PROTALEX INC
Form 10-K
August 29, 2012

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, 2012

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 x

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 x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§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 x No ¨

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

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 filero Non-accelerated filero Smaller Reporting Company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ¨ No x

The approximate aggregate market value of Common Stock held by non-affiliates of the registrant was $6,400,000 as of November 30, 2011, 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 24, 2012 was 18,926,615.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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 which has been engaged in developing a class of biopharmaceutical drugs designed to treat autoimmune and inflammatory diseases including, but not to limited to, rheumatoid arthritis (RA). Our lead product, PRTX-100, is formulated with highly-purified staphylococcal protein A, which is an immune modulating protein produced by bacteria. We do not anticipate generating operating revenue for the foreseeable future. We currently do not have any products that are marketed.

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. 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 RA 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 RA Study. A total of 37 patients were enrolled in four cohorts ranging from 0.15 μg/kg to 1.50 μg/kg of PRTX-100 or placebo, administered weekly for four weeks. Safety and disease were evaluated over 16 weeks following the first dose. The RA 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 mg/kg and 1.50 mg/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.

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 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") (the "Financing"). 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 our 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 Note"). The $2 Million Secured Note is convertible 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), bears interest at a rate of 3% per annum and matures on December 31, 2012.

The $2 Million Secured Note is 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 Note will automatically be converted if we undertake certain Fundamental Transactions, as defined in the $2 Million Secured 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 Note also provides 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 Note.

On February 1, 2012, we raised $1 million of working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1 million, which bears interest at a rate of 3% per annum and matures on February 1, 2014 (the "February 2012 Secured Note").

On June 5, 2012, we raised an additional $1 million of working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1 million, which bears interest at a rate of 3% per annum and matures on May 31, 2014 (the "June 2012 Secured Note"). Collectively, the February 2012 Secured Note and the June 2012 Secured Note are hereinafter referred to as the "2012 Notes."

In addition, payment of the principal and accrued interest on the 2012 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 2012 Notes.

Our obligations under the $2 Million Secured Note and the 2012 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 highly-purified form of the Staphylococcal bacterial protein known as Protein A. PRTX-100 has the ability, at very low concentrations, to bind to and to regulate activation of human B-lymphocytes and macrophages which are the key cells mediating 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 RA Study demonstrated that doses from 0.15 to 1.50 ug/kg were well tolerated in patients with active RA, and that more patients in the higher dose cohorts than the lower dose cohorts showed improvements in their CDAI scores.

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 clinical trial in December 2005 and completed the Phase I clinical trial in March 2006. This Phase I clinical trial was performed in healthy volunteers and was designed primarily to assess the safety and tolerability 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 another 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 in South Africa was approved. The RA Study commenced in August 2010 and was completed in January 2012 as detailed below (South Africa RA Study).

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. This clinical study was conducted under the Australian and New Zealand Clinical Trial Notification procedure, not under US IND (the "Australian Study"). After the approval of the clinical protocol by ethics committees at six sites in Australia and one in New Zealand, the trial 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 Australian 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 Australian 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 formed the basis for the clinical trial application to evaluate PRTX-100 in patients with rheumatoid arthritis.

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 is modeled on an effective precedent medical device treatment approved for RA which also exposed patients to low doses of staphylococcal protein A. PRTX-100 shows measurable activity in a standard mouse model of autoimmune arthritis. Accordingly, RA is believed to represent the most likely and significant treatment indication for 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.

South Africa RA 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 RA 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 RA Study. A total of 37 patients were enrolled in four cohorts ranging from 0.15 µg/kg to 1.50 µg/kg of PRTX-100 or placebo, administered weekly for four weeks. Safety and disease were evaluated over 16 weeks following the first dose. The RA 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 µg/kg, and 0.45 µg/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 µk/kg and 1.50 µk/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 µk/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 RA Study demonstrated an acceptable safety profile, we are preparing to study PRTX-100 in adult patients with active RA on methotrexate at doses of 1.50 µk/kg and higher in a new clinical trial that is expected to provide a better understanding of safety and treatment effect on RA disease activity measurements as well as help define the optimal dose (the “New Study”). It is expected that the New Study will have study centers at sites in both the United States and South Africa and will commence enrollment in the fourth quarter 2012.

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 the New Study as well as other future studies. The product formulations, stability testing and packaging of the final drug product for clinical supplies are conducted at several other FDA-approved facilities in the United States. These companies 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 South African RA trial used, and the New Study will use, 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 United States 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. In contrast, we believe that PRTX-100 could potentially provide these patients with a choice of 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. 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. This potential advantage has not yet been, and may not ever be, validated in clinical trials. Current RA treatments are characterized by complex manufacturing methods and have resulted in an average annual retail cost of approximately $15,000 to $25,550 per patient in 2011. The cost can increase according to the size/weight of a patient and the number of doses required. The $15,000 cost per year may be for one dose when up to four doses are 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®); and
- Anti CD20 B-cell-directed therapy, rituximab (Rituxan®).

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 2011 annual reports, Enbrel generated revenue approximately $7 billion combined for Amgen and Pfizer, Remicade generated revenue of more than $7 billion combined for Johnson & Johnson and Merck, and Abbot earned $6.5 billion for Humira. The final two TNFa inhibitors, usually second line use, have also increased their earnings. Cimzia earned $387 million for UCB and Astellas, and Simponi earned $674 million for Johnson & Johnson and Merck. Orencia earned Bristol Myers Squibb $917 million. Rituxan earned Genentech and Roche approximately $8 billion. Kineret earned Amgen $58 million, and Actemra earned $638 million in revenue for Roche. These earnings 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. Findings such as these indicate that new and safer treatments for autoimmune diseases such as RA are needed. We believe that PRTX-l00 and its other products will provide such opportunity, but there can be no assurance that such results will occur, which will be dependent upon the completion of extensive clinical trials.

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

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice or GLP regulations and other regulations;

- submission to the FDA of an IND application which must become effective before clinical trials may begin;

- performance of multiple adequate and well-controlled clinical trials meeting FDA requirements to establish the safety and efficacy of the product candidate for each proposed indication;

- submission of a Biological License Application or BLA to the FDA;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product candidate is produced, and potentially other involved facilities as well, to assess compliance with cGMP, regulations and other applicable regulations; and

- the FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the drug.

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

Foreign Regulation

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

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

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

Patents, Trademarks, and Proprietary Technology

Our success will also depend on our ability to maintain trade secrets and proprietary technology in the United States and in other countries, and to obtain and maintain patents for our bioregulatory technology. We filed an initial usage patent application with the U.S. Patent and Trademark Office or PTO, in April 2002. In October 2006, the PTO notified us of the allowance of the patent and in May 2007, the PTO issued U.S. Patent #7,211,258. In November 2006, we filed a further usage patent application with the PTO for PRTX-100 and in October 2010, the PTO issued U.S. patent #7,807,170. In September 2010 we filed a further continuation patent application with the PTO for PRTX-100 and in May 2012, the PTO issued patent #8,168,189. We have also filed for foreign protection relating to this patent in Canada, Japan and the European Union. In December 2010, we were informed that the Japan Patent Office approved our patent application and issued Japanese Letters Patent, Japanese patent #4598404. The Japanese patent has an expiration date of March 6, 2023.

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, 2012 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, 2012, our cumulative net loss was $55,454,819. Our net loss was $4,444,584 for the fiscal year ended May 31, 2012. Our continued operational 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, 2012, we had cash and cash equivalents of $190,395 and negative net working capital of $2,121,018 compared to cash and cash equivalents of $1,542,025 and working capital of $1,144,294 as of May 31, 2011. We have suffered recurring losses from operations and negative cash flows.

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 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.

In January 2012, we completed the RA Study enrolling a total of 37 patients out of a potential enrollment of 40 patients. As of the date of this Report, ITP clinical trials have been suspended due to poor enrollment, among other things, pending an evaluation of the clinical trial data and programs. If we are not able to enroll enough patients to complete the RA clinical trials, 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 United States, 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.

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 a U.S. patent application related to PRTX-100. In July 2006, the PTO issued an office action final rejection. In August 2006, we met with the patent examiner and his supervisor and as a result of that meeting, the rejection was retracted. In October 2006, the PTO notified us of the allowance of the patent and in May 2007, the PTO issued U.S. Patent #7,211,258. In November 2006, we filed a further usage patent application with the PTO for PRTX-100 and in June 2010, the PTO notified us of the allowance of patent #7,807,170, which was issued on October 5, 2010. In September 2010 we filled a further continuation patent application with the PTO for PRTX-100 and in May 2012, the PTO issued patent #8,168,189. We have also filed for foreign protection relating to this patent in Canada,, Japan and the European Union. In December 2010, we were

informed that the Japan Patent Office approved our patent application and issued Japanese Letters Patent, Japanese patent #4598404. The Japanese patent has an expiration date of March 6, 2023. Because the patent position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own may not provide any protection against competitors. Patents that we may file in the future or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed, or designed around any patents we may have issued to us. Moreover, the laws of foreign countries do not protect intellectual property rights to the same extent as the laws of the United States.

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

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

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

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

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

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

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

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

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 proposed 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 having 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

equipment. 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, Board, Scientific Advisory Board and numerous 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 to 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. In the fiscal year ended May 31, 2012, our stock price ranged from a high of $1.90 to a low of $0.60 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.

We may be the subject of securities class action litigation due to future stock price volatility.

In the past, when the market price of a stock has been volatile, holders of that stock have periodically instituted securities class action litigation against us that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

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. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

Control by existing stockholder

Niobe beneficially owns over 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
2011*		
First Quarter	$0.59	$0.185
Second Quarter	0.50	**
Third Quarter	1.70	**
Fourth Quarter	1.95	0.63
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

* The prices for the fiscal years ended May 31, 2011 and 2012 are actual sale prices because the bid price information was not available.

** Less than $0.01.

(b) *Holders*. As of August 13, 2012, there were approximately 67 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, 2012, we issued non-qualified stock options exercisable for an aggregate of 750,000 shares of our Common Stock, at a price of $1.01 per share, to five of our consultants. All of these options expire 10 years from the date of grant.

In July 2012, we issued a non-qualified stock option exercisable for 400,000 shares of our Common Stock, at a price of $1.25 per share, to a consultant. This option expires 5 years from the date of grant.

All of the foregoing options are subject to vesting and forfeiture and were issued in reliance upon the exemptions from the registration requirements of the Act pursuant to Sections 4(2) and 4(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 2012 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 which has been engaged in developing a class of biopharmaceutical drugs designed to treat autoimmune and inflammatory diseases including, but not limited to, RA. Our lead product PRTX-100, is formulated with highly-purified staphylococcal protein A, which is an immune modulating protein produced by bacteria. We currently do not have any products that are marketed.

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. 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 RA 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 RA Study. A total of 37 patients were enrolled in four cohorts ranging from 0.15 µg/kg to 1.50 µg/kg of PRTX-100 or placebo, administered weekly for four weeks. Safety and disease were evaluated over 16 weeks following the first dose. The RA 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 mg/kg and 1.50 mg/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.

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 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 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") (the "Financing"). 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 our 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 Note"). The $2 Million Secured Note is convertible 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), bears interest at a rate of 3% per annum and matures on December 31, 2012.

The $2 Million Secured Note is 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 Note will automatically be converted if we undertake certain Fundamental Transactions, as defined in the $2 Million Secured 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 Note also provides 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 Note.

On February 1, 2012, we raised $1 million of working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1 million, which bears interest at a rate of 3% per annum and matures on February 1, 2014 (the "February 2012 Secured Note").

On June 5, 2012, we raised an additional $1 million of working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1 million, which bears interest at a rate of 3% per annum and matures on May 31, 2014 (the "June 2012 Secured Note"). Collectively, the February 2012 Secured Note and the June 2012 Secured Note are hereinafter referred to as the "2012 Notes."

In addition, payment of the principal and accrued interest on the 2012 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 2012 Notes.

Our obligations under the $2 Million Secured Note and the 2012 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 United States, requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and equity and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. These estimates have a material impact on our financial statements and are discussed in detail throughout this 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, 2012 compared to fiscal year ended May 31, 2011

Research and Development Expenses – Research and Development expenses increased from $1,597,257 in our 2011 fiscal year to $1,900,002 in our 2012 fiscal year. The increase of $303,000, or 19%, was primarily the result of increased activity associated with our clinical study in South Africa, as disclosed above. 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 $1,291,867 in our 2012 fiscal year from $594,314 in our 2011 fiscal year. The increase of almost $700,000 was all related to an increase in share-based employee expense. In FY 2011, we had $125,000 of non-cash stock compensation expense compared to $829,000 in FY 2012.

Professional Fees - Professional fees decreased from $446,073 in our 2011 fiscal year to $309,696 in FY 2012. The decrease of approximately $136,000, or 31%, was due primarily to decreases in legal expenses.

Interest Expense – Interest expense increased from $724,079 in fiscal year 2011 to $943,607 in fiscal year 2012. The increase was attributable to us having more significant amounts of debt outstanding during FY 2012 compared to FY 2011.

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, 2012 was $55,454,819 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. 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 Note. On the same date, Niobe converted the $1 Million Secured Note and accrued interest thereon, into 4,510,870 shares of our Common Stock.

On February 1, 2012 and June 5, 2012, we raised an aggregate of $2 million of working capital pursuant to two loans from Niobe, each in the principal amount of $1,000,000, and issued to Niobe the 2012 Notes.

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

Our operating cash outflows for the fiscal years ended May 31, 2012 and 2011 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 United States. We expect to continue to use our cash and investments resources to fund operating and investing activities.

Off-Balance Sheet Arrangements

As of May 31, 2012, 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, 2012. 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, 2012, 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

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth information concerning our officers and directors as of August 1, 2012:

Name	Age	Title
Arnold P. Kling	54	President and Director
Kirk M. Warshaw	54	Chief Financial Officer, Secretary and Director
John E. Doherty	58	Director

Arnold P. Kling. Mr. Kling has served as our president and director since November 2009. Mr. Kling is currently a Managing Director of GH Venture Partners, LLC, a private equity boutique for which he also served as a Managing Director and General Counsel from 1995 to 1999. From 1999 through August 2005, Mr. Kling was the President of Adelphia Holdings, LLC, a merchant-banking firm, as well as the managing member of several private investment funds. 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. During the past five years, Mr. Kling was a director of Enthrust Financial Services, Inc., n/k/a Direct Markets Holdings Corp. (NASDAQ: MKTS). Mr. Kling currently also serves as a Director and President of Mattmar Minerals, Inc. (OTCBB: MTMS), 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 a multitude of different 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. During the past five years, Mr. Warshaw was a director of Empire Financial Holding Company, n/k/a Jesup & Lamont, Inc. (OTC Markets: JLIC). Mr. Warshaw is currently also the Chief Financial Officer of Mattmar Minerals, Inc. (OTCBB: MTMS) and 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, and has a background in pharmacology, clinical immunology, and experimental medicine. Dr. Bernton prior to this was Senior Director, Clinical Strategy, 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 board range of experience across therapeutic categories. Dr. Gannon has managed clinical trials and operations as well as the design, corporate and regulatory strategies, regulatory submissions and execution of Phase I through Phase IV clinical trials in the United States, Europe and Asia. Additionally, Dr. Gannon is involved in philanthropy in the Washington, DC area and currently serves on the Board of Directors for 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, 2012, 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, 2012 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, 2012 and 2011:

Name and Principal Position	Year	Salary ($) (1)	Option Awards ($) (1)	Total ($)
Arnold P. Kling,	2012	$72,000	*	$72,000
President	2011	$72,000	*	$72,000
Kirk M. Warshaw,	2012	$72,000	$211,850	$370,830
Chief Financial Officer	2011	$72,000	$55,657	$127,657

* None.

(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 8 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, 2012:

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	300,217	450,326	(1)	$ 0.25	12/29/2019
	125,000	125,000	(2)	$ 1.01	11/01/2021

(1) This option, granted on December 29, 2009, vests and becomes exercisable on December 29, 2012, subject to earlier vesting and exercisability if we achieved certain performance milestones in advance of such vesting date. As of May 31, 2012, as a result of our achieving of certain performance milestones, this option was exercisable to acquire 300,217.

(2) Granted on November 1, 2011 (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 1st 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, 2012:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	All Other Compensation ($)		Total ($)
John E. Doherty(3)	$ 24,000	$55,781	$ 24,000	(2)	$103,781

(1) Reflects the value of the stock option that was charged to income as reported on 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 8 of our financial statements, included elsewhere in this Report.

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

(3) At May 31, 2012, Mr. Doherty held options exercisable for an aggregate of 402,000 shares at exercise prices ranging from $0.50 to $8.50 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 15, 2012, 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)		
Name and Title	Number	Percent	
Arnold P. Kling, president and director (2)(6)	22,144,918	79.0	%
Kirk M. Warshaw, CFO, secretary and director (3)	425,217	2.2	%
John E. Doherty, director (4)	722,532	3.8	%
Officers and Directors as a group (3 persons) (5)	23,292,667	81.4	%
5% Beneficial Owners			
Niobe Ventures LLC (6)	22,139,536	79.0	%
410 Park Avenue – Suite 1710			
New York, NY 10022			

(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 300,417 shares of Common Stock at an exercise price of $0.25 per share and 125,000 shares of Common Stock at an exercise price of $1.01 per share.

(4) Includes options to purchase 80,000 shares of Common Stock at an exercise price of $0.50 per share and 100,000 shares of Common Stock at an exercise price of $1.01 per share.

(5) Includes: (i) 9,096,377 shares of Common Stock issuable upon conversion of the $2 Million Secured Note and accrued interest thereon as of August 15, 2012 deemed to be beneficially owned by Arnold P. Kling as the manager of Niobe Ventures, LLC; and (ii) options to purchase an aggregate of 605,417 shares of Common Stock beneficially owned by Messrs. Warshaw and Doherty.

(6) Includes 9,096,377 shares of Common Stock issuable upon conversion of the $2 Million Secured Note including accrued interest thereon as of August 15, 2012.

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	288,384	$ 8.33	611,616
Equity compensation plans not approved by security holders – Stand Alone Option Grants	1,980,543	$ 0.65	Not applicable
Total	2,268,927	$ 1.27	611,616

During the fiscal year ended May 31, 2012, options for an aggregate of 60,000 shares of our Common Stock were granted under Equity Compensation Plans Not Approved by Security Holders as compensation to two professionals who provide us with services. These options are ten year options with exercise prices $0.50, vest on the third anniversary from the date of grant and 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, on February 1, 2012 and June 1, 2012, we raised an aggregate of $2,000,000 of working capital from two separate loans, in the principal amount of $1,000,000 each, from Niobe and issued to Niobe the 2012 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 Note.

Our obligations under the $2 Million Secured Note and the 2012 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.

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, 2012 and 2011 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, Sherb & Co., LLP, for the fiscal years ended May 31, 2012 and 2011 are as follows:

	2012	2011
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.	Filed herewith.
4.4	$1 Million Secured Convertible Promissory Note dated June 5, 2012.	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	Filed herewith.
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.	Filed herewith.
10.15**	Form of Non-Qualified Stock Option Agreement with John Doherty, dated November 1, 2011.	Filed herewith.
10.16**	Form of Non-Qualified Stock Option Agreement with each of Edward Bernton and Valerie Jackson, dated November 1, 2011.	Filed herewith.
23.1	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 27, 2012 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 27, 2012

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

Date: August 27, 2012

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

Date: August 27, 2012

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

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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 sheets of Protalex, Inc. (A Development Stage Company) as of May 31, 2012 and 2011 and the related statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years then ended May 31, 2012 and 2011. 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 2011 and the results of its operations and its cash flows for each of the years ended May 31, 2012 and 2011 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

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PROTALEX, INC.

(A Development Stage Company)

BALANCE SHEETS

	May 31, 2012	May 31, 2011
CURRENT ASSETS:		
Cash and cash equivalents	$190,395	$1,542,025
Prepaid expenses	42,679	38,441
Total current assets	233,074	1,580,466
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $12,048 and $11,028 as of May 31, 2012 and May 31, 2011, respectively	7,487	8,507
Total other assets	7,487	8,507
Total Assets	$240,561	$1,588,973
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$182,861	$182,861
Accrued expenses	576,733	253,311
Current portion – long term debt	1,594,498	0
Total current liabilities	2,354,092	436,172
LONG TERM LIABILITIES:		
Senior Secured Note – related party	1,000,000	0
Senior Secured Note Accrued Interest – related party	10,083	0
Senior Secured Convertible Note – net of debt discount - related party	0	660,975
Total liabilities	3,364,175	1,097,147
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	52,331,016	51,501,872
Deficit accumulated during the development stage	(55,454,819)	(51,010,235)
Total stockholders' equity (deficit)	(3,123,614)	491,826
Total liabilities and stockholders' equity (deficit)	$240,561	$1,588,973

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

	Year Ended May 31, 2012	Year Ended May 31,2011	From Inception (September 17, 1999) Through May 31, 2012 (Unaudited)
Revenues	$0	$0	$0
Operating Expenses			
Research and development (including depreciation and amortization)	1,900,001	1,597,257	32,542,093
Administrative (including depreciation and amortization)	1,291,867	594,314	18,469,283
Professional fees	309,696	446,073	4,630,851
Depreciation and amortization	1,020	1,020	181,946
Operating loss	(3,502,584)	(2,638,664)	(55,824,173)
Other income (expense)			
Interest income	1,607	4,861	2,207,890
Interest expense	(943,607)	(724,079)	(1,838,536)
Net loss	$(4,444,584)	$(3,357,882)	$(55,454,819)
Weighted average number of common shares outstanding	18,926,615	15,766,527	
Loss per common share – basic and diluted	$(0.23)	$(0.22)	

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, 2012

(Unaudited)

	Common Stock Shares	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
	0	0	40,000	0	0	40,000

May 31, 2001 — Forgiveness of debt owed to stockholder						
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, 2012

(Unaudited)

	Common Stock Shares	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, 2012

(Unaudited)

	Common Stock Shares	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, 2012

	Common Stock Shares	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
	0	0	521,793	0	0	521,793

November 11, 2009 – record beneficial conversion value attached to senior secured convertible debt						
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, 2012 – 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 May 31, 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 May 31, 2012	0	0	0	0	(4,444,584)	(4,444,584)
	18,926,615	$ 189	$52,331,016	$ 0	$(55,454,819)	$(3,123,614)

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, 2012	Year Ended May 31, 2011	From Inception (September 17, 1999) Through May 31, 2012 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(4,444,584)	$(3,357,882)	$(55,454,819)
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	934,544	725,099	1,970,123
Equity based expense	829,144	124,722	7,686,996
(Increase)/decrease in:			
Prepaid expenses and deposits	(4,239)	563	(50,669)
Increase/(decrease) in:			
Accounts payable and accrued expenses	333,505	(143,567)	769,677
Payroll and related liabilities	0	(156,994)	0
Net cash and cash equivalents used in operating activities	(2,351,630)	(2,808,059)	(45,160,239)
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 provided by (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	1,000,000	2,000,000	4,368,546
Acquisition of common stock	0	0	(400,000)
Net cash and cash equivalents provided by financing activities	1,000,000	2,000,000	46,289,445
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,351,630)	(808,059)	190,395
Cash and cash equivalents, beginning	1,542,025	2,350,084	0
Cash and cash equivalents, ending	$190,395	$1,542,025	$190,395
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	$1,037,500	$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, 2012 and 2011

1. ORGANIZATION AND BUSINESS ACTIVITIES

The Company is a development stage company which has been engaged in developing a class of biopharmaceutical drugs for treating autoimmune inflammatory diseases. Its lead product, PRTX-100, is formulated with highly-purified staphylococcal protein A, which is an immune modulating protein produced by bacteria. The Company does not currently have any products on the market and does not anticipate generating operating revenue for the foreseeable future.

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. In August 2010, the Company commenced a multi-center Phase 1b clinical trial of PRTX-100 in South Africa in adult patients with active RA on methotrexate. The RA 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, the Company completed patient dosing in the fourth cohort of the RA Study. A total of 37 patients were enrolled in four cohorts ranging from 0.15 µg/kg to 1.50 µg/kg of PRTX-100 or placebo, administered weekly for four weeks. Safety and disease were evaluated over 16 weeks following the first dose. The RA 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 mg/kg and 1.50 mg/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. The Company currently markets no products.

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 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”) (the “Financing”). 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") 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 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 matures on December 31, 2012.

The $2 Million Secured Note is convertible at any time, by the holder, subject only to the requirement that the Company has 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 Note will automatically be converted if the Company undertakes certain Fundamental Transactions, as defined in the $2 Million Secured Note, (such as a merger, sale of all of its assets, exchange or tender offer, or reclassification of its stock or compulsory exchange). The $2 Million Secured Note also provides 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 Note.

On February 1, 2012, the Company raised $1 million of working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1 million, which bears interest at a rate of 3% per annum and matures on February 1, 2014 (the "February 2012 Secured Note"). Payment of the principal and accrued interest on the February 2012 Secured Note 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 February 2012 Secured Note.

The Company's obligations under the $2 Million Secured Note and the February 2012 Secured Note are secured by a security agreement (see Note 9, below) granting Niobe a security interest in substantially all of the Company's personal property and assets, including its intellectual property.

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

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

The securities issued in the Financing 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 $55,454,819 through May 31, 2012. For the years ended May 31, 2012 and 2011, the Company had net losses of $4,444,584 and $3,357,882, respectively. The Company has used $2,351,630 and $2,808,059 of cash in operating activities for the years ended May 31 2012 and 2011, respectively. As of May 31, 2012, the Company had cash and cash equivalents of $190,395 and negative net working capital of $2,121,018. 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, 2012 and 2011, the Company had a total of 2,268,927 and 1,538,927 potentially dilutive securities comprised solely of stock options, respectively.

Share-Based Compensation

Effective June 1, 2006, the Company adopted the FASB accounting guidance for fair value recognition provisions of the “Accounting for Share-Based Payment” using the modified prospective method. 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. Under the modified prospective method, compensation cost included in operating expenses was $829,144 and $124,722 for the years ended May 31, 2012 and 2011, 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. In accordance with the modified prospective application transition method, prior period results are not restated. Incremental compensation cost for a modification of the terms or conditions of an award is measured by comparing the fair value of the modified award with the fair value of the award immediately before the modification. No tax benefit was recorded as of May 31, 2012 in connection with these compensation costs due to the uncertainty regarding ultimate realization of certain net operating loss carryforwards. The Company has also implemented the SEC interpretations in Staff Accounting Bulletin (“SAB”) for “Share-Based Payments”, in connection with the adoption of FASB accounting guidance.

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 288,384 have been issued and 800 were exercised. The Company has issued 1,980,543 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 issued 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, 2012, there were 2,268,927 stock options outstanding. At May 31, 2012, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model was approximately $315,349 (net of estimated forfeitures) will be recognized over a weighted average period of six months. For the year ended May 31, 2012, the Company granted 750,000 stock options, with a fair value of $664,050 (net of estimated forfeitures). 20,000 options expired and none were forfeited.

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

Year Ended May, 31, 2012	Year Ended May, 31, 2011	From Inception Through May 31, 2012

Dividends per year	0	0	0
Volatility percentage	97.5 %	97.5 %	90%-112%
Risk free interest rate	3.47 %	3.47 %	2.07%-5.11%
Expected life (years)	7-10	5-9	3-9
Weighted Average Fair Value	$ 1.01	$ 1.10	$2.41

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 $12,048 for the years ended May 31, 2012, 2011 and from inception through May 31, 2012, 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, 2012. 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, *Accounting for Income Taxes* and 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

In January 2010, the FASB issued ASU 2010-06, Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements, which enhances the usefulness of fair value measurements. The amended guidance requires both the disaggregation of information in certain existing disclosures, as well as the inclusion of more robust disclosures about valuation techniques and inputs to recurring and nonrecurring fair value measurements. The amended guidance is effective for interim and annual reporting periods beginning after December 15, 2009, except for the disaggregation requirement for the reconciliation disclosure of Level 3 measurements, which is effective for fiscal years beginning after December 15, 2010 and for interim periods within those years. The Company does not anticipate that this pronouncement will have a material impact on its results of operations or financial position.

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

5. REVERSE MERGER

On November 15, 1999, Enerdyne Corporation or Enerdyne acquired all of the outstanding Common Stock of Protalex, Inc. in exchange for the issuance of additional shares of Enerdyne stock. The ratio of exchange was 822 shares of Enerdyne stock issued for each share of Protalex stock received. For accounting purposes, the acquisition has been treated as an acquisition of Enerdyne by Protalex and as a recapitalization of Protalex or Reverse Merger. The historical statement of operations presented herein include only those of the accounting acquirer and the retained earnings or deficit of only the accounting acquirer carries over consistent with the requirements of reverse merger accounting. Concurrently with the share exchange, Enerdyne changed its name to Protalex, Inc.

The details of the reverse merger transaction are as follows:

Account Description	Protalex, Inc.	Enderdyne Corporation	Transaction Adjustments	Balance Sheet at November 16, 1999
Cash	$23,531	$0	$0	$23,531

Note receivable stockholder	0	118,547	0	118,547
License	20,300	0	0	20,300
Investment in Enerdyne	368,547	0	(368,547)	0
Other current assets	8,212	0	0	8,212
Other current liabilities	(17,555)	0	0	(17,555)
Accounts payable Alex	(40,000)	0	0	(40,000)
Note payable	(368,546)	0	0	(368,546)
Common stock	(25,300)	(833,459)	714,912	(143,847)
Additional paid in capital	0	(1,105,014)	1,105,014	0
Treasury stock	0	430,424	(430,424)	0
Accumulated deficit	30,811	1,389,502	(1,389,502)	30,811
Common stock – contra	0	0	368,547	368,547
	$0	$0	$0	$0

6. **INCOME TAXES**

For the years ended May 31, 2012 and 2011, the components of income tax benefit (expense) consist of the following:

	Year Ended May 31, 2012	Year Ended May 31, 2011
Current:		
Federal	$0	$0
State	0	0
Deferred:		
Federal	1,511,000	1,142,000
State	267,000	201,000
Tax credits	109,000	97,000
Permanent timing difference	(727,000)	(374,000)
Increase in valuation allowance	(1,160,000)	(1,066,000)
Income tax benefit	$0	$0

Income tax as a percentage of income for the year ended May 31, 2012 and 2011 differ from statutory federal income tax rates due to the following:

	Year Ended May 31, 2012	Year Ended May 31, 2010
Statutory federal income tax rate	(34 %)	(34 %)
State income taxes, net of federal income tax impact	(6 %)	(6 %)
Change in valuation allowance	26 %	32 %
Permanent timing differences	18 %	11 %
General business credit/other	(2 %)	(3 %)
	0 %	0 %

The components of the net deferred tax asset as of May 31, 2012 and 2011 are as follows:

Assets:	May 31, 2012	May 31, 2011
Net operating losses	$17,770,000	$16,720,000

Severance accrual	0	0
General business credit	2,106,000	1,996,000
Deferred tax assets	19,876,000	18,716,000
Liability:		
Gross deferred tax asset	19,876,000	18,716,000
Less valuation allowance	(19,876,000)	(18,716,000)
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 $44,351,000 as of May 31, 2012 expires beginning in 2021 through 2032. 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, 2012, 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.

7. **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 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 matures on December 31, 2012.

On February 1, 2012, the Company raised $1 million of working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1 million, which bears interest at a rate of 3% per annum and matures on February 1, 2014 (the "February 2012 Secured Note").

Niobe, a majority stockholder of the Company and the holder of the $2 Million Secured Note and the February 2012 Secured Note, is controlled by the Company's President and Director, Arnold P. Kling.

During the fiscal year ended May 31, 2011, the Company issued an aggregate of 950,543 options to John Doherty, one of the Company's directors, and Kirk M Warshaw, chief financial officer and a director of the Company. The 950,542 options issued during the fiscal year ended May 31, 2011 are ten year options with exercise prices ranging from $0.25 to $0.50. These options vest in three tranches, upon commencement of the drug test trial, upon demonstrated efficacy of the drug trial and finally, upon the execution of a licensing or financing deal. The 950,542 options have been valued at $493,200 for which $384,177 of compensation expense has been recorded.

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.

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.

8. 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, 2012, options to purchase 2,268,927 shares of the Company's Common Stock were outstanding, of which 288,384 were issued and 800 were exercised under the Company's 2003 Stock Option Plan and the remaining 1,980,543 were issued and 400 were exercised as standalone options. As of May 31, 2012, 1,099,602 are exercisable.

The 750,000 options issued during the year ended May 31, 2012 are seven and one half year and ten year options with exercise prices of $1.01 per share. These options vested 50% upon issuance and the remainder vest on November 1, 2012. The options issued during the year ended May 31, 2012 have been valued at $664,050 for which $525,706 of compensation expense has been recorded. The balance of the option expense recorded 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, 2012 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, 2010	1,478,927	$ 2.05	4.65
Granted	60,000	$ 0.50	0
Exercised	0	0	0
Forfeited	0	0	0
Expired	0	0	0
Outstanding at May 31, 2011	1,538,927	$ 1.99	3.70
Granted	750,000	$ 1.01	0
Exercised	0	0	0
Forfeited	0	---	0
Expired	(20,000)	$ 6.25	0
Outstanding at May 31, 2012	2,268,927	$ 1.27	7.65
Exercisable at May 31, 2012	1, 099,601	$ 2.41	0

The outstanding and exercisable stock options as of May 31, 2012 and 2011 had an intrinsic value of $692,902 and $598,236, respectively.

The 750,000 options issued during the year were issued at an exercise price that was equal to the market price.

The following summarizes certain information regarding stock options at May 31, 2012:

	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 – 5.00	1,980,543	$ 0.65	8.6	811,217	$ 0.67	9.0
$5.01 – 10.00	251,384	$ 7.52	1.0	251,384	$ 7.52	1.0
$10.01 – 15.00	37,000	$ 13.86	4.0	37,000	$ 13.86	4.0
	2,268,927	$ 1.27	7.65	1,099,601	$ 2.41	7.60

9. 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 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 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 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 Note bears interest at a rate of 3% per annum and matures on December 31, 2012.

The Company evaluated the conversion feature of the $2 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 February 11, 2011, the date of issuance of the $2 million Secured 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 is being amortized over 22 months and serves to increase the interest expense of the Secured Note during its term. As of May 31, 2012, $485,001 of the original discount remained resulting in the net amount of the debt being $1,514,999 as of May 31, 2012.

In connection with the Facility, on December 2, 2009, the Security Agreement securing the Company's obligations under the 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.

On February 1, 2012 and June 5, 2012, the Amended Security Agreement was amended in connection with the Company's issuance of the February 2012 Secured Note (as described in Note 10, below) and the June 2012 Secured Note (as described in Note 12, below).

10. SENIOR SECURED NOTE – RELATED PARTY

On February 1, 2012, the Company raised $1 million of working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1 million, which bears interest at a rate of 3% per annum and matures on February 1, 2014 (the "February 2012 Secured Note").

In addition, payment of the principal and accrued interest on the February 2012 Secured Note 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 February 2012 Secured Note.

The Company's obligations under the $2 Million Secured Note and the February 2012 Secured Note 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.

11. 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.

In December 2006, the FASB issued accounting guidance "Accounting for Registration Payment Arrangements", which specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement should be separately recognized and measured in accordance with the accounting guidance, "Accounting for Contingencies." For the Company’s private placement transactions in September 2003, May 2005, December 2005 and July 2006, the Company granted registration rights which included payment arrangements of liquidated damages under certain circumstances, as noted in each respective registration rights agreement, including in the event an effective registration statement registering the resale of shares of Common Stock issuable upon exercise of the warrants does not remain effective. The Company generally uses its best efforts or all commercially reasonable efforts to maintain effective registration statements. The Company completed its evaluation, and believes that an obligation to transfer consideration under its registration payment arrangement for all registrations since inception was not required.

12. SUBSEQUENT EVENTS

On June 5, 2012, the Company raised an additional $1 million of working capital pursuant to a loan from Niobe and issued to Niobe a secured promissory note in the principal amount of $1 million, which bears interest at a rate of 3% per annum and matures on May 31, 2014 (the “June 2012 Secured Note”). In addition, payment of the principal and accrued interest on the June 2012 Secured Note 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 June 2012 Secured Note.

The Company’s obligations under the $2 Million Secured Note and the 2012 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.

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

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