flows for the year ended May 31, 2013, and the amounts presented for the period June 1, 2012 to May 31, 2013 included in the statements of stockholders' equity (deficit) and in the total amounts presented in the statements of operations and cash flows for the period from September 17, 1999 (inception) to May 31, 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 27, 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Directors
Protalex, Inc.
(A Development Stage Company)
Summit, New Jersey

We have audited the accompanying balance sheet of Protalex, Inc. (A Development Stage Company) as of May 31, 2012 and the related statements of operations, changes in stockholders' equity (deficit) , and cash flows for the year then ended May 31, 2012. We have also audited the amounts presented for the period June 1, 2009 to May 31, 2012, included in the statements of stockholders' equity (deficit) and in the total amounts presented in the statements of operations and cash flows for the period from September 17, 1999 (inception) to May 31, 2012. We did not audit the period September 17, 1999 (inception) to May 31, 2009. 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, 2012 , and the amounts presented for the period June 1, 2009 to May 31, 2012 included in the statements of stockholders' equity (deficit) and in the total amounts presented in the statements of operations and cash flows for the period from September 17, 1999 (inception) to May 31, 2012 and the results of its operations and its cash flows for each of the years ended May 31, 2012 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/SHERB & CO, LLP
Certified Public Accountants

New York, NY
August 24, 2012

PROTALEX, INC.
(A Development Stage Company)
BALANCE SHEETS

	May 31, 2013	May 31, 2012
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,457,046	$ 190,395
Prepaid expenses	42,320	42,679
Total current assets	2,499,366	233,074
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $13,068 and $12,048 as of May 31, 2013 and May 31, 2012, respectively	6,467	7,487
Total other assets	6,467	7,487
Total Assets	$ 2,505,833	$ 240,561
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 671,738	$ 182,861
Accrued expenses	62,517	576,733
Current portion – long term debt– related party	4,210,833	1,594,498
Total current liabilities	4,945,088	2,354,092
LONG TERM LIABILITIES:		
Senior Secured Note – related party	6,000,000	1,000,000
Senior Secured Note Accrued Interest – related party	57,616	10,083
Total liabilities	11,002,704	3,364,175
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; 18,926,615 and 18,926,615 shares issued and outstanding, respectively	189	189
Additional paid in capital	53,237,993	52,331,016
Deficit accumulated during the development stage	(61,735,053)	(55,454,819)
Total stockholders' equity (deficit)	(8,496,871)	(3,123,614)
Total liabilities and stockholders' equity (deficit)	$ 2,505,833	$ 240,561

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

PROTALEX, INC.
(A Development Stage Company)

STATEMENTS OF OPERATIONS

	Year Ended May 31, 2013	Year Ended May 31, 2012	From Inception (September 17, 1999) Through May 31, 2013
			(Unaudited)
Revenues	$ 0	$ 0	$ 0
Operating Expenses			
Research and development (including depreciation and amortization)	3,833,401	1,900,001	36,375,494
Administrative (including depreciation and amortization)	1,345,152	1,291,867	19,814,435
Professional fees	440,751	309,696	5,071,602
Depreciation and amortization	1,020	1,020	182,966
Operating loss	(5,620,324)	(3,502,584)	(61,444,497)
Other income (expense)			
Interest income	3,956	1,607	2,211,846
Interest expense	(663,866)	(943,607)	(2,502,402)
Net loss	$ (6,280,234)	$ (4,444,584)	$ (61,735,053)
Weighted average number of common shares outstanding	18,926,615	18,926,615	
Loss per common share – basic and diluted	$ (0.33)	$ (0.23)	

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

From Inception (September 17, 1999) through May 31, 2013

(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock-Contra	Deficit Accumulated During The Development Stage	Total
September 17, 1999 — initial issuance of 2,000 shares for intellectual technology license at $.15 per share	2,000	$ 300	$ 0	$ 0	$ 0	$ 300
September 30, 1999 — cost of public shell acquisition over net assets acquired to be accounted for as a Recapitalization	0	0	0	(250,000)	0	(250,000)
October 27, 1999 — issuance of 17 shares to individual for $25,000	17	25,000	0	0	0	25,000
November 15, 1999 — reverse merger transaction with Enerdyne Corporation, net transaction amounts	1,794,493	118,547	0	(118,547)	0	0
November 18, 1999 — February 7, 2000 — issuance of 91,889 shares to various investors at $1.80 per share	91,889	165,400	0	0	0	165,400
January 1, 2000 — issuance of 20,000 shares in exchange for legal services	20,000	15,000	0	0	0	15,000
May 1 - 27, 2000 — issuance of 128,000 shares to various investors at $5.00 per share	128,000	640,000	0	0	0	640,000
May 27, 2000 — issuance of 329 shares to an individual in exchange for interest Due	329	1,644	0	0	0	1,644
Net loss for the year ended May 31, 2000	0	0	0	0	(250,689)	(250,689)
Balance, May 31, 2000	2,036,728	965,891	0	(368,547)	(250,689)	346,655
December 7, 2000 — issuance of 85,000 shares to various investors at $5.00 per share	85,000	425,000	0	0	0	425,000
May 31, 2001 — Forgiveness of debt owed to stockholder	0	0	40,000	0	0	40,000
Net loss for the year ended May 31, 2001	0	0	0	0	(553,866)	(553,866)
Balance, May 31, 2001	2,121,728	1,390,891	40,000	(368,547)	(804,555)	257,789

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)- (continued)

From Inception (September 17, 1999) through May 31, 2013
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated During The Development Stage	Total
August 13, 2001 — Contribution by Stockholders	0	0	143,569	0	0	143,569
November 7, 2001 — issuance of 176,320 Shares at $6.25 per share	176,320	1,102,000	0	0	0	1,102,000
November 26, 2001 — options issued to board member	0	0	133,000	0	0	133,000
Net loss for the year ended May 31, 2002	0	0	0	0	(1,280,465)	(1,280,465)
Balance, May 31, 2002	2,298,048	2,492,891	316,569	(368,547)	(2,085,020)	355,893
July 5, 2002 — issuance of 168,400 shares at $7.50 per share	168,400	1,263,000	0	0	0	1,263,000
July 1, 2002 - May 1, 2003 – purchase of common stock from stockholder at $3.50 per share	(26,191)	(91,667)	0	0	0	(91,667)
January 15, 2003 - May 15, 2003 — common stock issued to Company president	8,334	82,841	0	0	0	82,841
May 14, 2003 — common stock issued to employee	1,000	11,250	0	0	0	11,250
June 1, 2002 - May 31, 2003 – compensation related to stock options issued to board members, employees and consultants	0	0	287,343	0	0	287,343
Net loss for the year ended May 31, 2003	0	0	0	0	(1,665,090)	(1,665,090)
Balance, May 31, 2003	2,449,591	3,758,315	603,912	(368,547)	(3,750,110)	243,570
June 15, 2003, common stock issued to Company president	1,667	16,418	0	0	0	16,418
June 15, 2003, purchase of common stock from stockholder	(2,419)	(8,333)	0	0	0	(8,333)
September 18, 2003 – issuance of 1,489,129 of common stock issued in private placement At $8.50 per share, net of transaction costs	1,489,129	11,356,063	0	0	0	11,356,063
September 19, 2003 – repurchase and retired 598,961 shares for $300,000	(598,961)	(300,000)	0	0	0	(300,000)
December 12, 2003 – issuance of 7,880 shares to terminated employees at $13.00 per share	7,880	102,438	0	0	0	102,438
March 1, 2004 – common stock issued to employee at $12.75 per share	10,000	127,500	0	0	0	127,500
May 31, 2004 – reclassify common stock contra to common stock	0	(368,547)	0	368,547	0	0

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)- (continued)

From Inception (September 17, 1999) through May 31, 2013
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated During The Development Stage	Total
June 1, 2003 – May 31, 2004 – compensation related to stock options issued to board members, employees and consultants	0	0	448,096	0	0	448,096
Net loss for the year ended May 31, 2004	0	0	0	0	(2,989,364)	(2,989,364)
Balance, May 31, 2004	3,356,887	14,683,854	1,052,008	0	(6,739,474)	8,996,388
November 30, 2004 – adjust March 1, 2004 common stock issued to employee	0	(20,000)	0	0	0	(20,000)
January 13, 2005 – common stock issued to employee at $12.75 per share	3,000	38,250	0	0	0	38,250
February 28, 2005 – Reclass Par Value for Reincorporation into DE as of 12/1/04	0	(14,702,070)	14,702,070	0	0	0
May 25, 2005 - issuance of 518,757 shares of common stock issued in private placement At $9.75 per share, net of transaction costs	518,757	5	4,851,188	0	0	4,851,193
June 1, 2004 – May 31, 2005 – compensation related to stock options issued to board members, employees and consultants	0	0	308,711	0	0	308,711
Net loss for the year ended May 31, 2005	0	0	0	0	(5,567,729)	(5,567,729)
Balance, May 31, 2005	3,878,644	39	20,913,977	0	(12,307,203)	8,606,813
August 23, 2005 – common stock issued to employee	8,000	0	100,000	0	0	100,000
October 19, 2005 – common stock issued to employee	2,000	0	25,000	0	0	25,000
December 30, 2005 – issuance of 519,026 shares of common stock issued in private placement at $11.25 per share, net of transaction costs	519,026	5	5,510,962	0	0	5,510,967
June 1, 2005 – May 31, 2006 – warrants exercised	70,320	1	786,537	0	0	786,538
June 1, 2005– May 31, 2006 – compensation related to stock options issued to board members, employees and consultants	0	0	404,679	0	0	404,679
Net loss for the year ended May 31, 2006	0	0	0	0	(6,104,402)	(6,104,402)
Balance, May 31, 2006	4,477,990	45	27,741,155	0	(18,411,605)	9,329,595

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)- (continued)

From Inception (September 17, 1999) through May 31, 2013

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated During The Development Stage	Total
July 7, 2006 – issuance of 1,214,203 shares of common stock issued in private placement at $12.50 per share, net of transaction costs	1,214,203	12	14,217,709	0	0	14,217,721
June 1, 2006 – May 31, 2007 – warrants exercised	26,700	0	300,374	0	0	300,374
June 1, 2006 – May 31, 2007 – stock options exercised	1,200	0	15,200	0	0	15,200
June 1, 2006 – May 31, 2007 – share based compensation to board members, employees and consultants	0	0	1,826,850	0	0	1,826,850
Net loss for the year ended May 31, 2007	0	0	0	0	(8,451,942)	(8,451,942)
Balance, May 31, 2007 – (Unaudited)	5,720,093	57	44,101,288	0	(26,863,547)	17,237,798
June 1, 2007 – May 31, 2008 – share based compensation to board members, employees and consultants	0	0	1,011,025	0	0	1,011,025
Net loss for the year ended May 31, 2008	0	0	0	0	(10,490,758)	(10,490,758)
Balance, May 31, 2008 – (Unaudited)	5,720,093	57	45,112,313	0	(37,354,305)	7,758,065
June 1, 2008 – May 31, 2009 – shared-based compensation to board members, employees and consultants	0	0	753,268	0	0	753,268
Net loss for the year ended May 31, 2009	0	0	0	0	(7,230,206)	(7,230,206)
Balance, May 31, 2009	5,720,093	57	45,865,581	0	(44,584,511)	1,281,127
June 1, 2009 – May 31, 2010 – shared-based expense to employees and debt holders	0	0	335,741	0	0	335,741
November 11, 2009 – record beneficial conversion value attached to senior secured convertible debt	0	0	521,793	0	0	521,793
November 11, 2009 – issuance of 8,695,692 shares of common stock at $.23	8,695,652	87	1,999,913	0	0	2,000,000
Net loss for the year ended May 31, 2010	0	0	0	0	(3,067,842)	(3,067,842)
Balance, May 31, 2010	14,415,745	144	48,723,028	0	(47,652,353)	1,070,819
June 1, 2010 – May 31, 2011 – shared-based expense to employees and debt holders	0	0	124,722	0	0	124,722
February 11, 2011 – record beneficial conversion value attached to senior secured convertible debt	0	0	1,616,667	0	0	1,616,667
February 11, 2011 – issuance of 4,510,870 shares of common stock	4,510,870	45	1,037,455	0	0	1,037,500
Net loss for the year ended May31, 2011	0	0	0	0	(3,357,882)	(3,357,882)
Balance, May 31, 2011	18,926,615	189	51,501,872	0	(51,010,235)	491,826
June 1, 2011 – May 31, 2012 – shared-based expense to employees and debt holders	0	0	829,144	0	0	829,144
Net loss for the year ended May31, 2012	0	0	0	0	(4,444,584)	(4,444,584)
Balance, May 31, 2012	18,926,615	189	52,331,016	0	(55,454,819)	(3,123,614)
June 1, 2012 – May 31, 2013 – shared-based expense to employees and debt holders	0	0	906,977	0	0	906,977
Net loss for the year ended May31, 2013	0	0	0	0	(6,280,234)	(6,280,234)
Balance, May 31, 2013	18,926,615	$ 189	$ 53,237,993	$ 0	$(61,735,053)	$ (8,496,871)

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

PROTALEX, INC.
(A Development Stage Company)

STATEMENTS OF CASH FLOWS

	Year Ended May 31, 2013	Year Ended May 31, 2012	From Inception (September 17, 1999) Through May 31, 2013
			(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (6,280,234)	$ (4,444,584)	$ (61,735,053)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities			
(Gain) on disposal of equipment, net	0	0	(81,544)
Depreciation and amortization	1,020	934,544	1,971,143
Equity based expense	906,977	829,144	8,593,971
(Increase)/decrease in:			
Prepaid expenses and deposits	360	(4,239)	(50,310)
Increase/(decrease) in:			
Accounts payable and accrued expenses	638,528	333,505	1,408,205
Net cash and cash equivalents used in operating activities	(4,733,349)	(2,351,630)	(49,893,588)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition of intellectual technology license – fee portion	0	0	(20,000)
Refund of security deposits	0	0	7,990
Acquisition of equipment	0	0	(905,936)
Excess of amounts paid for public shell over assets acquired to be accounted for as a recapitalization	0	0	(250,000)
Proceeds from disposal of equipment	0	0	229,135
Net cash and cash equivalents used in investing activities	0	0	(938,811)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from stock issuance, including options and warrants exercised	0	0	42,658,458
Principal payment on equipment notes payable and capital leases	0	0	(295,411)
Contribution by stockholders	0	0	183,569
Principal payment on note payable to individuals	0	0	(225,717)
Issuance of note payable to individuals	7,000,000	1,000,000	11,368,546
Acquisition of common stock	0	0	(400,000)
Net cash and cash equivalents provided by financing activities	7,000,000	1,000,000	53,289,445
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	2,266,651	(1,351,630)	2,457,046
Cash and cash equivalents, beginning	190,395	1,542,025	0
Cash and cash equivalents, ending	$ 2,457,046	$ 190,395	$ 2,457,046
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:			
Interest paid	$ 0	$ 0	$ 66,770
Taxes paid	$ 0	$ 0	$ 100
NON-CASH FINANCING ACTIVITIES:			
Conversion of debt to equity	$ 0	$ 0	$ 1,037,500

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

PROTALEX, INC.
(A Development Stage Company)
NOTES TO FINANCIAL STATEMENTS
Years Ended May 31, 2013 and 2012

1. ORGANIZATION AND BUSINESS ACTIVITIES

The Company is a development stage company 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 Summit, 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.

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 provided for conversion of interest and principal into shares of the Company's 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 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 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 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 bears interest at a rate of 3% per annum and matures on February 1, 2014.

On June 5, 2012, the Company raised an additional $1,000,000 of working capital pursuant to a 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 May 31, 2014 (the "June 2012 Secured Note").

On October 1, 2012, the Company raised $800,000 of additional working capital pursuant to loans from Niobe and issued to Niobe secured promissory notes in the principal amount of $800,000, which bear interest at a rate of 3% per annum and matures on October 1, 2014 (the "October 2012 Secured Note").

On December 3, 2012, the Company raised $700,000 of additional working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $700,000, which bears interest at a rate of 3% per annum and matures on 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 a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,500,000, which bears interest at a rate of 3% per annum and matures on January 15, 2015 (the "January 2013 Secured Note").

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

Collectively, the January 2013 Secured Note and the May 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 $8,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

Payment of the principal and accrued interest on the Secured Notes will, at Niobe's election, automatically become immediately due and payable if the Company undertakes certain Fundamental Transactions or upon an Event of Default, both as defined in the Secured Notes.

The Company's obligations under the Secured Notes and the Secured Notes are secured by a security agreement granting Niobe a security interest in substantially all of its personal property and assets, including its intellectual property.

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(6) 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.

3. GOING CONCERN

Since inception, the Company has incurred an accumulated deficit of $61,735,053 through May 31, 2013. For the years ended May 31, 2013 and 2012, the Company had net losses of $6,280,234 and $4,444,584, respectively. The Company has used $4,733,349 and $2,351,630 of cash in operating activities for the years ended May 31 2013 and 2012, respectively. As of May 31, 2013, the Company had cash and cash equivalents of $2,457,046 and negative net working capital of $2,445,722. 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 fiscal year 2013 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.

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, 2013 and 2012, the Company had a total of 3,057,543 and 2,268,927, 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 $906,977 and $829,144 for the years ended May 31, 2013 and 2012, 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, 2013 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 77,000 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 the Company's 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, 2013, there were 3,057,543 stock options outstanding. At May 31, 2013, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model was approximately $351,821 (net of estimated forfeitures) and will be recognized over a weighted average period of six months. For the year ended May 31, 2013, the Company granted 1,000,000 stock options, with a fair value of $943,450 (net of estimated forfeitures). 211,385 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, 2013	Year Ended May 31, 2012	From Inception Through May 31, 2013
Dividends per year	0	0	0
Volatility percentage	418%-426 %	97.5 %	90%-426 %
Risk free interest rate	2.13 %	3.47 %	2.07%-5.11 %
Expected life (years)	7-10	7-10	3-10
Weighted Average Fair Value	$ 1.22	$ 1.01	$ 2.30

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, $1,020 and $13,068 for the years ended May 31, 2013, 2012 and from inception through May 31, 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, 2013. 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

Management does not believe that any 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.

5. INCOME TAXES

For the years ended May 31, 2013 and 2012, the components of income tax benefit (expense) consist of the following:

	Year Ended May 31, 2013	Year Ended May 31, 2012
Current:		
Federal	$ 0	$ 0
State	0	0
Deferred:		
Federal	2,135,000	1,511,000
State	377,000	267,000
Tax credits	249,000	109,000
Permanent timing difference	(467,000)	(727,000)
Increase in valuation allowance	(2,294,000)	(1,160,000)
Income tax benefit	$ 0	$ 0

Income tax as a percentage of income for the year ended May 31, 2013 and 2012 differ from statutory federal income tax rates due to the following:

	Year Ended May 31, 2013	Year Ended May 31, 2012
Statutory federal income tax rate	(34)%	(34)%
State income taxes, net of federal income tax impact	(6)%	(6)%
Change in valuation allowance	37 %	26 %
Permanent timing differences	7 %	18 %
General business credit/other	(4)%	(2)%
	0 %	0 %

The components of the net deferred tax asset as of May 31, 2013 and 2012 are as follows:

	May 31, 2013	May 31, 2012
Assets:		
Net operating losses	$ 19,810,000	$ 17,770,000
Severance accrual	0	0
General business credit	2,355,000	2,106,000
Deferred tax assets	22,165,000	19,876,000
Liability:		
Gross deferred tax asset	22,165,000	19,876,000
Less valuation allowance	(22,165,000)	(19,876,000)
Deferred tax asset, net of valuation allowance	$ 0	$ 0

The gross deferred tax assets have been fully offset by a valuation allowance since the Company cannot currently conclude that it is more likely than not that the benefits will be realized. The net operating loss carryforward for income tax purposes of approximately $49,528,000 as of May 31, 2013 expires beginning in 2021 through 2033. 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 and 383 limitations on the amount to be utilized in a given year.

The Company adopted the provisions of the FASB issued accounting guidance, Accounting for Uncertainty in Income Taxes. Previously, the Company had accounted for tax contingencies in accordance with the FASB issued accounting guidance, Accounting for Contingencies. As required by the accounting guidance, Accounting for Income Taxes, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. As of May 31, 2013, the Company has no uncertain tax positions to be disclosed.

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 Company consummated a financing transaction in which it raised $3,000,000 of working capital. 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) the Secured Note.

On February 11, 2011: (i) Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of Common Stock; and (ii) 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") between the Company and 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 Note is 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), bears interest at a rate of 3% per annum and had an original maturity date of December 31, 2012. 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 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bear interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on 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 bears interest at a rate of 3% per annum and matures on May 13, 2015 (the "May 2013 Secured Note").

Collectively, the January 2013 Secured Note and the May 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 $8,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

Payment of the principal and accrued interest on the Secured Notes will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Secured Notes.

The Company's obligations under the $2 Million Secured Convertible Note and the Secured Notes are secured by a security agreement granting Niobe a security interest in substantially all of the Company's personal property and assets, including its intellectual property.

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(6) 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, 2012, the Company issued an aggregate of 450,000 options to Mr. Doherty and Mr. Warshaw. The 450,000 options issued during the fiscal year ended May 31, 2012 have lives that range from 7.5 years to ten years with an exercise price of $1.01. These options vested 50% upon issuance and the remainder will vest on November 1, 2012. The 450,000 options have been valued at $392,730 for which $310,911 of compensation expense has been recorded.

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.

The Company's principal offices are located at 133 Summit Avenue, Suite 22, Summit, New Jersey which are owned by Kirk M. Warshaw, LLC (the "LLC"), an affiliated company of Kirk Warshaw, the Company's chief financial officer. The Company occupies its principal offices on a month to month basis. On March 1, 2010, it began paying a monthly fee of $500 to the LLC for the use and occupancy, and administrative services, related to its principal offices.

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 the Company's 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 the 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, 2013, options to purchase 3,057,543 shares of the Company's Common Stock were outstanding, of which 77,000 were issued and 800 were exercised under the Company's 2003 Stock Option Plan and the remaining 2,980,543 were issued and 400 were exercised as standalone options. As of May 31, 2013, options to purchase 2,302,543 shares of the Company's 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 $943,450 for which $591,629 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.

A summary of the Common Stock option activity for employees, directors, officers and consultants as of May 31, 2013 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
Expired	(211,385)	$ 7.52	0
Outstanding at May 31, 2013	3,057,542	$ 1.09	8.08
Exercisable at May 31, 2013	2,332,543	$ 1.10	7.60

The outstanding and exercisable stock options as of May 31, 2013 and 2012 had an intrinsic value of $351,821 and $692,902, respectively.

The 1,000,000 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, 2013:

	Total			Exercisable		
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	7.07	1,230,543	$ 0.44	7.07
$1.01 – 5.00	1,750,000	$ 1.13	8.95	1,025,000	1.13	8.95
$5.01 – 10.00	40,000	$ 7.50	.3	40,000	$ 7.50	.3
$10.01 – 15.00	37,000	$ 13.86	2.6	37,000	$ 13.86	2.6
	3,057,543	$ 1.09	8.08	2,332,543	$ 1.10	7.60

8. SENIOR SECURED CONVERTIBLE NOTE - RELATED PARTY

On November 11, 2009, the Company issued a $1 Million Secured Note to Niobe, its majority stockholder, which is controlled by the Company's President and Director, Arnold P. Kling. The $1 Million Secured Note bears interest at a rate of 3% per annum and matures on November 13, 2012. In order to secure its obligations under the $1 Million Secured Note, the Company also entered into a Security Agreement dated November 11, 2009 (the "Security Agreement") granting Niobe a security interest in substantially all of its personal property and assets, including its intellectual property.

The Company evaluated the conversion feature of the $1 Million Secured Note and determined that under the accounting guidance for "Accounting for Convertible Securities with Beneficial Conversion Features" that a value should be attributed to the embedded conversion feature. On November 11, 2009, the date of issuance of the $1 Million Secured Note, the fair market value of each of the Company's shares was $0.35. The Company has determined that the maximum allocation to the conversion feature should be $521,793 and will reduce the face amount of the convertible debt carried on its balance sheet. This discount will be amortized over 36 months and will serve to increase the interest expense of the $1 Million Secured Note during its term.

On December 2, 2009, the Company entered into a Credit Facility Agreement dated December 2, 2009 (the "Facility") with Niobe which will provide up to $2.0 million of additional capital in the form of secured loans from Niobe at any time prior to June 30, 2012 subject to the achievement of certain predetermined benchmarks.

On February 11, 2011, pursuant to the terms of the $1 Million Secured Note, Niobe exercised their right to convert the debt into equity. As a result, the Company issued 4,510,870 shares of Common Stock to Niobe and canceled the $1 million obligation as well as $37,500 of accrued interest thereon.

For the purpose of providing the Company with additional working capital, on February 11, 2011, pursuant to the Credit Facility Agreement, Niobe acquired from the Company a senior secured convertible promissory note, dated February 11, 2011 (the "$2 Million Secured Convertible Note"), in the principal amount of $2,000,000, convertible into Common Stock at a conversion price equal to $0.23 per share for an aggregate of 8,695,652 shares of Common Stock (not including accrued interest thereon.) The $2 Million Secured Convertible Note bears interest at a rate of 3% per annum and had an original maturity date of December 31, 2012. In December 2012, Niobe agreed, for no consideration, to extend the maturity date to December 31, 2013.

The Company evaluated the conversion feature of the $2 Million Secured Convertible Note and determined that under the accounting guidance for "Accounting for Convertible Securities with Beneficial Conversion Features" that a value should be attributed to the embedded conversion feature. On February 11, 2011, the date of issuance of the $2 Million Secured Convertible Note, the fair market value of each of the Company's shares was $1.20. The Company determined that the maximum allocation to the conversion feature should be $1,616,667 and reduced the face amount of the convertible debt carried on its balance sheet. This discount was amortized over 22 months and served to increase the interest expense of the Secured Note during its term. As of May 31, 2013, none of the original discount remained.

In connection with the Facility, on December 2, 2009, the Security Agreement securing the Company's obligations under the $1 Million Secured Note was amended and restated to also secure any incremental obligations under the Facility (the "Amended Security Agreement"). Pursuant to the Amended Security Agreement, Niobe has a security interest in substantially all of its personal property and assets, including its intellectual property to collateralize all amounts due to it under the Secured Note and the Facility.

The Amended Security Agreement was amended in connection with the Company's issuance of the Secured Notes (as described in Note 9, below).

9. SENIOR SECURED NOTE – RELATED PARTY

On February 1, 2012, the Company raised $1,000,000 of working capital pursuant to a loan from Niobe its majority stockholder, which is controlled by the Company's President and Director, Arnold P. Kling. 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 bears interest at a rate of 3% per annum and matures on February 1, 2014.

On June 5, 2012, the Company raised an additional $1,000,000 of working capital pursuant to a 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 May 31, 2014 (the "June 2012 Secured Note").

On October 1, 2012, the Company raised $800,000 of additional working capital pursuant to loans from Niobe and issued to Niobe secured promissory notes in the principal amount of $800,000, which bear interest at a rate of 3% per annum and matures on October 1, 2014 (the "October 2012 Secured Note").

On December 3, 2012, the Company raised $700,000 of additional working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $700,000, which bears interest at a rate of 3% per annum and matures on 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 a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $2,500,000, which bears interest at a rate of 3% per annum and matures on January 15, 2015 (the "January 2013 Secured Note").

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

Collectively, the January 2013 Secured Note and the May 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 $8,000,000 in principal amount of loans from Niobe and are hereinafter referred to as the "Secured Notes."

Payment of the principal and accrued interest on the Secured Notes will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Secured Notes.

The Company's obligations under the $2 Million Secured Convertible Note and the Secured Notes are secured by a security agreement granting Niobe a security interest in substantially all of the Company's personal property and assets, including its intellectual property.

10. 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.

The data presented for stockholders' equity for the period of September 2003 to May 31, 2008 is unaudited.

On September 18, 2003, the Company raised $12,657,599 through the sale of 1,489,129 shares of Common Stock at $8.50 per share, with warrants to purchase an additional 632,879 shares of 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, the Company's proceeds were $11,356,063.

On May 25, 2005, the Company raised $5,057,885 through the sale of 518,758 shares of Common Stock at $9.75 per share, with warrants to purchase an additional 184,024 shares of 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, the Company's proceeds were $4,851,168.

On December 30, 2005, the Company raised $5,839,059 through the sale of 519,026 shares of Common Stock at $11.25 per share, with warrants to purchase an additional 129,757 shares of Common Stock, at an exercise price of $14.95 per share. The Company also issued warrants to purchase 45,415 shares of 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, the Company's 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, the Company raised $14,217,660, net of transaction costs of $959,874, through the sale of 1,214,203 shares of Common Stock at $12.50 per share, with warrants to purchase an additional 303,551 shares of Common Stock, at an exercise price of $19.25 per share. The Company also issued warrants to purchase 106,243 shares of 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 (the "Effective Date"), the Company consummated a financing transaction in which it raised $3,000,000 of additional working capital pursuant to a Securities Purchase Agreement dated that date (the "Purchase Agreement") with Niobe Ventures, LLC ("Niobe"), a Delaware limited liability company (the "Financing"). Pursuant to the Purchase Agreement, the Company issued to the Investor (i) 8,695,652 restricted shares of Common Stock at a purchase price of $0.23 per share (or $2,000,000 in the aggregate) and (ii) a senior secured convertible promissory note in the principal amount of $1,000,000 and convertible into shares of Common Stock at an initial conversion price equal to $0.23 per share (the "$1 Million Secured Note").

On December 2, 2009, the Company entered into the Facility with Niobe, which will provide up to $2.0 million of additional capital in the form of secured loans from Niobe to the Company at any time prior to June 30, 2012 subject to its achievement of certain predetermined benchmarks. On February 11, 2011, Niobe, pursuant to the Facility, advanced the Company $2 million. On the same date, Niobe converted the $1 million Secured Note and $37,500 of accrued interest thereon, into 4,510,870 shares of Common Stock.

11. SUBSEQUENT EVENTS

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

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

THIS NOTE HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), NOR UNDER ANY STATE SECURITIES LAW AND MAY NOT BE SOLD, PLEDGED, OFFERED FOR SALE, ASSIGNED OR TRANSFERRED UNLESS (a) A REGISTRATION STATEMENT WITH RESPECT THERETO IS EFFECTIVE UNDER THE SECURITIES ACT, AND ANY APPLICABLE STATE SECURITIES LAW REQUIREMENTS HAVE BEEN MET OR (B) EXEMPTIONS FROM THE REGISTRATION REQUIREMENTS UNDER THE SECURITIES ACT AND THE REGISTRATION OR QUALIFICATION REQUIREMENTS OF APPLICABLE STATE SECURITIES LAWS ARE AVAILABLE.

PROMISSORY NOTE

$1,000,000

August 27, 2013
New York, New York

FOR VALUE RECEIVED, Protalex, Inc., a Delaware corporation (the "Company"), promises to pay to the order of Niobe Ventures, LLC ("Holder"), at the offices of Morse, Zelnick, Rose & Lander LLP, 405 Park Avenue, Suite 1401, New York, New York 10022, the principal sum of **One Million U.S. Dollars** (U.S. $1,000,000) with interest thereon at the rate of three percent (3%) per annum. Any amounts that remain unpaid after the Maturity Date shall thereafter bear interest at the rate of twelve percent (12%) per annum. Interest as aforesaid shall be calculated on the basis of actual number of days elapsed over a year of 360 days.

The principal amount and all accrued interest of this Note are due on August 27, 2015 (the "Maturity Date"). The Maturity Date is subject to acceleration in accordance with Section 3.

This Note is subject to the following additional provisions:

Section 1. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Note the following terms shall have the following meanings:

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

"Event of Default" shall have the meaning set forth in Section 4.

"Fundamental Transaction" shall have the meaning set forth in Section 3.

"Original Issue Date" means the date of the first issuance of this Note regardless of the number of transfers of any Note and regardless of the number of instruments which may be issued to evidence such Note.

"Person" means a corporation, an association, a partnership, organization, a business, an individual, a government or political subdivision thereof or a governmental agency.

"Security Agreement" means the Seventh Amended and Restated Security Agreement dated as of May 13, 2013 by and between the Company and the Holder.

"Subsidiary" means any Person in which the Company owns more than 50% of the outstanding equity.

"Transaction Documents" means the Security Agreement and this Note.

Section 2. Registration of Transfers and Exchanges.

a) Different Denominations. This Note is exchangeable for an equal aggregate principal amount of Notes of different authorized denominations as requested by the Holder surrendering the same, No service charge will be made for such registration of transfer or exchange.

b) Reliance on Note Register. Prior to due presentment to the Company for transfer of this Note, the Company and any agent of the Company may treat the Person in whose name this Note is duly registered on the Company's books and records as the owner hereof for the purpose of receiving payment as herein provided and for all other purposes, whether or not this Note is overdue, and neither the Company nor any such agent shall be affected by notice to the contrary.

Section 3. Acceleration of Maturity Date.

If, at any time while this Note is outstanding (A) the Company receives aggregate gross proceeds of $7,500,000 or more from the sale of any of its equity securities, (B) the Company effects any merger or consolidation of the Company with or into another Person, (C) the Company effects any sale of all or substantially all of its assets in one or a series of related transactions, (D) any tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to tender or exchange their shares for other securities, cash or property, or (E) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (in any such case, a "Fundamental Transaction"), then, immediately prior to the occurrence of such Fundamental Transaction the principal and accrued but unpaid interest payable hereunder shall automatically become, at the Holder's election, immediately due and payable in cash.

Section 4. Events of Default.

a) Event of Default. Wherever used herein, means any one of the following events (whatever the reason and whether it shall be voluntary or involuntary or effected by operation of law or pursuant to any judgment, decree or order of any court, or any order, rule or regulation of any administrative or governmental body):

i. any default in the payment of (A) the principal, or (B) interest on this Note or any other note issued by the Company to the Holder as and when the same shall become due and payable (whether on the Maturity Date or by acceleration or otherwise) which default is not cured within ten (10) Business Days after written notice from the Holder;

ii. (A) there is commenced against the Company or any Subsidiary thereof a case under any applicable bankruptcy or insolvency laws as now or hereafter in effect or any successor thereto, or any other proceeding under any reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction whether now or hereafter in effect relating to the Company or any Subsidiary thereof which remains undismissed for a period of 60 days; or (B) the Company or any Subsidiary thereof is adjudicated by a court of competent jurisdiction insolvent or bankrupt; or any order of relief or other order approving any such case or proceeding is entered; or (C) the Company or any Subsidiary thereof suffers any appointment of any custodian or the like for it or any substantial part of its property which continues undischarged or unstayed for a period of 60 days.

b) Remedies Upon Event of Default. If any Event of Default occurs, the full principal amount of this Note, together with interest and other amounts owing in respect thereof, to the date of acceleration shall become, at the Holder's election, immediately due and payable in cash. The Holder need not provide and the Company hereby waives any presentment, demand, protest or other notice of any kind, and the Holder may immediately and without expiration of any grace period enforce any and all of its rights and remedies hereunder and all other remedies available to it under applicable law. Such declaration may be rescinded and annulled by Holder at any time prior to payment hereunder and the Holder shall have all rights as a Note holder until such time, if any, as the full payment under this Section shall have been received by it. No such rescission or annulment shall affect any subsequent Event of Default or impair any right consequent thereon.

Section 5. Miscellaneous.

a) Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder shall be in writing and delivered personally, by facsimile, sent by a nationally recognized overnight courier service, addressed to the Company, at 133 Summit Avenue, Suite 22, Summit, NJ 07901, attention: Chief Financial Officer, or such other address or facsimile number as the Company may specify for such purposes by notice to the Holder delivered in accordance with this Section. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile, sent by a nationally recognized overnight courier service addressed to the Holder at the facsimile, telephone number or address of such Holder appearing on the books of the Company, or if no such facsimile telephone number or address appears, at the principal place of business of the Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile telephone number specified in this Section prior to 5:30 p.m. (New York City time), (ii) the date after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile telephone number specified in this Section later than 5:30 p.m. (New York City time) on any date and earlier than 11:59 p.m. (New York City time) on such date, (iii) the second Business Day following the date of mailing, if sent by nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

b) Absolute Obligation. Except as expressly provided herein, no provision of this Note shall alter or impair the obligation of the Company, which is absolute and unconditional, to pay the principal of, interest and liquidated damages (if any) on, this Note at the time, place, and rate, and in the coin or currency, herein prescribed. This Note is a direct debt obligation of the Company.

c) Lost or Mutilated Note. If this Note shall be mutilated, lost, stolen or destroyed, the Company shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated Note, or in lieu of or in substitution for a lost, stolen or destroyed Note, a new Note for the principal amount of this Note so mutilated, lost, stolen or destroyed but only upon receipt of evidence of such loss, theft or destruction of such Note, and of the ownership hereof; and indemnity, if requested, all reasonably satisfactory to the Company.

d) Security Interest. This Note is a direct debt obligation of the Company and, pursuant to the Security Agreement all of the Company's obligations hereunder are secured by a first priority perfected security interest in all of the assets of the Company for the benefit of the Holder.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Note, and any claim, controversy or dispute arising under or related to this Note, the relationship of the parties, and/or the interpretation and enforcement of the rights and duties of the parties hereunder 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 any of the Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state or federal courts sitting in the City of New York, Borough of Manhattan (the "New York Courts"). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the New York Courts 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, or such New York Courts are improper or 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 Note 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 manner permitted by law. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Note or the transactions contemplated hereby. If either party shall commence an action or proceeding to enforce any provisions of this Note, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Waiver. Any waiver by the Company or the Holder of a breach of any provision of this Note shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Note. The failure of the Company or the Holder to insist upon strict adherence to any term of this Note on one or more occasions shall not be considered a waiver or deprive that party of the right thereafter to insist upon strict adherence to that term or any other term of this Note. Any waiver must be in writing.

g) Severability. If any provision of this Note is invalid, illegal or unenforceable, the balance of this Note shall remain in effect, and if any provision is inapplicable to any person or circumstance, it shall nevertheless remain applicable to all other persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates applicable laws governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum permitted rate of interest. The Company covenants (to the extent that it may lawfully do so) that it shall not at any time insist upon, plead, or in any manner whatsoever claim or take the benefit or advantage of, any stay, extension or usury law or other law which would prohibit or forgive the Company from paying all or any portion of the principal of or interest on this Note as contemplated herein, wherever enacted, now or at any time hereafter in force, or which may affect the covenants or the performance of this indenture, and due Company (to the extent it may lawfully do so) hereby expressly waives all benefits or advantage of any such law, and covenants that it will not, by resort to any such law, binder, delay or impeded the execution of any power herein granted to the Holder, but will suffer and permit the execution of every such as though no such law has been enacted.

h) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

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

IN WITNESS WHEREOF, the Company has caused this Note to be duly executed by a duly authorized officer as of the date first above indicated.

PROTALEX, INC.

By: /s/ Kirk M. Warshaw
Kirk M. Warshaw, Chief Financial Officer

EIGHTH AMENDED AND RESTATED SECURITY AGREEMENT

THIS EIGHTH AMENDED AND RESTATED SECURITY AGREEMENT (this "**Agreement**"), dated as of August 27, 2013, is made by and among Protalex, Inc. a Delaware corporation, (the "**Grantor**"), and Niobe Ventures, LLC (the "**Secured Party**") and amends and restates in its entirety the Seventh Amended and Restated Security Agreement dated as of May 13, 2013 by and between Grantor and Secured Party.

WHEREAS, the Grantor has issued and outstanding to the Secured Party senior secured promissory notes in the aggregate principal amount of $8,000,000 (the "**Outstanding Notes**").

WHEREAS, the Secured Party has made an additional loan to the Grantor and, in that connection, the Grantor has issued to the Secured Party a secured promissory note in the principal amount of One Million Dollars ($1,000,000) dated of even date herewith (such note, as amended or modified from time to time, the "**New Note**").

WHEREAS, the Grantor and the Secured Party have agreed to execute and deliver this Agreement, among other things, to secure the obligations of the Grantor under the Outstanding Notes and the New Note (hereinafter collectively the "**Notes**").

The Grantor and the Secured Party hereby agree as follows:

SECTION 1. Definitions; Interpretation.

(a) As used in this Agreement, the following terms shall have the following meanings:

"**Collateral**" means the property described on Exhibit A attached hereto and all Negotiable Collateral and Intellectual Property to the extent not described on Exhibit A, except (i) to the extent any such property is nonassignable by its terms without the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, applicable provisions of the New York Uniform Commercial Code as amended or supplemented from time to time.), or (ii) the granting of a security interest in such property is contrary to applicable law, provided that upon the cessation of any such restriction or prohibition, such property shall automatically become part of the Collateral.

"**Copyrights"** means any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret, now or hereafter existing, created, acquired or held.

"**Event of Default**" has the meaning set forth in the Notes.

"Intellectual Property" means all of Grantor's right, title, and interest in and to the following, except to the extent any security interest hereunder would cause any application for a Trademark to be deemed invalidated, canceled or abandoned due to the grant and/or enforcement of such security interest, including, without limitation, all U.S. trademark applications that are based on an intent-to-use, unless and until such time that the grant and/or enforcement of the security interest will not affect the status or validity of such trademark:

(a) Copyrights, Trademarks and Patents;

(b) and all trade secrets, and any and all intellectual property rights in computer software and computer software products now or hereafter existing, created, acquired or held;

(c) and all design rights which may be available to Grantor now or hereafter existing, created, acquired or held;

(d) and all claims for damages by way of past, present and future infringement of any of the rights included above, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the intellectual property rights identified above;

(e) licenses or other rights to use any of the Copyrights, Patents or Trademarks, and all license fees and royalties arising from such use to the extent permitted by such license or rights;

(f) amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents; and

(g) proceeds and products of the foregoing, including without limitation all payments under insurance or any indemnity or warranty payable in respect of any of the foregoing.

"**Lien**" means any mortgage, deed of trust, pledge, security interest, assignment, deposit arrangement, charge or encumbrance, lien, or other type of preferential arrangement.

"**Obligations**" means the indebtedness, liabilities and other obligations of the Grantor to the Secured Party under Notes including without limitation, the unpaid principal of the Notes and all interest accrued thereon payable by the Grantor to the Secured Party thereunder or in connection therewith.

"Patents" means all patents, patent applications and like protections, including, without limitation, improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"**Permitted Liens**" mean: (i) Liens in favor of the Secured Party in respect of the Obligations hereunder; (ii) Liens for taxes, fees, assessments or other governmental charges or levies, either not delinquent or being contested in good faith by appropriate proceedings and which are adequately reserved for in accordance with GAAP; (iii) Liens of materialmen, mechanics, warehousemen, carriers or employees or other like Liens arising in the ordinary course of business and securing obligations either not delinquent or being contested in good faith by appropriate proceedings; (iv) Liens consisting of deposits or pledges to secure the payment of worker's compensation, unemployment insurance or other social security benefits or obligations, or to secure the performance of bids, trade contracts, leases, public or statutory obligations, surety or appeal bonds or other obligations of a like nature incurred in the ordinary course of business; (v) easements, rights of way, servitudes or zoning or building restrictions and other minor encumbrances on real property and irregularities in the title to such property which do not in the aggregate materially impair the use or value of such property or risk the loss or forfeiture of title thereto; and (vi) Liens upon or in any equipment now or hereafter acquired or held by the Grantor to secure the purchase price of such equipment or indebtedness incurred solely for the purpose of financing or refinancing the acquisition of such equipment, provided that the Lien is confined solely to the equipment so acquired and accessions thereon and proceeds thereof.

"**Person**" means an individual, corporation, partnership, joint venture, trust, unincorporated organization, governmental agency or authority, or any other entity of whatever nature.

"Trademarks" means any trademark and service mark rights, whether registered or not, applications to register and registrations of the same and like protections, and the parts of the goodwill of the business connected with the use of and symbolized by such marks.

"**UCC**" means the Uniform Commercial Code as the same may, from time to time, be in effect in the State of New York.

(b) Where applicable and except as otherwise defined herein, terms used in this Agreement shall have the meanings assigned to them in the UCC.

(c) In this Agreement, (i) the meaning of defined terms shall be equally applicable to both the singular and plural forms of the terms defined; (ii) the captions and headings are for convenience of reference only and shall not affect the construction of this Agreement; (iii) the words "hereof," "herein," "hereto," "hereunder" and the like mean and refer to this Agreement as a whole and not merely to the specific Article, Section, subsection, paragraph or clause in which the respective word appears; (iv) the words "including," "includes" and "include" shall be deemed to be followed by the words "without limitation;" and (v) the term "or" shall not be limiting.

SECTION 2. Security Interest.

(a) Subject to the Permitted Liens, as security for the payment and performance of the Obligations, the Grantor hereby pledges, assigns and grants to the Secured Party a security interest in all of the Grantor's right, title and interest in, to and under all of the Collateral (other than as set forth in Section 2(b) hereof).

(b) Notwithstanding the foregoing, except for fixtures (to the extent covered by Article 9 of the UCC), such grant of a security interest shall not extend to, and the term "Collateral" shall not include, any asset which would be real property under the law of the jurisdiction in which it is located.

(c) This Agreement shall create a continuing security interest in the Collateral that shall remain in effect until terminated in accordance with the provisions hereof.

SECTION 3. Financing Statements, Etc. The Grantor hereby authorizes the Secured Party to file (with a copy thereof to be provided to the Grantor contemporaneously therewith), at any time and from time to time thereafter, all financing statements, financing statement assignments, continuation financing statements, and UCC filings, in form reasonably satisfactory to the Secured Party. The Grantor shall execute and deliver and shall take all other action, as the Secured Party may reasonably request, to perfect and continue perfected, maintain the priority of or provide notice of the security interest of the Secured Party in the Collateral (subject to the terms hereof) and to accomplish the purposes of this Agreement. Without limiting the generality of the foregoing, the Grantor ratifies and authorizes the filing by the Secured Party of any financing statements filed prior to the date hereof that accomplish the purposes of this Agreement.

SECTION 4. Representations and Warranties. The Grantor represents and warrants to the Secured Party that:

(a) Grantor is a business entity duly formed, validly existing and in good standing under the law of the jurisdiction of its organization and has all requisite power and authority to execute, deliver and perform its obligations under this Agreement.

(b) The execution, delivery and performance by the Grantor of this Agreement has been duly authorized by all necessary corporate action of the Grantor, and this Agreement constitutes the legal, valid and binding obligation of the Grantor, enforceable against the Grantor in accordance with its terms, except as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance and other laws of general application affecting enforcement of creditors' rights generally, as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(c) Except for the filing of appropriate financing statements, no authorization, consent, approval, license, exemption of, or filing or registration with, any governmental authority or agency, or approval or consent of any other Person, is required for the due execution, delivery or performance by the Grantor of this Agreement unless the same has already been obtained or is being obtained simultaneously in connection herewith.

(d) This Agreement creates a security interest that is enforceable against the Collateral in which the Grantor now has rights and will create a security interest that is enforceable against the Collateral in which the Grantor hereafter acquires rights at the time the Grantor acquires any such rights.

(e) The Grantor has the right and power to grant the security interests in the Collateral to the Secured Party in the Collateral, and the Grantor is the sole and complete owner of the Collateral, free from any Lien other than the Permitted Liens.

SECTION 5. Covenants of the Grantor. Until this Agreement has terminated in accordance with the terms hereof, the Grantor agrees to do the following:

(a) The Grantor shall give prompt written notice to the Secured Party (and in any event not later than ten (10) days following any change described below in this subsection) of: (i) any change in the Grantor's name; (ii) any changes in the Grantor's identity or structure in any manner which might make any financing statement filed hereunder incorrect or misleading; or (iii) any change in jurisdiction of organization; provided that the Grantor shall not locate any Collateral outside of the United States nor shall the Grantor change its jurisdiction of organization to a jurisdiction outside of the United States.

(b) The Grantor shall not surrender or lose possession of, sell, lease, rent or otherwise dispose of or transfer any of the Collateral or any right or interest therein, except in the ordinary course of business consistent with past practice and except to the extent of equipment that is obsolete or no longer useful to its business.

(c) The Grantor shall keep the Collateral free of all Liens except the Permitted Liens.

SECTION 6. Collection of Accounts. The Grantor shall endeavor in the first instance diligently to collect all amounts due or to become due on or with respect to the accounts and other rights to payment.

SECTION 7. Authorization; Secured Party Appointed Attorney-in-Fact. The Secured Party shall have the right, to, in the name of the Grantor, or in the name of the Secured Party or otherwise, upon notice to, but without the requirement of assent by the Grantor, and the Grantor hereby constitutes and appoints the Secured Party (and any employees or agents designated by a Secured Party) as the Grantor's true and lawful attorney-in-fact, with full power and authority to: (i) assert, adjust, sue for, compromise or release any claims under any policies of insurance; and (ii), execute any and all such other documents and instruments, and do any and all acts and things for and on behalf of the Grantor, that such Secured Party may deem necessary or advisable to maintain, protect, realize upon and preserve the Collateral and the Secured Party's security interests therein and to accomplish the purposes of this Agreement. The Secured Party agrees that, except upon and during the continuance of an Event of Default, it shall not exercise the power of attorney, or any rights granted to the Secured Party under this Section 7. The foregoing power of attorney is coupled with an interest and is irrevocable so long as the Obligations have not been indefeasibly paid and performed in full and the commitments not terminated. The Grantor hereby ratifies, to the extent permitted by law, all that the Secured Party shall lawfully and in good faith do or cause to be done by virtue of and in compliance with this Section 7.

SECTION 8. Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, the Secured Party shall have, in addition to all other rights and remedies granted to the Secured Party in this Agreement or the Notes, all rights and remedies of a secured party under the UCC and other applicable laws. Without limiting the generality of the foregoing, upon the occurrence and during the continuance of an Event of Default, the Secured Party may sell, resell, lease, use, assign, license, sublicense, transfer or otherwise dispose of any or all of the Collateral in its then condition or following any commercially reasonable preparation or processing (utilizing in connection therewith any of Grantor's assets, without charge or liability to any Secured Party therefor) at public or private sale, by one or more contracts, in one or more parcels, at the same or different times, for cash or credit, or for future delivery without assumption of any credit risk, all as the Secured Party deem advisable; provided, however, that the Grantor shall be credited with the net proceeds of sale only when such proceeds are finally collected by the Secured Party. Each Secured Party shall have the right upon any such public sale, and, to the extent permitted by law, upon any such private sale, to purchase the whole or any part of the Collateral so sold, free of any right or equity of redemption, which right or equity of redemption the Grantor hereby releases, to the extent permitted by law. The Grantor hereby agrees that the sending of notice by ordinary mail, postage prepaid, to the address of the Grantor set forth herein or subsequent address that the Grantor provides to the Secured Party in writing, of the place and time of any public sale or of the time after which any private sale or other intended disposition is to be made, shall be deemed reasonable notice thereof if such notice is sent ten (10) business days prior to the date of such sale or other disposition or the date on or after which such sale or other disposition may occur.

(b) The cash proceeds actually received from the sale or other disposition or collection of the Collateral, and any other amounts received in respect of the Collateral the application of which is not otherwise provided for herein shall be applied first, to the payment of the reasonable costs and expenses of the Secured Party in exercising or enforcing their rights hereunder and in collecting or attempting to collect any of the Collateral, and to the payment of all other amounts payable to the Secured Party pursuant to Section 12 hereof; and second, to the payment of the Obligations. Any surplus thereof that exists after payment and performance in full of the Obligations shall be promptly paid over to the Grantor or otherwise disposed of in accordance with the UCC or other applicable law. The Grantor shall remain liable to the Secured Party for any deficiency that exists after any sale or other disposition or collection of the Collateral.

SECTION 9. Certain Waivers.

(a) The Grantor waives, to the fullest extent permitted by law: (i) any right of redemption with respect to the Collateral, whether before or after sale hereunder, and all rights, if any, of marshalling of the Collateral or other collateral or security for the Obligations; (ii) any right to require the Secured Party to: (A) proceed against any Person, (B) exhaust any other collateral or security for any of the Obligations, (C) pursue any remedy in the Secured Party's power or (D) except as provided herein or in any of the Notes, make or give any presentments, demands for performance, notices of nonperformance, protests, notices of protests or notices of dishonor in connection with any of the Collateral; and (iii) all claims, damages and demands against the Secured Party arising out of the repossession, retention, sale or application of the proceeds of any sale of the Collateral.

SECTION 10. Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally or sent by nationally-recognized overnight courier or by registered or certified mail, postage prepaid, return receipt requested or by facsimile, with confirmation as provided above addressed as follows:

If to Grantor:

Protalex, Inc.
133 Summit Avenue, Suite 22,
Summit, NJ 07901
Attention: Chief Financial Officer

With copies to:

Morse, Zelnick, Rose & Lander LLP
405 Park Avenue, Suite 1401
New York, NY 10022
Attention: Kenneth S. Rose, Esq.
Fax: 212-208-6809

If to the Secured Party:

Niobe Ventures, LLC
c/o Arnold P. Kling
410 Park Avenue, Suite 1710
New York, NY 10022
Attention: Arnold Kling, Managing Member
Fax: 212-713-1818

With a copy to:

Morse, Zelnick, Rose & Lander LLP
405 Park Avenue, Suite 1401
New York, NY 10022
Attention: Kenneth S. Rose, Esq.
Fax: 212-208-6809

SECTION 11. No Waiver; Cumulative Remedies. No failure on the part of the Secured Party to exercise, and no delay in exercising, any right, remedy, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, remedy, power or privilege preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege. The rights and remedies under this Agreement are cumulative and not exclusive of any rights, remedies, powers and privileges that may otherwise be available to the Secured Party.

SECTION 12. Costs and Expenses. The Grantor agrees to pay all reasonable costs and expenses of the Secured Party, in connection with the enforcement and preservation of any rights or interests under, this Agreement and the protection, sale or collection of, or other realization upon, any of the Collateral, including all reasonable expenses of taking, collecting, holding, sorting, handling, preparing for sale, selling or the like and other such expenses of sales and collections of the Collateral.

SECTION 13. Binding Effect. This Agreement shall be binding upon, inure to the benefit of and be enforceable by the Grantor, the Secured Party and their respective successors and assigns.

SECTION 14. Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York without regard to principles of conflict of laws.

SECTION 15. Entire Agreement; Amendment. This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and shall not be amended except by the written agreement of the Grantor and the Secured Party. Notwithstanding the foregoing, this Agreement may not be amended and any term hereunder may not be waived with respect to any Secured Party without the written consent of such Secured Party unless such amendment or waiver applies to all Secured Party in the same fashion.

SECTION 16. Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be valid, legal and enforceable under all applicable laws and regulations. If, however, any provision of this Agreement shall be invalid, illegal or unenforceable under any such law or regulation in any jurisdiction, it shall, as to such jurisdiction, be deemed modified to conform to the minimum requirements of such law or regulation, or, if for any reason it is not deemed so modified, it shall be invalid, illegal or unenforceable only to the extent of such invalidity, illegality or limitation on enforceability without affecting the remaining provisions of this Agreement, or the validity, legality or enforceability of such provision in any other jurisdiction.

SECTION 17. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

SECTION 18. Termination. Upon the payment and performance in full of all Obligations, this Agreement shall terminate and the Secured Party shall promptly, at the cost of the Grantor, execute and deliver to the Grantor such documents and instruments reasonably requested by the Grantor as shall be necessary to evidence termination of all security interests given by the Grantor to the Secured Party hereunder; provided, however, that the obligations of the Grantor under Section 12 hereof shall survive such termination.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement, as of the date first above written.

GRANTOR:

PROTALEX, INC.

By: /s/ Kirk M. Warshaw
Kirk M. Warshaw, Chief Financial Officer

NIOBE VENTURES, LLC

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

EXHIBIT A

COLLATERAL DESCRIPTION ATTACHMENT TO SEVENTH AMENDED AND RESTATED SECURITY AGREEMENT

DEBTOR **PROTALEX, INC., a Delaware corporation**

SECURED PARTY: **Niobe Ventures, LLC**

All personal property of Grantor (herein referred to as "Grantor" or "Debtor") whether presently existing or hereafter created or acquired, and wherever located including, without limitation:

(a) all accounts (including health-care-insurance receivables), chattel paper (including tangible and electronic chattel paper), deposit accounts, documents (including negotiable documents), equipment (including all accessions and additions thereto), general intangibles (including payment intangibles and software), goods (including fixtures), instruments (including promissory notes), inventory (including all goods held for sale or lease or to be furnished under a contract of service, and including returns and repossessions), investment property (including securities and securities entitlements), letter of credit rights, money, and all of Grantor's books and records with respect to any of the foregoing, and the computers and equipment containing said books and records; provided that notwithstanding the foregoing, "Collateral" shall not include more than 65% of the stock of any subsidiary that is not incorporated, formed or organized under the laws of the United States, any state thereof or the District of Columbia (a "Foreign Subsidiary"), or more than 65% of the stock of any subsidiary substantially all of the assets of which are stock in Foreign Subsidiaries;

(b) all common law and statutory copyrights and copyright registrations, applications for registration, now existing or hereafter arising, in the United States of America or in any foreign jurisdiction, obtained or to be obtained on or in connection with any of the foregoing, or any parts thereof or any underlying or component elements of any of the foregoing, together with the right to copyright and all rights to renew or extend such copyrights and the right (but not the obligation) of Secured Party to sue in their own name and/or in the name of the Debtor for past, present and future infringements of copyright;

(c) all trademarks, service marks, trade names and service names and the goodwill associated therewith, together with the right to trademark and all rights to renew or extend such trademarks and the right (but not the obligation) of Secured Party to sue in their own name and/or in the name of the Debtor for past, present and future infringements of trademark;

(d) all (i) patents and patent applications filed in the United States Patent and Trademark Office or any similar office of any foreign jurisdiction, and interests under patent license agreements, including, without limitation, the inventions and improvements described and claimed therein, (ii) licenses pertaining to any patent whether Debtor is licensor or licensee, (iii) income, royalties, damages, payments, accounts and accounts receivable now or hereafter due and/or payable under and with respect thereto, including, without limitation, damages and payments for past, present or future infringements thereof, (iv) right (but not the obligation) to sue in the name of Debtor and/or in the name of Secured Party for past, present and future infringements thereof, (v) rights corresponding thereto throughout the world in all jurisdictions in which such patents have been issued or applied for, and (vi) reissues, divisions, continuations, renewals, extensions and continuations-in-part with respect to any of the foregoing; and

(e) any and all cash proceeds and/or non-cash proceeds of any of the foregoing, including, without limitation, insurance proceeds, and all supporting obligations and the security therefor or for any right to payment. All terms above have the meanings given to them in the New York Uniform Commercial Code, as amended or supplemented from time to time.

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 27, 2013, with respect to the financial statements, which appear in the Annual Report of Protalex, Inc. on Form 10-K for the year ended May 31, 2013.

/s/ Liggett, Vogt & Webb, P.A.
LIGGETT, VOGT & WEBB, P.A.

New York, NY
August 28, 2013

EXHIBIT 23.2

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 24, 2012, with respect to the financial statements, which appear in the Annual Report of Protalex, Inc. on Form 10-K for the year ended May 31, 2013.

/s/ *SHERB & CO, LLP.*
SHERB & CO, LLP.

New York, NY
August 28, 2013

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 28, 2013

/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 28, 2013

/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, 2013 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 28, 2013

/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, 2013 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 28, 2013

/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.