PROTALEX INC
Form 10-K
August 28, 2009

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

FORM 10-K

(Mark One)

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

For Fiscal Year Ended May 31, 2009

OR

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

For the Transition Period from to

Commission File 000-28385

PROTALEX, INC.
(Exact name of registrant as specified in its charter)

Delaware	91-2003490
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)
145 Union Square Drive, New Hope, Pennsylvania	18938
(Address of principal executive offices)	(Zip Code)

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

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
None	None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock
(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 o Noþ

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 o No þ
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 þ No ¨

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

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

Large accelerated filer ¨	Accelerated filer ¨	Non-accelerated filer ¨	Smaller Reporting Company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No þ

The approximate aggregate market value of Common Stock held by non-affiliates of the registrant was $5,422,375 as of November 30, 2008, 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, 2009 was 28,600,464.

DOCUMENTS INCORPORATED BY REFERENCE

None.

PROTALEX, INC.

FORM 10-K

May 31, 2009

TABLE OF CONTENTS

	PART I	
ITEM 1.	BUSINESS	2
ITEM 1A.	RISK FACTORS	7
ITEM 1B.	UNRESOLVED STAFF COMMENTS	13
ITEM 2.	PROPERTIES	13
ITEM 3.	LEGAL PROCEEDINGS	13
ITEM 4.	SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS	13
	PART II	
ITEM 5.	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	13
ITEM 6.	SELECTED FINANCIAL DATA	14
ITEM 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	14
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	18
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	18
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTS ON ACCOUNTING AND FINANCIAL DISCLOSURES	18
ITEM 9A.	CONTROLS AND PROCEDURES	18
ITEM 9B.	OTHER INFORMATION	18
	PART III	
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	19
ITEM 11.	EXECUTIVE COMPENSATION	21
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	24
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	25
ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	25
	PART IV	

ITEM 15.	EXHIBITS, FINANCIAL STATEMENT SCHEDULES	26
EXHIBIT INDEX		27
SIGNATURES		29

Exhibit Index
Ex-31.1 Section 302 Certification of the CEO
Ex-31.2 Section 302 Certification of the CFO
Ex-32.1 Section 906 Certification of the CEO
Ex-32.2 Section 906 Certification of the CFO

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 product 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 by us;
- 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.

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 included elsewhere in this Annual Report and the Risk Factors in Item 1A of this Report.

PART I

ITEM 1. BUSINESS

Overview

In September 1999, Protalex acquired a majority of the issued and outstanding shares of common stock of Enerdyne from Don Hanosh, pursuant to a Stock Purchase Agreement between Protalex, Enerdyne and Mr. Hanosh. In November 1999, Protalex merged with and into Enerdyne pursuant to a Merger Agreement and Plan of Reorganization, and Enerdyne changed its name to Protalex, Inc. After the merger, Protalex's former stockholders held approximately 92% of the shares of our common stock, and Enerdyne's former stockholders held approximately 8% of the shares of our common stock. On December 1, 2004, Protalex, Inc., a New Mexico corporation, consummated a merger with and into its newly-formed, wholly-owned subsidiary, Protalex Delaware, in order to reincorporate in the State of Delaware. Our authorized capital stock consists of 100,000,000 shares of $0.00001 par value common stock.

As of the date of this Report, the Company has no employees and it has insufficient funds to cover future clinical trials and Chemistry, Manufacturing and Control or CMC related expenses beyond the third calendar quarter of 2009. If the Company is unable to raise sufficient additional funds, it will likely be required to suspend or cease further operations on or about the end of the third calendar quarter of 2009 until such financing is obtained, if ever.

These matters raise substantial doubt about the ability of the Company to continue as a going concern.

We are a development stage company which has been engaged in developing a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases. Our lead product, PRTX-100, has demonstrated effectiveness in pre-clinical studies in regulating the immune system with persisting effects. 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 clinical trials. We currently have no product on the market. We initially targeted the autoimmune diseases idiopathic thrombocytopenic purpura, or ITP and rheumatoid arthritis, or RA.

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 United States Food and Drug Administration or 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 with 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. The basic safety data demonstrated that PRTX-100 was safe and well tolerated. There were no deaths or serious adverse events. The pharmacokinetic (PK) profile was favorable and the pre-clinical PK data were confirmed by the data in this Phase I clinical trial. 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.

RA is an autoimmune disease that causes the inflammation of the membrane lining multiple joints, resulting in pain, stiffness, warmth, redness and swelling. The inflamed joint lining, the synovium, can invade and damage bone and cartilage. Inflammatory cells release enzymes and cytokines that may damage bone and cartilage. The involved joint can lose its shape and alignment, resulting in pain and loss of movement. In July 2007, we commenced with an additional Phase I clinical trial designed to gain more detailed information on biomarkers, including gene expression profiling and platelet functional assessments which will allow for more optimized patient selection and targeting in the upcoming clinical trials. This second Phase I clinical trial extended the clinical investigation of PRTX-100 tolerability, PK, and pharmacodynamics, or PD, at higher dose ranges. Dosing was completed in July 2007 and final results

indicated that the drug was safe and well tolerated. A Phase Ib randomized, double-blind, placebo-controlled, multiple dose, dose escalation safety and tolerability study of PRTX-100 in combination with methotrexate in patients with active RA in South Africa has been approved.

ITP is an uncommon autoimmune bleeding disorder characterized by too few platelets in the blood. Affected individuals may have bruising, small purple marks on the skin called petechiae, bleeding from the gums after having dental work, nosebleeds or other bleeding that is hard to stop, and in women, heavy menstrual bleeding. Although bleeding in the brain is rare, it can be life threatening if it occurs. The affected individuals make antibodies against their own platelets leading to the platelets' destruction, which in turn leads to the abnormal bleeding. In ITP, we contracted Trident Clinical Research Pty Ltd, a leading Australian clinical research organization, to manage and monitor our first-in-patient ITP clinical trial. This clinical trial is designed to provide initial multiple dose safety and PK data as well as preliminary efficacy information. We have been approved for six sites in Australia and one in New Zealand, all regional referral centers for treatment of chronic ITP, to conduct a repeated dose study of PRTX-100 in chronic ITP patients. This clinical trial began enrolling patients in the second calendar quarter of 2008. In calendar 2008, we enrolled nine patients of which five completed the trial and final results indicated that the drug was safe and well tolerated, although no efficacy data was obtained. Subsequently, the Company obtained protocol approval to increase the dose range. While the Company has actively solicited patients in calendar 2009 under this new protocol, no patients have been enrolled as of the date of this Report.

As of the date of this Report, the Company has suspended further recruitment of patients for its ITP clinical trials pending the raising of additional funding, the retention of additional clinical personnel and an evaluation of the Company's clinical trial programs.

Our bioregulatory compounds are based on the principle of normalizing the activities of immune cells at a more basic level than traditional pharmaceutical agents, which act upon the end products of complex body functions. In autoimmune disease models, PRTX-100, which is a natural compound, has reversed the pathologic process resulting in a restoration and maintenance of normal healthy tissue. This biotechnology could be applied to a range of serious autoimmune diseases that affect millions of sufferers worldwide, such as pemphigus, systemic lupus erythematosus or lupus, psoriasis, inflammatory bowel diseases such as Crohn’s disease and ulcerative colitis, insulin-dependent diabetes mellitus, and multiple sclerosis. To date, however, we have not conducted any pre-clinical trials related to the treatment of these diseases and to do so would require substantial additional capital infusions.

. Our business and laboratory operations are located in New Hope, Pennsylvania. We currently outsource all of our activities to contract organizations and facilities. For example, we refine the manufacturing process of PRTX-100 under Current Good Manufacturing Practice, or cGMP. Without adequate additional financing in the third calendar quarter of 2009, however, the Company runs the risk of not having adequate clinical trial material available to complete our ITP clinical trails if we continue to pursue ITP, which could also lead to a significant delay in commencing future clinical trial programs.

Our in-house research previously included demonstrating the efficacy of PRTX-100 in well established and characterized animal models of RA and other autoimmune diseases. For example, we have tested PRTX-100 in the murine collagen induced arthritis model, or CIA, which is considered to be a predictive efficacy model for RA in humans. This is the model that was used to test the efficacy of the FDA approved drug, etanercept, or Enbrel®. PRTX-100 has also demonstrated its efficacy in an animal model of systemic lupus erythematosus. Additionally, our laboratory personnel have developed a pre-clinical ITP model with data showing that PRTX-100 inhibits the phagocytosis (ingestion) of platelets in vitro. Platelet phagocytosis is the effector limb of ITP.

We have concluded eight private placements of our common stock, raising a total of $42.2 million in the aggregate and carrying us through basic research, pre-clinical and early stage clinical trials. Our research and development expenditures were $3,490,956, $7,657,127, and $5,562,485, for the years ended May 31, 2009, 2008, and 2007, respectively. The private placement in July 2006 raised approximately $15.2 million. We have completed two Phase I clinical trials, commenced with the Phase Ib clinical trial for ITP in Australia and previously commenced the planning process for a Phase Ib clinical trial for RA in South Africa. Without adequate additional financing, however, the Company will be unable to fund the ongoing FDA approval process.

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 down regulate activation of human B-lymphocytes and macrophages which are key cells mediating inflammation in certain autoimmune diseases. Laboratory studies indicate the mechanism involves interference with specific intracellular signaling pathways. Pre-clinical studies also demonstrate that very low doses of PRTX-100 have potent therapeutic effects on model inflammatory diseases.

Animal Studies

Protalex’s lead candidate PRTX-100 has proven effective in two clinical standard mouse autoimmune models:

Collagen-Induced Arthritis - PRTX-100 has demonstrated reproducible efficacy in a 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 been used to serve 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, Crohn’s disease 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. Treatment with PRTX-100 also reduced non-specific immunoglobulin production and specific autoantibody production and restored the number and function of immune cells known as T and B lymphocytes. These results represent improvement in a whole animal setting in this complex disease syndrome.

Completed pre-clinical safety studies in animals have shown no drug-related toxicity. The studies were conducted in New Zealand white rabbits which are a very sensitive model to show any potential toxicity of immunomodulatory drugs such as PRTX-100. All of the animals in this study survived to scheduled euthanasia. 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, or the same dilutive material less PRTX-100. These study results were a crucial component of our IND application with the FDA.

We have performed additional studies in non-human primates to determine the pharmacokinetics of PRTX-100. The results of those studies have indicated more favorable dosing schedules due to longer half lives than studies obtained from rodents. Since non-human primates are more closely related to humans, we decided to perform additional toxicology studies in monkeys to establish the toxicity and starting doses in humans.

Manufacturing

We currently contract the manufacturing of our lead drug substance PRTX-100 to Eurogentec S.A. in Belgium where it is produced under cGMP conditions. The product formulations, stability testing and packaging of the final drug product for clinical supplies are conducted at several other reputable FDA-approved companies 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.

Markets

RA is a key focus for the Company. 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 a Cowen and Company, LLC report entitled “Therapeutic Categories Outlook” dated March 2009, RA affects about 1.0% of the U.S. population with a female to male ratio of 2 to 1 and approximately 10% of RA patients enter remission without treatment. Of the remaining 90%, one third has mild disease, one-third has moderate disease and has some response to methotrexate and one-third has significant disease and has failed methotrexate.

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. Current treatments are costly, and in most cases must be continued for decades. In contrast, we believe that bioregulatory therapy such as 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. If ever developed and approved, we believe that our products would be used to treat patients with moderate to severe cases of RA, and particularly those individuals for whom other treatments have failed. Additionally, preliminary information gained in the laboratory on the mechanism of action of PRTX-100 suggests potential efficacy in a wide range of autoimmune diseases, including, but not limited to, lupus, type I diabetes, and pemphigus.

ITP is an uncommon autoimmune bleeding disorder characterized by too few platelets in the blood. Affected individuals may have bruising, small purple marks on the skin called petechiae, bleeding from the gums after having dental work, nosebleeds or other bleeding that is hard to stop, and in women, heavy menstrual bleeding. Although bleeding in the brain is rare, it can be life threatening if it occurs. The affected individuals make antibodies against their own platelets leading to the platelets' destruction, which in turn leads to the abnormal bleeding. According to the Platelet Disorders Support Association, approximately 200,000 individuals are affected by ITP, with women affected approximately three times as often as men. It can affect all ages and ethnic groups, and about 50% of the new cases occur in children. Current treatment includes corticosteroids and removal of the spleen. Although most cases can be controlled with therapy, the treatments can have significant side effects and there is currently no broadly effective curative therapy. We believe that PRTX-100 would offer these patients an alternative therapy which is potentially more cost effective, efficacious, and results in fewer side effects.

Additionally, the Company’s business model 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. The BXSB animal model is a generalized autoimmune model, and suggests PRTX-100 may be utilized to treat a host of other autoimmune indications.

Competition

We believe, based on the pre-clinical trials and the result of the two Phase I clinical trials, that our compound, PRTX-100, has a potential competitive advantage, as it may require lower doses and has the potential to be more convenient, safer and more efficacious than existing 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 $19,980 per patient, according to a Cowen and Company, LLC report entitled “Therapeutic Categories Outlook” dated March 2009. 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®);
- Soluble Interleukin-l (IL-I) Receptor Therapy, Anakinra (Kineret®).
- Costimulatory molecule inhibitor (abatacept, Orencia® Anti CD20 therapy, rituximab (Rituxan®)
- “Immunoadsorption Therapy,” also known as Prosorba®, now in limited use in Europe and the United States, entailing weekly sessions during which a patient’s blood is separated and passed through a molecular filter. The use of such extreme treatment modalities emphasizes the unmet need for a new treatment for patients who cannot respond to existing therapies.

Many large and small pharmaceutical companies are active in this market, with Amgen Corporation, Johnson & Johnson, Inc. and Abbott Laboratories, dominating the market with their respective products, Enbrel®, Remicade®

and Humira®. According to the Cowen and Company, LLC report dated March 2009 for RA in 2008 Enbrel® generated revenue of $2.09 billion; Remicade® generated revenue of $1.55 billion; and Abbot's Humira®, generated revenue of $1.38 billion. Other recent entrants into the RA market are Orencia® from Bristol-Myers Squibb and Rituxan® from Biogen Idec/Genentech which generated revenue of $360 million and $300 million for RA in 2008, respectively.

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. The Company anticipates that PRTX-l00 and its other products will provide such opportunity, but there can be no assurance that such results will occur.

There are several companies that are developing thrombopietin agonists for treating ITP. GlaxoSmithKline's Promacta® received FDA advisory panel approval in June 2008, Amgen's AMG531 is in Phase III, Ligand Pharmaceuticals' LGD4665 is in Phase II and Genzyme's GMA161 is in Phase I.

We expect the Company's U.S. patent issued in May 2007 to be a potential barrier to entry that could prevent competitors from implementing the same procedures as the Company. However, the Company may be unable to protect these proprietary rights. See the risk factor titled "If we are unable to protect, obtain and maintain our proprietary rights, we may not be able to compete effectively or operate profitably" on page 9 of this annual report.

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 United States federal, state, local and foreign laws.

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

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

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

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

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

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

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

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

Preclinical tests may include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity and other effects in animals. The results of preclinical tests, together with manufacturing information and analytical data, among other information, are submitted to the FDA as part of an IND application. Subject to certain exceptions, an IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, issues a clinical hold to delay a proposed clinical investigation due to concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND, or those of our collaboration partners, may not result in the FDA authorization to commence a clinical trial. A separate submission to 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 Ib" 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 dose tolerance and 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.

Orphan Drug Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an BLA. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to seven years of orphan drug exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity (superior efficacy, safety, or a major contribution to patient care). Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication. We intend to seek orphan drug designation for our products at the appropriate time.

Under European Union medicines laws, the criteria for designating a product as an "orphan medicine" are similar but somewhat different from those in the United States. A drug is designated as an orphan drug if the sponsor can establish that the drug is intended for a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union or that is unlikely to be profitable, and if there is no approved satisfactory treatment or if the drug would be a significant benefit to those persons with the condition. Orphan medicines are entitled to ten years of marketing exclusivity, except under certain limited circumstances comparable to United States law. During this period of marketing exclusivity, no "similar" product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan designation change or the sponsor makes excessive profits.

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 US Patent #7,211,258. We have also filed for foreign protection relating to this patent in Canada, Japan and the European Union.

Employees

We currently have no employees. The only management member of the Company providing services to the Company at this time is the Chief Financial Officer, Marc L. Rose, who is being compensated beyond his severance payments as a consultant as previously described in the Company's Form 8-K Report filed on July 2, 2009. We have never experienced an employee-related work stoppage. We will need to hire and retain highly-qualified experienced technical, management and sales personnel in order to execute our business plan, carry out product development and secure advantages over our competitors, all of which is subject to raising adequate additional financing, if ever.

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

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. As of the date of this Report, the Company has no employees and it has insufficient funds to cover future clinical trials and CMC related expenses beyond the third calendar quarter of 2009. 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, 2009, our cumulative net loss was $44,584,511. Our net loss was $7,230,206 for the fiscal year ended May 31, 2009. Our continued operational loss may lower 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. Furthermore, if the Company is unable to raise sufficient additional funds, it will likely be required to suspend or cease further operations on or about the end of the third calendar quarter of 2009 until such financing is obtained, if ever.

As of the date of this Report, the Company has suspended the further recruitment of patients for its ITP clinical trials pending the raising of additional funding, the retention of additional clinical personnel and an evaluation of the Company's clinical trial programs.

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 the Company is unable to raise sufficient additional funds, it will likely be required to suspend or cease further operations on or about the end of the third calendar quarter of 2009 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, 2009, we had cash and cash equivalents of $2,637,292 and net working capital of $1,237,428 compared to cash and cash equivalents of $8,442,809 and working capital of $7,542,741 as of May 31, 2008. We have suffered recurring losses from operations and negative cash flows. As of the date of this Report, the Company has no employees and it has insufficient funds to cover future clinical trials and CMC related expenses beyond the third calendar quarter of 2009. As a result, our independent registered accountants, Grant Thornton LLP, indicated in their report on our 2009 financial statements that there is substantial doubt about our ability to continue as a going concern.

We are considering all strategic options and also options for generating additional cash to fund our continuing business operations. If 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 shareholders 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.

ITP is an uncommon autoimmune bleeding disorder characterized by too few platelets in the blood. Affected individuals may have bruising, small purple marks on the skin called petechiae, bleeding from the gums after having dental work, nosebleeds or other bleeding that is hard to stop, and in women, heavy menstrual bleeding. Although bleeding in the brain is rare, it can be life threatening if it occurs. The affected individuals make antibodies against their own platelets leading to the platelets' destruction, which in turn leads to the abnormal bleeding. In ITP, we contracted Trident Clinical Research Pty Ltd, a leading Australian clinical research organization, to manage and monitor our first-in-patient ITP clinical trial. This clinical trial is designed to provide initial multiple dose safety and PK data as well as preliminary efficacy information. We have been approved for six sites in Australia and one in New Zealand, all regional referral centers for treatment of chronic ITP, to conduct a repeated dose study of PRTX-100 in chronic ITP patients. This clinical trial began enrolling patients in the second calendar quarter of 2008. In calendar 2008, we enrolled nine patients of which five completed the trial and final results indicated that the drug was safe and well tolerated, although no efficacy data was obtained. Subsequently, the Company obtained protocol approval to increase the dose range. While the Company has actively solicited patients in calendar 2009 under this new protocol, no patients have been enrolled as of the date of this Report.

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 US Patent #7,211,258. 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 U.S., patent applications may remain confidential after filing or published 18 months after filing.

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

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

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

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

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

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

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

- Contract manufacturers are obliged to operate in accordance with FDA-mandated cGMPs. Their failure to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the availability of material for clinical study and may delay or prevent filing or approval of marketing applications for our products. Additionally, failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.
- It may be difficult or impossible for us to find replacement manufacturers quickly on acceptable terms, or at all. For example, we have initially relied on a single contract drug substance manufacturer, Eurogentec S.A., to produce PRTX-100. Changing this manufacturer, or changing the manufacturer for any other products we develop, may be difficult 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 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 delayed, and our ability to commercialize this product could be impaired or precluded.

Without adequate additional financing in the third calendar quarter of 2009, the Company runs the risk of not having adequate clinical trial material available to complete our clinical trails, which could also lead to a significant delay in continuing and /or commencing our clinical trial programs.

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 beyond our Board of Directors due to a lack of management. To market our product directly, we must develop a direct marketing and sales force with technical expertise and supporting distribution capability. Alternatively, we may engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. There can be no assurance that we will successfully establish sales and distribution capabilities either on our own or in collaboration with third-parties or gain market acceptance for our product. To the extent we enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third-parties. Those efforts may not succeed.

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

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

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

Most 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 previously depended on the principal members of our management staff, including Steven H. Kane, our president and chief executive officer, and Marc L. Rose, CPA, our vice president of finance, chief financial officer, treasurer and corporate secretary and consultants such as Edward W. Bernton, MD, who served as our medical director. With the exception of Mr. Rose, who currently provides various financial services to the Company as a consultant, none of these individuals presently provide any services to the Company. The Company has also subsequently retained a vendor to provide similar services previously provided by Dr. Bernton as the Company may request from time to time. As previously disclosed in our Form 10-Q filed on April 14, 2009, Messers. Kane and Rose have voluntarily terminated their employment with the Company. Messers. Kane and Rose remain the CEO and CFO, respectively, of the Company. As of the date of this Report, while Mr. Rose has not accepted full time employment elsewhere, Mr. Kane is now also currently the Chairman and CEO of Patient Safety Technologies, Inc. The loss 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 the Company raising 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 from that which the Company had previously retained. 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, the trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations and 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 $3,000,000 clinical liability insurance policy and as required, country specific clinical liability insurance will be procured. As required by local regulations, an AUD $10,000,000 clinical liability insurance has been procured for the ITP trial in Australia and New Zealand. 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; and

- depth and liquidity of the market for our common stock;
- inability to raise adequate financing.

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, 2009, our stock price ranged from a high of $1.01 to a low of $0.02 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 the company 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.

Our common stock is quoted on the OTC Bulletin Board which may have an unfavorable impact on our stock price and liquidity.

Our common stock is quoted on the OTC Bulletin Board. The OTC Bulletin Board is a significantly more limited market than the New York Stock Exchange or NASDAQ system. The quotation of our shares on the OTC Bulletin Board may result in a less liquid market available for existing and potential stockholders to trade shares of our common stock, 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

Not Applicable

ITEM 2. PROPERTIES

We originally entered into a three year operating lease in New Hope, PA for 3,795 square feet of office and laboratory space. The lease commenced on January 9, 2004 and was to expire on February 28, 2007. On November 18, 2005, we modified the existing lease which added an additional 2,147 square feet and extended the lease term to January 31, 2008. In the fiscal third quarter of 2006, we invested $62,907 in leasehold improvements, which was amortized

through January 2008. On April 30, 2007, we modified the existing lease and extended the lease term to January 31, 2009 with an option for an additional one year. In August 2008, we exercised the one year option and extended the lease term to January 31, 2010. In July 2009, we subleased the original 3,795 square feet of office and laboratory space through January 31, 2010.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any pending material legal proceedings and we are not aware of threatened material legal proceedings to which any person, officer, affiliate of the Company or any owner of more than 5% of the Company's stock is an adverse party to or has a material interest adverse to, the Company.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of security holders in the fourth quarter of the fiscal year ended May 31, 2009.

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 Over the Counter – Bulletin Board (OTCBB) under the symbol "PRTX". The price range per share reflected in the table below is the highest and lowest per share sales price for our stock as reported on the OTCBB during each quarter of the two most recent fiscal years. Such over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	High	Low
2008		
First Quarter	$ 1.85	$ 1.20
Second Quarter	1.50	1.05
Third Quarter	1.50	1.01
Fourth Quarter	1.18	0.68
2009		
First Quarter	$ 0.92	$ 0.36
Second Quarter	1.01	0.16
Third Quarter	0.30	0.04
Fourth Quarter	0.30	0.02

(b) Holders. As of May 31, 2009, there were approximately 397 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.

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable

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 2009 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 engaged in developing a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases. Our lead product, PRTX-100, has demonstrated effectiveness in pre-clinical studies in regulating the immune system with persisting effects. However, the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we will see in our clinical trials. We currently have no product on the market. The Company's initial business model initially targeted the autoimmune diseases idiopathic thrombocytopenic purpura, or ITP, and Rheumatoid Arthritis, or RA.

As of the date of this Report, the Company has no employees and it has insufficient funds to cover future clinical trials and Chemistry, Manufacturing and Control or CMC related expenses beyond the third calendar quarter of 2009. If the Company is unable to raise sufficient additional funds, it will likely be required to suspend or cease further operations on or about the end of the third calendar quarter of 2009 until such financing is obtained, if ever. These matters raise substantial doubt about the ability of the Company to continue as a going concern.

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 United States Food and Drug Administration or 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 with 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. The basic safety data demonstrated that PRTX-100 was safe and well tolerated. There were no deaths or serious adverse events. The pharmacokinetic (PK) profile was favorable and the pre-clinical PK data were confirmed by the data in this Phase I clinical trial. 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.

RA is an autoimmune disease that causes the inflammation of the membrane lining multiple joints, resulting in pain, stiffness, warmth, redness and swelling. The inflamed joint lining, the synovium, can invade and damage bone and cartilage. Inflammatory cells release enzymes and cytokines that may damage bone and cartilage. The involved joint

can lose its shape and alignment, resulting in pain and loss of movement. In July 2007, we commenced with an additional Phase I clinical trial designed to gain more detailed information on biomarkers, including gene expression profiling and platelet functional assessments which will allow for more optimized patient selection and targeting in the upcoming clinical trials. This second Phase I clinical trial extended the clinical investigation of PRTX-100 tolerability, PK, and pharmacodynamics, or PD, at higher dose ranges. Dosing was completed in July 2007 and final results indicated that the drug was safe and well tolerated. A Phase Ib randomized, double-blind, placebo-controlled, multiple dose, dose escalation safety and tolerability study of PRTX-100 in combination with methotrexate in patients with active RA in South Africa has been approved and subject to adequate additional financing, we anticipate starting this clinical trial.

ITP is an uncommon autoimmune bleeding disorder characterized by too few platelets in the blood. Affected individuals may have bruising, small purple marks on the skin called petechiae, bleeding from the gums after having dental work, nosebleeds or other bleeding that is hard to stop, and in women, heavy menstrual bleeding. Although bleeding in the brain is rare, it can be life threatening if it occurs. The affected individuals make antibodies against their own platelets leading to the platelets' destruction, which in turn leads to the abnormal bleeding. In ITP, we contracted Trident Clinical Research Pty Ltd, a leading Australian clinical research organization, to manage and monitor our first-in-patient ITP clinical trial. This clinical trial is designed to provide initial multiple dose safety and PK data as well as preliminary efficacy information. We have been approved for six sites in Australia and one in New Zealand, all regional referral centers for treatment of chronic ITP, to conduct a repeated dose study of PRTX-100 in chronic ITP patients. This clinical trial began enrolling patients in the second calendar quarter of 2008. In calendar 2008, we enrolled nine patients of which five completed the trial and final results indicated that the drug was safe and well tolerated, although no efficacy data was obtained. Subsequently, the company obtained approval of the protocol to increase the dose range and continues to actively solicit patients in calendar 2009; however no patients have been enrolled as of the date of this report.

As of the date of this Report, the Company has suspended the further recruitment of patients for its ITP clinical trials pending the raising of additional funding, the retention of additional clinical personnel and an evaluation of the Company's clinical trial programs.

In the area of intellectual property and derivative drug development, our patent application was filed in April 2002 and in May 2007 the PTO issued patent #7,211,258 titled “Protein A Compositions and Methods of Use.” Additionally, patent applications relating to the manufacturing process of PRTX-100 and new compounds are currently in process.

Critical Accounting Policies

Our financial statements are prepared in conformity with accounting principles generally accepted in the United States of America. Note 2 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.

Significant management judgment is required in determining the valuation allowance recorded against net deferred tax assets, which primarily consist of net operating loss carry-forwards. We have recorded a full valuation allowance of $18,842,000 as of May 31, 2009, due to uncertainties related to our ability to utilize such net operating loss carry-forwards before they expire. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable, if at all.

We account for our stock option grants under the provisions of SFAS No. 123R, Share-Based Payments (“SFAS 123R”). SFAS 123R 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 SFAS 123R, 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 SFAS 123R. Prior to the adoption of SFAS 123R, we accounted for our stock option grants under the provisions of Accounting Principles Board (“APB”) Opinion No. 25, Accounting for Stock Issued to Employees (“APB25”) and made pro forma footnote disclosures as required by SFAS No. 148, Accounting for Stock-Based Compensation—Transition and Disclosure, which amends SFAS No. 123, Accounting for Stock-Based Compensation.

Results of Operations

Fiscal year ended May 31, 2009 compared to fiscal year ended May 31, 2008

Research and Development Expenses – Research and Development expenses decreased from $7,657,127 in 2008 to $3,490,956 in 2009. The decrease of $4,166,171, or 54%, was primarily the result of fewer personnel along with lower manufacturing and regulatory consulting related expenses. Also, included in Research & Development expenses in 2009 was $223,961 compared to $334,228 in 2008 for stock option compensation expense subsequent to the adoption of SFAS No. 123R.

Administrative Expenses - Administrative expenses increased from $2,759,463 in 2008 to $3,505,259 in 2009. The increase of $745,796, or 27%, was primarily due to the impact of accruing for the severance which totaled $1,185,638, along with $529,307 compared to $676,797 in 2008 for stock option compensation expense subsequent to the adoption of SFAS No. 123R.

Professional Fees - Professional fees decreased from $619,314 in 2007 to $365,670 in 2009. The decrease of $253,644, or 41%, was due to a decrease in business development activities pertaining to potential strategic partnerships and investor relations activity as compared to the same period last year.

Interest income - Interest income decreased from $549,292 in 2008 to $57,651 in 2009. The decrease of $491,641 or 90% was attributed to a decrease in interest bearing cash balances resulting from the use of cash for operations and lower interest rates as compared to the same period last year.

Fiscal year ended May 31, 2008 compared to fiscal year ended May 31, 2007

Research and Development Expenses – Research and Development expenses increased from $5,562,485 in 2007 to $7,657,127 in 2008. The increase of $2,094,642, or 38%, was primarily the result of conducting and planning clinical trials including regulatory consulting along with product manufacturing, formulation and qualification related costs. On January 2, 2007, the Company terminated the employment of Victor S. Sloan, MD, former Senior Vice President and Chief Medical Officer, under the terms of his employment agreement, which resulted in an expense related to severance of approximately $290,000. Also, included in Research & Development expenses in 2008 was $334,228 compared to $395,625 in 2007 for stock option compensation expense subsequent to the adoption of SFAS No. 123R.

Administrative Expenses - Administrative expenses decreased from $3,360,252 in 2007 to $2,759,463 in 2008. The decrease of $600,789, or 18%, was primarily due to stock option compensation expense. Included in Administrative expenses in 2008 was $676,797 for stock option compensation expense compared to $1,431,255 in 2007.

Professional Fees - Professional fees increased from $544,903 in 2007 to $619,314 in 2008. The increase of $74,411, or 14%, was due to an increase in business development activities pertaining to potential strategic partnerships as compared to the same period last year.

Interest income - Interest income decreased from $1,020,820 in 2007 to $549,292 in 2008. The decrease of $471,528, or 46% was attributed to a decrease in interest bearing cash balances resulting from the use of cash in operations and lower interest rates as compared to the same period last year.

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. Our primary source of cash to meet short-term and long-term liquidity needs is the sale of shares of our common stock. If the Company is unable to raise sufficient additional funds, it will likely be required to suspend or cease further operations on or about the end of the third calendar quarter of 2009 until such financing is obtained, if ever. These matters raise substantial doubt about the ability of the Company to continue as a going concern. We issue shares in private placements at a discount to the current market price, as such the resale of privately-placed shares are restricted under the Securities Act, which reduces their liquidity and, accordingly, their value as compared to freely-tradable shares on the open market.

On September 18, 2003, we raised $12,657,599 through the sale of 7,445,646 shares of our common stock at $1.70 per share, with warrants to purchase an additional 3,164,395 shares of our common stock, at an exercise price of $2.40 per share. The 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 2,593,788 shares of our common stock at $1.95 per share, with warrants to purchase an additional 920,121 shares of our common stock, at an exercise price of $2.25 per share. The warrants expire on May 25, 2010. As part of this transaction, the exercise price for the warrants from the September 2003 transaction were lowered from $2.40 per share to $2.25 per share. 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 2,595,132 shares of our common stock at $2.25 per share, with warrants to purchase an additional 648,784 shares of our common stock, at an exercise price of $2.99 per share. We also issued warrants to purchase 227,074 shares of our common stock, at an exercise price of $2.99 per share, to the placement agent. All the warrants expire 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 351,598 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 6,071,013 shares of our common stock at $2.50 per share, with warrants to purchase an additional 1,517,753 shares of our common stock, at an exercise price of $3.85 per share. We also issued warrants to purchase 531,214 shares of our common stock, at an exercise price of $3.85 per share, to the placement agent. All the warrants expire on July 7, 2011.

In the first fiscal quarter of 2007, existing investors and option holders exercised 133,500 warrants and 6,000 options which resulted in $315,574 in cash proceeds.

To the extent any further warrants are exercised, we intend to use the proceeds for general working capital and corporate purposes. If all warrants are exercised in cash, our proceeds would be approximately $18.9 million.

The following is a summary of selected cash flow information for the fiscal years ended May 31, 2009, 2008 and 2007:

	Year Ended	Year Ended	Year Ended

	May 31, 2009	May 31, 2008	May 31, 2007
Net loss	$ (7,230,206)	$ (10,490,758)	$ (8,451,942)
Adjustments for non-cash operating items	803,067	1,188,064	1,996,715
Net cash operating loss	$ (6,427,139)	$ (9,302,694)	$ (6,455,227)
Net change in assets and liabilities	421,622	199,349	(120,785)
Net cash used in operating activities	$ (6,005,517)	$ (9,103,345)	$ (6,576,012)
Net cash provided/(used) in investing activities	$ 200,000	$ —	$ (403,674)
Net cash provided by financing activities	$ —	$ —	$ 14,533,295

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

Our operating cash outflows for the fiscal years ended May 31, 2009, 2008 and 2007 were primarily for research and development expenditures for PRTX-100 and administrative operations. We expect to continue to use cash resources to fund operating losses and/or the wind-down of our operations if additional financing is not obtained . Even with additional financing, we would expect to continue to incur operating losses in fiscal 2010 and beyond due to continuing research and development activities.

Net Cash Used In Investing Activities and Investing Requirements Outlook

Net cash provided by investing activities for the fiscal year ended May 31, 2009 resulted from the sale of capital equipment and net cash used by investing activities for fiscal year ended May 31, 2007 relates primarily to the acquisition of capital equipment. Subject to adequate additional financing, we expect to continue to require investments in information technology, laboratory and office equipment to support our research and development activities.

Net Cash Provided by Financing Activities and Financing Requirements Outlook

Net cash inflows provided by financing activities for the fiscal years ended May 31, 2007 resulted primarily from the sale of shares of common stock and the exercise of warrants and stock options.

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. Our existing cash and cash equivalents of $2,637,292 as of May 31, 2009 will be sufficient to fund operations into the third calendar quarter of 2009. 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. In order to raise additional capital, we expect to seek financing through the private or public sales of our securities, which may include common stock, debt and/or warrants to purchase common stock.

Off Balance Sheet Arrangements and Contractual Obligations

We have entered into the following contractual obligations:

- Employee Agreements-Officers. As previously disclosed in our Form 10-Q filed on April 14, 2009, Messers. Kane and Rose voluntarily terminated their employment. Messers. Kane and Rose remain the CEO and CFO, respectively, of the Company. As of the date of this report, while Mr. Rose has not accepted full time employment elsewhere, Mr. Kane is now currently also the Chairman and CEO of Patient Safety Technologies, Inc.
- Directors Agreements. To attract and retain qualified candidates to serve on the board of directors, we have previously entered into agreements with G. Kirk Raab, Chairman of the Board, Carleton A. Holstrom, Chairman of the Audit Committee, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro under which Messrs. Raab, Holstrom, Dr. Bauer, Mr. Tombros, Mr. Dougherty and Mr. Stagnaro receive aggregate annual cash payments aggregating $150,000, $20,000, $20,000, $20,000, $20,000 and $20,000 respectively, as directors' fees. Pursuant to a Cash Waiver & Option Termination Agreement dated April 10, 2009, each of the outside Directors of the Company, G. Kirk Raab, Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro who are currently entitled to a Director's cash fee agreed to waive all such accrued and unpaid Director cash fees and terminate any rights for further cash fees. For Mr. Raab, those cash fees ceased as of April 1, 2009. For the other Directors, those cash fees ceased as of February 1, 2009. In addition, each of these Directors agreed to terminate immediately all of their existing stock options in the Company (vested and unvested).
- Operating Lease – Office Space. We have entered into a three-year operating lease in New Hope, PA for 3,795 square feet of office and laboratory space. The lease commenced on January 9, 2004 and was originally to expire on February 28, 2007. On November 18, 2005, we modified the existing lease which added an additional 2,147 square feet and extended the lease term to January 31, 2008 and on April 30, 2007, we modified the existing lease and extended the lease term to January 31, 2010.
- Operating Lease – Copier. We entered into a sixty-three month operating lease for a multi-function copier. The lease commenced on December 16, 2004 and will expire on March 16, 2010.

Recently Issued Accounting Pronouncements

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles-a replacement of FASB Statement No.162 ("SFAS 168"). SFAS 168 establishes the FASB Accounting Standards Codification as the single source of authoritative US generally accepted accounting principles recognized by the FASB to be applied to nongovernmental entities. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of SFAS

168 will not have an impact on the Company's financial position, results of operations or cash flow. The Company will update the disclosures for the appropriate FASB codification reference after adoption in the second quarter of fiscal 2010.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events ("SFAS 165"). SFAS 165 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. The Company has evaluated subsequent events after the balance sheet date of May 31, 2009 through the date this annual report is filed on August 28, 2009.

In December 2007, the FASB issued SFAS No. 141R (revised 2007) Business Combinations ("SFAS 141R"). SFAS 141R states that all business combinations (whether full, partial or step acquisitions) will result in all assets and liabilities of an acquired business being recorded at their fair values. Certain forms of contingent considerations and certain acquired contingencies will be recorded at fair value at the acquisition date. SFAS 141R also states acquisition costs will generally be expensed as incurred and restructuring costs will be expensed in periods after the acquisition date. This statement is effective for financial statements issued for fiscal years beginning after December 15, 2008. Earlier adoption is prohibited. We are currently evaluating the impact, if any, of SFAS 141R upon adoption on our financial statements.

In December 2007, the FASB ratified the Emerging Issue Task Force ("EITF") Issue 07-01, Accounting for Collaborative Arrangements ("EITF 07-01"). EITF 07-01 clarifies the accounting for contractual arrangements wherein two or more parties come together to participate in a joint operating activity which is conducted based on provisions of a contract. EITF 07-01 provides guidance on income statement classification of revenues and expenses related to such activities, and specifies disclosures that should be made with respect to such activities. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of EITF 07-01 on its financial statements.

The Company adopted the provisions of FASB Interpretation 48, Accounting for Uncertainty in Income Taxes. Previously, the Company had accounted for tax contingencies in accordance with Statement of Financial Accounting Standards 5, Accounting for Contingencies. As required by Interpretation 48, which clarifies Statement 109, 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. At the adoption date, the Company applied Interpretation 48 to all tax positions for which the statute of limitations remained open. The impact of adopting FIN 48 was not material as of the date of adoption or in subsequent periods. As a result of the implementation of Interpretation 48, the Company did not recognize any change in the liability for unrecognized tax benefits and there was no change to the June 1, 2007 balance of retained earnings.

The Company is subject to US 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K and incorporated by reference herein.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management of our company is responsible for establishing and maintaining effective disclosure controls and procedures as defined under Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934. As of May 31, 2009, an evaluation was performed, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that as of May 31, 2009, our disclosure controls and procedures were effective at the reasonable assurance level to ensure that information required to be disclosed by the Company in reports filed under the Exchange Act was recorded, processed, summarized and reported within the time period required by the Securities and Exchange Commission's rules and forms and accumulated and communicated to management, including our Chief Executive

Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

As previously disclosed in our Form 10-Q filed on April 14, 2009, Messers. Kane and Rose voluntarily terminated their employment. Messers. Kane and Rose remain the CEO and CFO, respectively, of the Company. As of the date of this report, while Mr. Rose has not accepted full time employment elsewhere, Mr. Kane is now currently also the Chairman and CEO of Patient Safety Technologies, Inc.

Changes in Internal Control Over Financial Reporting

During the quarter ended May 31, 2009 and thereafter, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of May 31, 2009.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

ITEM 9B. OTHER INFORMATION

As of the date of this Report, the Company and each of its current directors and executive officers have agreed to enter into an indemnification agreement (the "Indemnification Agreement"). It is anticipated that future directors and officers of the Company will enter into an Indemnification Agreement with the Company in substantially similar form. The Indemnification Agreement provides, among other things, that the Company 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 the Company or serving at the request of the Company as a director, officer, employee, fiduciary or agent of another entity. The Indemnification Agreement further provides that, upon an Indemnified Party's request, the Company 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 the Company has the burden of proving otherwise. The Indemnification Agreement also requires the Company 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, the Company, 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.

The foregoing summary of the Indemnification Agreement does not purport to be complete and is qualified in its entirety by reference to the form of Indemnification Agreement attached as Exhibit 10.21 and incorporated herein by reference.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers and Directors

Our current directors and executive officers are as follows:

Name	Age	Position and Offices Held with the Company
G. Kirk Raab + #	73	Chairman of the Board
Steven H. Kane +	56	President, Chief Executive Officer and Director
Marc L. Rose, CPA	44	Vice President, Chief Financial Officer, Treasurer and Corporate Secretary
Eugene A. Bauer, M.D. #	67	Director
Frank M. Dougherty + #	61	Director
Carleton A. Holstrom *	73	Director
Dinesh Patel, Ph.D. *	58	Director
Thomas P. Stagnaro *	66	Director
Peter G. Tombros #	67	Director

* Member of the Audit Committee
\# Member of Compensation Committee
\+ Member of the Nominating and Corporate Governance Committee

G. Kirk Raab has served as Chairman of the Company's Board of Directors since August 2003. Mr. Raab currently sits on the Boards and serves as Chairman of Transcept Pharmaceuticals, Inc., Follica, Inc., Velos Medical Informatics, Inc., and BiPar Sciences, Inc. Mr. Raab also serves on the board of The National Foundation for Science and Technology Medals. From February 1990 to July 1995, Mr. Raab served as the President and Chief Executive Officer of Genentech. He originally joined Genentech in February 1985, as President and Chief Operating Officer. Prior to joining Genentech, Mr. Raab worked for Abbott Laboratories for 10 years, most recently as President, Chief Operating Officer and a director. Mr. Raab served as the first Chairman of the Biotechnology Industry Organization and the California Health Care Institute. Mr. Raab graduated from Colgate University in 1959, and is a Trustee Emeritus. He is a former trustee of the San Francisco Ballet, the San Francisco Symphony, UCSF Foundation and Golden Gate Planned Parenthood.

Steven H. Kane has served on the Company's board of directors since December 2002. He is currently the Chairman and CEO of Patient Saftey Technologies, Inc., and President and Chief Executive Officer of the Company. He has over 25 years experience in the health care industry. From April 1997 to August 2000, Mr. Kane served as Vice President of North American Sales & Field Operations for Aspect Medical. While at Aspect, he helped guide the company to a successful initial public offering in January 2000. Prior to Aspect, Mr. Kane was Eastern Area Vice President for Pyxis Corporation, where he was instrumental in positioning the company for its successful initial public offering in 1992. Pyxis later was acquired by Cardinal Health for $1 billion. Prior to that Mr. Kane worked in sales management with Eli-Lilly and Becton Dickinson.

Marc L. Rose, CPA, has served as the Company's Vice President of Finance, Chief Financial Officer and Treasurer since November 2004 and in April 2005 Mr. Rose was elected Corporate Secretary. From March 2001 to November 2004, Mr. Rose served as Vice President and Chief Financial Officer of the DentalEZ Group, a privately held manufacturer of dental equipment and dental handpieces located in Malvern, PA. From January 1998 to March 2001, Mr. Rose was Practice Manager of Oracle Consulting Services for Oracle Corporation responsible for designing and implementing Oracle financial and project applications. From September 1990 to January 1998, Mr. Rose held several positions with the controllership organization of Waste Management, Inc and from June 1988 to September 1990, was an auditor with Ernst & Young in Philadelphia. Mr. Rose is a Certified Public Accountant in the Commonwealth of Pennsylvania and received his BA in Accounting/Finance from Drexel University.

Eugene A. Bauer, M.D. has served on the Company's Board of Directors since February 2005. Dr, Bauer is President & Chief Medical Officer and member of the Board of Directors of Peplin, Inc., a public company traded on the ASX in Australia. From 2004 to 2008 he was Chief Executive Officer and board member of Neosil Incorporated, a privately held biotechnology company that was acquired by Peplin in 2008. From 2002 to 2004 Dr. Bauer was a Senior Client Partner with Korn/ Ferry International. Dr. Bauer served as Vice President for the Stanford University Medical Center from 1997 to 2001, and as Dean of the Stanford University School of Medicine from 1995 through 2001. Dr. Bauer was a founder of Connetics and served as an Emeritus Director of Connetics Corp until its sale to Stiefel Laboratories in 2006. Since 1988 he has been Professor, Department of Dermatology, Stanford University School of Medicine, and was Chief of the Dermatology Service at Stanford University Hospital from 1988 to 1995. From 1982 to 1988, he was a professor at Washington University School of Medicine. Dr. Bauer has served as Chairman of two National Institutes of Health study sections of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and has served on a board of scientific counselors for the National Cancer Institute. Dr. Bauer also serves as a director of Medgenics, Inc., a development stage biotechnology company listed on the LSE/AIM. Dr. Bauer is a director of two privately held companies, Arbor Vita Corporation and Medisync Bioscience, Inc., and he is a director of the American Dermatological Association, a non-profit professional society. Dr. Bauer holds B.S. and M.D. degrees from Northwestern University.

Frank M. Dougherty has served on the Company's Board of Director since October 2001, and served as the Company's Corporate Secretary from June 2002 to December 2002. From January 2004 to April 2005, Mr. Dougherty served as the Corporate Secretary and Treasurer of the Company. Mr. Dougherty is a practicing attorney and founder and owner of Frank M. Dougherty P.C., a law firm in Albuquerque, New Mexico. He has practiced law since 1982, and founded his current law firm in November 2001. Prior to becoming a lawyer, Mr. Dougherty practiced as a CPA in Santa Fe, New Mexico. He has an undergraduate degree in economics from the University of Colorado, a graduate degree in accounting from the University of Arizona and a law degree from Texas Tech University.

Carleton A. Holstrom has served on the Company's Board of Directors since October 2004. From 1977 through 1987, Mr. Holstrom was the Chief Financial Officer of Bear, Stearns & Co. and its successor, The Bear Stearns Companies, Inc., and from 1987 until 2008 was the Managing Director Emeritus. From 1996 to 1997, Mr. Holstrom was the Chief Financial Officer of Scientific Learning Corporation. From 1983 until 2009, Mr. Holstrom served on the Board of Directors of Custodial Trust Company of Princeton, New Jersey, and from 1995 until 2009 was a director of Scientific Learning Corporation of Oakland, California. Since 2008, Mr. Holstrom has served on the board of Carl Marks & Co. LLC.

Dinesh Patel, PhD has served on the Company's Board of Director since September 2003. He is a Managing Director and Founding Partner of vSpring Capital, an early stage venture capital fund with $400 million under management. From 1999 to 2004 Dr. Patel was also the Founder, Chairman, President & CEO of Ashni Naturaceuticals, Inc. a company that specializes in the research, development and marketing of clinically tested and patent-protected naturaceutical products. In 1999, Dr. Patel co-founded and was the Chairman of Salus Therapeutics, Inc., a biotechnology company focused on the research and development of nucleic acid-based therapeutics, including antisense and gene therapy drugs.. From 1985 through 1999, Dr. Patel served as Co-founder, Chairman of the Board of Directors, President & CEO, of Thera Tech, Inc., a Salt Lake City, Utah based company, that has been a pioneer in the development and manufacture of innovative drug delivery products.. Dr. Patel has been the recipient of numerous awards, including US Small Business Administration's Business Achiever Award, and Scientific and Technology Award (State of Utah) and Entrepreneur of the Year Award (Mountain West Venture Group). Dr. Patel got his undergraduate degree from India and his doctorate degree from University of Michigan. Dr. Patel is active in the Indian and local community serving on several boards and as an active donor for various charitable causes.

Thomas P. Stagnaro has served on the Company's Board of Directors since July 2002. He is President & Chief Executive Officer of Americas Biotech Distributor (ABD), which he founded in June 2004. Previously, Mr. Stagnaro was President and Chief Executive Officer of Agile Therapeutics, a private company focused on developing women's healthcare products from September 2000 to August 2004. He also served as a director on the board of Life Science Research Organization and the National Science Foundation - Singapore. Mr. Stagnaro formerly was President and Chief Executive Officer of 3-Dimensional Pharmaceuticals and Univax Biologics. He began his career with Searle Laboratories and held increasingly important positions during his 30 years in the pharmaceutical industry. Mr. Stagnaro has raised over $200 million for three development stage companies and took Univax Biologics public in 1972. He holds three patents and has published numerous articles.

Peter G. Tombros has served on the Company's Board of Directors since November 2005. Mr. Tombros is currently Professor and Executive in Residence in the Eberly College of Science BS/MBA Program at the Pennsylvania State University. From 2002 to 2005, Mr. Tombros served as CEO and Chairman of the Board of VivoQuest, a private drug discovery company which combined proprietary natural product chemistry and proprietary biological assays to develop small molecule products for antiviral diseases. VivoQuest was sold to XTL Biosciences in September, 2005. Prior to that, Mr. Tombros served as President and CEO of Enzon Pharma. From 1968 to 1994 Mr. Tombros was at Pfizer Inc. where he helped to build the Pharmaceutical Business in a variety of positions including Vice President of Marketing, Senior Vice President and General Manager and Executive Vice President, Pfizer Pharmaceuticals. Mr. Tombros presently serves on two other public company boards including Cambrex (NYSE), and

NPS Pharmaceuticals (NASDQ). Mr. Tombros received his BS and MS degrees from Penn State and his MBA from the University Of Pennsylvania Wharton School Of Business.

Director Independence

Each of the following directors are “independent” under NASDAQ Stock Market LLC rules: Messers. Raab, Dougherty, Holstrom, Stagnaro, and Tombros; and Drs. Bauer and Patel. These persons represent a majority of the board of directors. All members of the Compensation and Audit Committees are independent. Mr. Kane, a director and the Company’s President and Chief Executive Officer is a member of the Nominating and Corporate Governance Committee and is not considered independent. The other two members of the Nominating and Corporate Governance Committee are independent directors.

Audit Committee

The members of the Audit Committee are Messrs. Holstrom, Stagnaro and Dr. Patel. As of May 31, 2009, the chair of the Audit Committee was Mr. Holstrom. The Company believes Mr. Holstrom is qualified as an audit committee financial expert within the meaning of Securities and Exchange Commission regulations. In addition, the Board has determined, in accordance with the listing standards of the NASDAQ Capital Market that Mr. Holstrom meets the standards of financial sophistication set forth therein and that each other member of the audit committee is able to read and understand fundamental financial statements.

The Audit Committee meets with our management periodically to consider the adequacy of our internal controls and the objectivity of our financial reporting. The Audit Committee also meets with the independent auditors and with our own appropriate financial personnel and internal auditors regarding these matters. The independent auditors meet privately with the Audit Committee and have unrestricted access to this committee. The Audit Committee recommends to our Board the appointment of the independent auditors. The Audit Committee is also responsible for the pre-approval of any non-audit services provided to the Company by the independent auditors, as described in more detail in the Audit Committee Charter. The Audit Committee held four meetings during the fiscal year ended May 31, 2009. The charter of the Audit Committee is available on the Investor Information section of the Company’s website (www.protalex.com).

Nominating and Corporate Governance Committee

The Corporate Governance and Nominating Committee is responsible for developing and implementing policies and practices relating to corporate governance, including reviewing and monitoring implementation of the Company's Corporate Governance Guidelines. In addition, the Committee develops and reviews background information on candidates for the Board and makes recommendations to the Board regarding such candidates. The Committee also prepares and supervises the Board's annual review of director independence and the Board's performance evaluation. The Nominating and Corporate Goverence Committee met two times during fiscal 2009. The charter of the Corporate Governance and Nominating Committee is available on the Investor Information section of the Company's website (www.protalex.com).

The members of the Nominating and Corporate Governance Committee are Messrs. Raab, Kane and Dougherty. Mr. Kane is not considered independent because he is the Company's President and Chief Executive Officer. As of May 31, 2009, the chair of the Nominating and Corporate Governance Committee was Mr. Dougherty. The functions of this committee include recommending to our full Board nominees for election as Directors. Prior to the establishment of the Nominating and Corporate Governance Committee, its functions were performed by the entire Board.

Although there is no formal procedure for stockholders to recommend nominees for the Board, the Nominating and Corporate Governance Committee will consider such recommendations if received at least 120 days in advance of the Annual Meeting of Stockholders. Such recommendations should be addressed to the Nominating and Corporate Governance Committee at our address and provide all information relating to such person that the stockholder desires to nominate that is required to be disclosed in solicitation of proxies pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended ("Exchange Act").

Compensation Committee

The Compensation Committee annually reviews the performance and total compensation package for the Company's executive officers, including the Chief Executive Officer; considers the modification of existing compensation and employee benefit programs, and the adoption of new plans; administers the terms and provisions of the Company's equity compensation plans; and reviews the compensation and benefits of non-employee directors. The Compensation Committee met three times during fiscal 2009. The charter of the Compensation Committee is available on the Investor Information section of the Company's website (www.protalex.com).

The members of the Compensation Committee are Messrs. Raab, Dougherty, Tombros and Dr. Bauer. As of May 31, 2009, the chair of the Compensation Committee was Mr. Raab. Except for our CEO and Director, Mr. Steven H. Kane, who also serves as the CEO and a Board member of Patient Safety Technologies, Inc., none of our executive officers serves as a member of the Board of Directors or compensation committee of an entity that has an executive officer serving as a member of our Board or our Compensation Committee.

Code of Ethics

Our board of directors adopted a code of ethics that applies to its directors, officers and employees as well as those of its 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., 145 Union Square Drive, New Hope, PA 18938.

Family Relationships

There are no family relationships between or among any officer or director of the Company.

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, 2009 and 2008:

Name and Principal Position	Year	Salary ($) (1)	Bonus ($)	Stock Awards ($)	Option Awards ($) (2)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation (4)	Total ($)
Steven H. Kane, President and Chief Executive Officer	2009	350,000	—	—	107,040	—	—	30,021	487,061
	2008	400,000	75,000	—	—	—	—	29,745	504,745
Marc L. Rose, CPA, Vice President and Chief Financial Officer	2009	201,250	—	—	35,680	—	—	—	236,930
	2008	230,000	40,000	—	37,644	—	—	—	307,644

(1) In January 2008 and 2009, the Compensation Committee did not authorize salary increases for Messrs. Kane and Rose for calendar years 2008 or 2009, respectively. Effective, April 16, 2009, salary payments ceased under Messrs. Kane and Rose Employment Agreements pursuant to Settlement Agreements as disclosed in our Form 10-Q filed on April 14, 2009.

(2) In July 2008, the Compensation Committee granted the following option awards: Mr. Kane 300,000 and Mr. Rose 100,000. In January 2008, the Compensation Committee granted the following option awards: Mr. Rose 40,000.

(3) Amounts are calculated in accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123R "Share-based Payment." See Note 3. of the financial statements of the Company's Annual Report for the year ended May 31, 2009 regarding assumptions underlying valuation of equity awards.

(4) This column represents the dollar amount for the Company paid portion of Mr. Kane's health insurance that is outside the Company's standard insurance provided to all other employees.

Employment Contracts, Termination of Employment and Change in Control Arrangements

Effective April 15, 2009, the Company's President and Chief Executive Officer, Steven H. Kane, pursuant to a Settlement Agreement voluntarily resigned and terminated his employment with the Company. Mr. Kane however, continues to serve as the President and Chief Executive Officer for the Company at the pleasure of the Board of Directors without any further compensation except his severance. Mr. Kane remains on the Board of Directors as of the date of this Report. On April 30, 2009, the Company commenced paying Mr. Kane pursuant to his existing severance arrangement thirty-six (36) equal bi-weekly installments of pay totaling Six Hundred Thousand Dollars ($600,000) together with a sum during this period equal to the existing premiums previously paid by the Company for Mr. Kane's health and dental insurance coverage. Mr. Kane agreed to cooperate with and assist the Company until he otherwise notifies the Company's Chairman, G. Kirk Raab, that he is ceasing such assistance, to achieve and to participate in the following for the Company: (1) oversight of the clinical trials in Australia; (2) assist with Securities and Exchange Commission filings; (3) facilitate accounts payable; and (4) otherwise cooperate with the reasonable requests of the Company's Chairman to provide information and assistance to the Company related to the performance of his former duties. In partial consideration of the compensation paid to Mr. Kane under his Settlement Agreement, Mr. Kane agreed that, not withstanding his entitlement to the immediate vesting of all unvested stock options currently held by Mr. Kane, all such stock options would not immediately vest but rather vest in accordance with their current vesting schedules until such time that Mr. Kane or Mr. Raab inform the other that Mr. Kane shall no longer provide the Company with the assistance described above. At such time, all further vesting of Mr. Kane's stock options will cease.

Effective April 15, 2009, the Company's Chief Financial Officer, Marc L. Rose, pursuant to a Settlement Agreement voluntarily resigned and terminated his employment with the Company. Mr. Rose, however, continues to serve as the Chief Financial Officer for the Company at the pleasure of the Board of Directors pursuant to a Consulting Agreement previously disclosed by the Company's 8-K filed on July 2, 2009 with the SEC. On April 30, 2009, the Company commenced paying Mr. Rose pursuant to his existing severance arrangement twenty-four (24) equal bi-weekly installments of severance pay totaling Two Hundred Thirty Thousand Dollars ($230,000) together with a sum equal to the existing premiums previously paid by the Company for Mr. Rose's health and dental coverage ("Severance Payments"). Any such Severance Payments will be offset by income which Mr. Rose may earn from third-parties as an employee or consultant during this period. In addition to his consulting arrangement, Mr. Rose has agreed to cooperate with and assist the Company until he resigns as the Company's Chief Financial Officer or otherwise obtains other full-time employment or his Severance Payments have been paid in full, whichever occurs first, to achieve and to participate in the following for the Company: (1) assist with Securities and Exchange Commission filings; (2) facilitate accounts payable; (3) work with the Company's accountants on tax issues and (4) otherwise cooperate with

the reasonable requests of the Company's Chief Executive Officer to provide information and assistance to the Company related to the performance of Mr. Rose's former duties.

Outstanding Equity Awards at Fiscal Year-End

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (1)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested
Steven H. Kane, President and Chief Executive Officer	863,242	—	—	$ 1.50	12/16/2012	—	—	—	—
	100,000	—	—	1.50	8/13/2013	—	—	—	—
	75,000	—	—	2.13	1/22/2014	—	—	—	—
	175,000	—	—	2.55	1/13/2015	—	—	—	—
	25,000	—	—	2.65	10/25/2015	—	—	—	—
	25,000	—	—	2.87	10/24/2016	—	—	—	—
	100,000	41,668(1)	—	2.30	1/18/2017	—	—	—	—
	300,000	237,500(2)	—	0.45	7/24/2018	—	—	—	—
Marc L. Rose, CPA, Vice President and Chief Financial Officer	100,000	—	—	2.55	1/13/2015	—	—	—	—
	13,571	566(3)	—	2.80	7/29/2015	—	—	—	—
	30,000	5,001(4)	—	2.85	1/11/2016	—	—	—	—
	50,000	17,709(5)	—	2.87	10/24/2016	—	—	—	—
	50,000	20,834(6)	—	2.30	1/18/2017	—	—	—	—
	40,000	26,664(7)	—	1.30	1/17/2018	—	—	—	—
	100,000	79,165(8)	—	0.45	7/24/2018	—	—	—	—

(1) These stock options, granted on January 18, 2007, vest over four years at the rate of 1/48th per month.
(2) These stock options, granted on July 24, 2008, vest over four years at the rate of 1/48th per month.
(3) These stock options, granted on July 29, 2005 vest over four years at the rate of 1/48th per month.
(4) These stock options, granted on January 11, 2006, vest over four years at the rate of 1/48th per month.
(5) These stock options, granted on October 24, 2006, vest over four years at the rate of 1/48th per month.
(6) These stock options, granted on January 18, 2007, vest over four years at the rate of 1/48th per month.
(7) These stock options, granted on January 17, 2008, vest over four years at the rate of 1/48th per month.
(8) These stock options, granted on July 24, 2008, vest over four years at the rate of 1/48th per month.

Compensation of Directors

The table below summaries the compensation paid by the Company to our Directors for the fiscal year ended May 31, 2009:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation ($)	Total ($)
G. Kirk Raab (2)	125,000	—	53,520	—	—	—	178,520
Eugene A. Bauer, M.D.(3)	13,336	—	53,520	—	—	—	66,856
Frank M. Dougherty (4)	8,335	—	53,520	—	—	—	61,855
Carleton A. Holstrom (5)	13,336	—	53,520	—	—	—	66,856
Dinesh Patel, Ph.D. (6)	—	—	108,870	—	—	—	108,870
Thomas P. Stagnaro (7)	8,335	—	53,520	—	—	—	61,855
Peter G. Tombros (8)	13,336	—	53,520	—	—	—	66,856

(1) These stock options, granted on July 24, 2008, 25% vested immediately and the remainder were scheduled to vest at 1/36th per moth starting in July 2009. and are determined in accordance with FAS 123R.

(2) As of May 31, 2009, Mr. Raab has 0 stock options outstanding.
(3) As of May 31, 2009, Dr. Bauer has 0 stock options outstanding.
(4) As of May 31, 2009, Mr. Dougherty has 0 stock options outstanding.
(5) As of May 31, 2009, Mr. Holstrom has 0 stock options outstanding.
(6) As of May 31, 2009, Dr. Patel has 150,000 stock options outstanding and 37,500 are vested and exercisable.
(7) As of May 31, 2009, Mr. Stagnaro has 0 stock options outstanding.
(8) As of May 31, 2009, Mr. Tombros has 0 stock options outstanding.

Directors received stock-based compensation for their services as directors during the fiscal year ended May 31, 2009. The Company issued 1,050,000 stock options to non-employee directors during such fiscal year, at an weighted average exercise price of $0.41 and aggregate expense in accordance with SFAS 123R of $429,990. Directors do not receive separate meeting fees, but are reimbursed for out-of-pocket expenses. We do not provide a retirement plan for our non-employee directors.

The Company had an agreement with its Chairman to pay $12,500 per month as a director fee. For the fiscal year ended May 31, 2009, the Company incurred $125,000 for this director's fee. The Company had an agreement with Carleton A. Holstrom, Eugene A. Bauer, MD , Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro to pay each of them $1,667 per month on a quarterly basis payable in arrears as a director fee. For the fiscal year ended May 31, 2009, the Company incurred $56,678 for these directors' fees.

Pursuant to a Cash Waiver & Option Termination Agreement dated April 10, 2009, each of the outside Directors of the Company, G. Kirk Raab, Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro who were entitled to a Director's cash fee agreed to waive all such accrued and unpaid Director cash fees and terminate any rights for further cash fees. For Mr. Raab, those cash fees ceased as of April 1, 2009. For the other Directors, those cash fees ceased as of February 1, 2009. In addition, each of these Directors agreed to terminate immediately all of their existing stock options in the Company (vested and unvested).

Compensation Committee Interlocks and Insider Participation

The members of the Compensation Committee are Messrs. Raab, Dougherty, Tombros and Dr. Bauer. As of May 31, 2009, the chair of the Compensation Committee was Mr. Raab. The functions of this committee include administering management incentive compensation plans, establishing the compensation of officers and reviewing the compensation of Directors. None of the Compensation Committee members has ever served as an executive officer of the Company. Except for our CEO and Director, Mr. Steven H. Kane, who also serves as the CEO and a Board member of Patient Safety Technologies, Inc.,, no executive officers of the Company served as a director or a member of the Compensation Committee of another entity, one of whose executive officers either served on our Board of Directors or on its Compensation Committee.

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

Set forth in the following table is the beneficial ownership of common stock as of August 24, 2009 for our directors, the named executive officers listed in the Summary Compensation Table, our directors and executive officers as a group and each person or entity known by us to beneficially own more than five percent of the outstanding shares of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person or a group and the percentage ownership of that person or group, shares of our common stock issuable currently or within 60 days of August 24, 2009, upon exercise of options or warrants held by

that person or group is deemed outstanding. These shares, however, are not deemed outstanding for computing the percentage ownership of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the stockholders named in the table below have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. Percentage ownership is based on 28,600,464 shares of common stock outstanding as of August 24, 2009, together with applicable options and warrants for each stockholder. Unless otherwise indicated, the address of each person listed below is in the care of Protalex, Inc., 145 Union Square Drive, New Hope, PA 18938.

	Shares Beneficially Owned	
Name and Title	Number	Percent
G. Kirk Raab, Chairman of the Board and Director	—	*
Steven H. Kane, Chief Executive Officer, President and Director	1,647,080(1)	5.5%
Marc L. Rose, CPA, Vice President, Chief Financial Officer, Treasurer and Corporate Secretary	302,827(2)	1.0%
Eugene A. Bauer, M.D., Director	—	*
Frank M. Dougherty, Director	360,581(3)	1.3%
Carleton A. Holstrom, Director	20,000	*
Thomas P. Stagnaro, Director	4,000	*
Peter G. Tombros, Director	50,000(4)	*
Dinesh Patel, Ph.D., Director	3,749,914(5)	12.9%
vSpring SBIC, L.P. Attn: Dinesh Patel 2795 E. Cottonwood Pkwy, Suite 360 Salt Lake City, UT 84121	3,749,914(6)	12.9%
John E. Doherty, Former Director	2,961,549(7)	10.3%
All officers and directors as a group (7 persons)	6,134,402(8)	20.0%

*Indicates less than 1%.

(1) Includes options to purchase 1,423,659 shares of our common stock and warrants to purchase 7,778 shares of our common stock exercisable within 60 days of August 24, 2009.

(2) Includes options to purchase 287,827 shares of our common stock exercisable within 60 days of August 24, 2009.

(3) Includes warrants to purchase 3,778 shares of our common stock exercisable within 60 days of August 24, 2009.

(4) Includes warrants to purchase 10,000 shares of our common stock exercisable within 60 days of August 24, 2009.

(5) Includes options to purchase 37,500 shares of our common stock and warrants to purchase 376,667 shares of our common stock exercisable within 60 days of August 24, 2009.

(6) Includes options to purchase 37,500 shares of our common stock and warrants to purchase 376,667 shares of our common stock exercisable within 60 days of August 24, 2009.

(7) Includes options to purchase 10,000 shares of our common stock and warrants to purchase 27,778 shares of our common stock exercisable within 60 days of August 24, 2009.

(8) Includes options to purchase 1,748,986 shares of our common stock and warrants to purchase 398,223 shares of our common stock exercisable within 60 days of August 24, 2009.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders – 2003 Stock Option Plan	1,939,890	$ 1.63	2,556,110
Equity compensation plans not approved by security holders – Stand Alone Option Grants	1,356,922	$ 1.48	—
Total	3,296,812	$ 1.57	2,556,110

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

During the years ended May 31, 2009, May 31, 2008 and May 31, 2007, the Company incurred $7,677, 48,633, and $81,352 respectively, of expenses related to air travel to a partnership principally owned by the Chief Executive Officer of the Company.

Currently the Company does not have written policies and procedures for the review, approval or ratification of related person transactions. However, given the Company’s small size, senior management and the audit committee is able to review all transactions consistent with applicable securities rules governing Company transactions and proposed transactions exceeding $120,000 in which a related person has a direct or indirect material interest. Currently the Board of Directors reviews related person transactions and has approval authority with respect to whether a related person transaction is within the Company's best interest.

Director Independence

Each of the following directors are “independent” under NASDAQ Stock Market LLC rules: Messers. Raab, Dougherty, Holstrom, Stagnaro, and Tombros; and Drs. Bauer and Patel. These persons represent a majority of the board of directors. All members of the Compensation and Audit Committees are independent. Mr. Kane, a director and the Company’s President and Chief Executive Officer is a member of the Nominating and Corporate Governance Committee and is not considered independent. The other two members of the Nominating and Corporate Governance Committee are independent directors.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Grant Thornton LLP served as our registered independent auditor for the most recently completed fiscal year, and has served in that role since its appointment by the Audit Committee on February 24, 2003.

Pre-Approval of Audit and Permissible Non-Audit Services

The Audit Committee 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 are required to periodically report to the Audit Committee 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 Audit Committee may also pre-approve particular services on a case-by-case basis.

Audit Fees

The aggregate fees billed or to be billed by Grant Thornton LLP for professional services rendered for the audit of the Company's annual financial statements for the fiscal year ended May 31, 2009 and review of the financial statements included in the Company's Form 10-Qs for the fiscal year ended May 31, 2009 totaled $79,351. The aggregate fees billed by Grant Thornton LLP for professional services rendered for the audit of the Company's annual financial statements for the fiscal year ended May 31, 2008 and review of the financial statements included in the Company's Form 10-Qs for the fiscal year ended May 31, 2008 totaled $129,400.

Audit-Related Fees

The aggregate fees billed by Grant Thornton LLP for professional services rendered for the audit of the Company's registration statements on Form S-1 during the fiscal year ended May 31, 2008 totaled $12,000.

Tax Fees

Grant Thornton LLP did not bill any fees for professional services rendered for tax compliance, tax advice or tax planning for the fiscal years ended May 31, 2008 and May 31, 2009.

All Other Fees

Except as described above, no other fees were billed by Grant Thornton LLP for any other services during the last two fiscal years.

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

2.1	Stock Purchase Agreement among the Company, Don Hanosh and Enerdyne Corporation, dated December 1999	Incorporated by reference, to Exhibit 2.1 to the Company's 10-SB filing on December 6, 1999
2.2	Merger Agreement and Plan of Re-organization between the Company and Enerdyne Corporation	Incorporated by reference, to Exhibit 2.2 to the Company's 10-SB filing on December 6, 1999
2.3	Plan of Merger and Agreement between Protalex, Inc., a New Mexico corporation and Protalex, Inc. a Delaware Corporation	Incorporated by reference, to Exhibit 2.1 to the Company's 8-K filing on December 6, 2004
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	Letter Agreement with Pembroke Financial Ltd. Dated July 9, 2001	Incorporated by reference, to Exhibit 10.9 to the Company's 10-KSB/A filed on September 24, 2003
4.2	Securities Purchase Agreement dated September 18, 2003 between the Company and certain of the Selling Stockholders	Incorporated by reference, to Exhibit 4.3 to the Company's SB-2 filed on October 20, 2003.
4.3	Investor Rights Agreement dated September 18, 2003 between the Company and certain of the Selling Stockholders	Incorporated by reference, to Exhibit 4.3 to the Company's SB-2 filed on October 20, 2003.
4.4	Form of Common Stock Purchase Warrant issued by the Company to the Selling Stockholders	Incorporated by reference, to Exhibit 4.4 to Company's SB-2 filed on October 20, 2003.
4.5	Warrant and Common Stock Purchase Agreement dated May 25, 2005 among the Company and the several purchasers thereunder	Incorporated by reference to Exhibit 4.5 to the Company's Form SB-2 filed on June 16, 2005
4.6	Registration Rights Agreement dated May 25, 2005 among the purchasers under the Warrant and Common Stock Purchase Agreement of even date therewith	Incorporated by reference to Exhibit 4.6 to the Company's Form SB-2 filed on June 16, 2005
4.7	Addendum 1 to Subscription Agreement and Questionnaire of vSpring SBIC, LP dated May 25, 2005	Incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-KSB filed on August 26, 2005
4.8	Warrant and Common Stock Purchase Agreement dated December 22, 2005 among the Company and the several purchasers thereunder	Incorporated by reference, to Exhibit 4.5 to the Company's SB-2 filed on January 27, 2006
4.9	Registration Rights Agreement dated December 22, 2005 among the purchasers under the Warrant and Common Stock Purchase Agreement of even date therewith	Incorporated by reference, to Exhibit 4.6 to the Company's SB-2 filed on January 27, 2006
4.10	Form of Warrant issued by the Company to the Selling Stockholders dated December 22, 2005 of even date therewith	Incorporated by reference, to Exhibit 4.7 to the Company's SB-2 filed on January 27, 2006
4.11	Warrant and Common Stock Purchase Agreement dated June 30, 2006 among the Company and the several purchasers thereunder	Incorporated by reference, to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 10, 2006.

4.12	Registration Rights Agreement dated June 30, 2006 among the purchasers under the Warrant and Common Stock Purchase Agreement of even date therewith	Incorporated by reference, to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 10, 2006
4.13	Form of Warrant issued by the Company to the Selling Stockholders dated June 30, 2006 of even date therewith	Incorporated by reference, to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 10, 2006
10.1	Employment offer letter executed by Steven H. Kane	Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-QSB filed on January 13, 2006.
10.2	Board appointment executed by G. Kirk Raab	Incorporated by reference, to Exhibit 10.4 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.3	Form of Option Agreement	Incorporated by reference, to Exhibit 10.6 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003
10.4	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
10.5	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.
10.6	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.
10.7	Stock Redemption Agreement dated August 15, 2003, by and between the Company, Paul L. Mann, Leslie A. McCament-Mann, Gail Stewe and Elizabeth Sarah Anne Wiley	Incorporated by reference, to Exhibit 10.10 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.8	Letter dated August 21, 2003 from Paul L. Mann to the Company	Incorporated by reference, to Exhibit 10.11 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.9	Technology License Agreement dated November 17, 1999, between the Company and Alex, LLC	Incorporated by reference, to Exhibit 10.4 to the Company's Registration of Securities on Form 10-QSB filed on December 6, 1999.
10.10	Letter Agreement, dated March 16, 2005, effective October 26, 2004, between the Company and Carleton A. Holstrom	Incorporated by reference, to Exhibit 10.3 to the Company's Quarterly Report on Form 10-QSB/A filed on April 14, 2005.
10.11	Description of the verbal agreement between the Company and Eugene A. Bauer, M.D.	Incorporated by reference to the Company's Current Report on Form 8-K filed on February 22, 2005.

10.12	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.
10.13	Description of the verbal agreement between the Company and Peter G. Tombros	Incorporated by reference to the Company's Current Report on Form 8-K filed on November 14, 2005.
10.14	Modified lease agreement with Union Square LP, dated November 18, 2005	Incorporate by reference to Exhibit 99.1 to the Company's Current Report Form 8-K filed on November 22, 2005.
10.15	Employment offer letter executed by Marc L. Rose, CPA, Vice President, Chief Financial Officer, Treasurer and Corporate Secretary	Incorporated by reference, to Exhibit 10.2 to the Company's Quarterly Report on Form 10-QSB filed on January 14, 2005.
10.16†	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.
10.17	Modified lease agreement with Union Square LP, dated April 30, 2007	Incorporate by reference to Exhibit 99.1 to the Company's Current Report Form 8-K filed on May 3, 2007.
10.18	Settlement Agreement with Steven H. Kane, President, Chief Executive Officer and Director dated April 14, 2009	Filed herewith
10.19	Settlement Agreement with Marc L. Rose, Vice President, Finance, Chief Financial Officer, Secretary and Treasurer dated April 14, 2009	Filed herewith
10.20	Cash Waiver & Option Termination Agreement dated April 10, 2009 with G. Kirk Raab, Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro	Filed herewith
10.21	Indemnification Agreement with Directors and Executive Officers dated August 28, 2009	Filed herewith
23.1	Consent of Grant Thornton 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

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Security Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 28, 2009

Protalex, Inc.
By: /s/ Steven H. Kane
Name: Steven H. Kane
Title: President, Chief Executive Officer and Director

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

/s/ G. Kirk Raab G. Kirk Raab	Chairman of the Board and Director	August 28, 2009
/s/ Steven H. Kane Steven H. Kane	President, Chief Executive Officer and Director (Principal Executive Officer)	August 28, 2009
/s/ Marc L. Rose, CPA Marc L. Rose	Vice President of Finance, Chief Financial Officer, Treasurer and Corporate Secretary (Principal Financial and Accounting Officer)	August 28, 2009
/s/ Eugene A. Bauer, MD Eugene A. Bauer	Director	August 28, 2009
/s/ Frank M. Dougherty Frank M. Dougherty	Director	August 28, 2009
/s/ Carleton A. Holstrom Carleton A. Holstrom	Director	August 28, 2009
/s/ Dinesh Patel, PhD Dinesh Patel	Director	August 28, 2009
/s/ Thomas P. Stagnaro Thomas P. Stagnaro	Director	August 28, 2009
/s/ Peter G. Tombros Peter G. Tombros	Director	August 28, 2009

29

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.

	Page
Financial Statements	
Balance Sheets at May 31, 2009 and 2008	3
Statements of Operations for the Years Ended May 31, 2009, 2008 and 2007, and from Inception (September 17, 1999) through May 31, 2009	4
Statement of Changes in Stockholders' Equity from Inception (September 17, 1999) through May 31, 2009	5
Statements of Cash Flows for the Years Ended May 31, 2009, 2008 and 2007 and from Inception (September 17, 1999) through May 31, 2009	9
NOTES TO FINANCIAL STATEMENTS	10

Report of Independent Registered Public Accounting Firm

The Board of Directors
Protalex, Inc.

We have audited the accompanying balance sheets of Protalex, Inc. (a Delaware corporation in the development stage) (the Company) as of May 31, 2009 and 2008, and the related statements of operations, changes in stockholders' equity, and cash flows for the years ended May 31, 2009, 2008, and 2007 and for the cumulative period from inception through May 31, 2009, as it relates to the fiscal years ended May 31, 2009, 2008, and 2007. 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years ended May 31, 2009, 2008, and 2007, and for the cumulative period from inception through May 31, 2009, as it relates to the fiscal years ended May 31, 2009, 2008, and 2007, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Notes 1 and 2 to the financial statements, the Company is in the development stage and has not commenced operations and thus since inception has incurred an accumulated deficit of $44,584,511 through May 31, 2009. Its ability to continue as a going concern is dependent upon developing products that are regulatory approved and market accepted. To achieve this successfully, additional sources of capital are needed to fund operations. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/Grant Thornton LLP

Philadelphia, Pennsylvania

August 28, 2009

PROTALEX, INC.

(A Company in the Development Stage)

BALANCE SHEETS

May 31,

	2009	2008
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,637,292	$ 8,442,809
Prepaid expenses	193,757	429,207
Total current assets	2,831,049	8,872,016
PROPERTY & EQUIPMENT:		
Lab equipment	327,287	692,761
Office and computer equipment	195,987	195,987
Furniture & fixtures	40,701	40,701
Leasehold improvements	89,967	89,967
	653,942	1,019,416
Less accumulated depreciation	(628,780)	(823,649)
	25,162	195,767
OTHER ASSETS:		
Deposits	7,990	7,990
Intellectual technology property, net of accumulated amortization of $9,753 and $8,733 as of May 31, 2009 and May 31, 2008, respectively	10,547	11,567
Total other assets	18,537	19,557
Total assets	$ 2,874,748	$ 9,087,340
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 398,734	$ 1,277,555
Payroll and related liabilities	1,185,638	35,262
Accrued expenses	8,057	15,000
Deferred rent	1,192	1,458
Total liabilities	1,593,621	1,329,275
STOCKHOLDERS' EQUITY		
Common stock, par value $0.00001, 100,000,000 shares authorized 28,600,464 shares issued and outstanding	286	286
Additional paid in capital	45,865,352	45,112,084
Deficit accumulated during the development stage	(44,584,511)	(37,354,305)
Total stockholders' equity	1,281,127	7,758,065

Total liabilities and stockholders' equity	$ 2,874,748	$ 9,087,340

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

PROTALEX, INC.
(A Company in the Development Stage)

STATEMENTS OF OPERATIONS

For the Years Ended May 31, 2009, 2008 and 2007, and
From Inception (September 17, 1999) through May 31, 2009

	Year Ended May 31, 2009	Year Ended May 31, 2008	Year Ended May 31, 2007	From Inception Through May 31, 2009
REVENUES	$ -	$ -	$ -	$ -
OPERATING EXPENSES:				
Research and development (including depreciation and amortization)	(3,490,956)	(7,657,127)	(5,562,485)	(27,753,874)
Administrative (including depreciation and amortization)	(3,505,259)	(2,759,463)	(3,360,252)	(15,614,637)
Professional fees	(365,670)	(619,314)	(544,903)	(3,245,134)
Depreciation and amortization	(4,146)	(4,146)	(5,122)	(163,816)
Operating Loss	(7,366,031)	(11,040,050)	(9,472,762)	(46,777,371)
Other income (expense)				
Interest income	57,651	549,292	1,020,820	2,195,878
Interest expense	-	-	-	(70,612)
Gain on disposal of equipment	78,174	-	-	67,594
Net Loss	$ (7,230,206)	$ (10,490,758)	$ (8,451,942)	$ (44,584,511)
Weighted average number of common shares outstanding	28,600,464	28,600,464	28,083,103	18,392,537
Loss per common share – basic and diluted	$ (.25)	$ (.37)	$ (.30)	$ (2.42)

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

PROTALEX, INC.
(A Company in the Development Stage)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

From Inception (September 17, 1999) through May 31, 2009

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock-Contra	Deficit Accumulated During The Development Stage	Total
September 17, 1999 — initial issuance of 10,000 shares for intellectual technology license at $.03 per share	10,000	$ 300	$ —$	—$	—$	300
September 30, 1999 — cost of public shell acquisition over net assets acquired to be accounted for as a Recapitalization	—	—	—	(250,000)	—	(250,000)
October 27, 1999 — issuance of 84 shares to individual for $25,000	84	25,000	—	—	—	25,000
November 15, 1999 — reverse merger transaction with Enerdyne Corporation, net transaction amounts	8,972,463	118,547	—	(118,547)	—	—
November 18, 1999 — February 7, 2000 — issuance of 459,444 shares to various investors at $0.36 per share	459,444	165,400	—	—	—	165,400
January 1, 2000 — issuance of 100,000 shares in exchange for legal services	100,000	15,000	—	—	—	15,000
May 1 - 27, 2000 — issuance of 640,000 shares to various investors at $1.00 per share	640,000	640,000	—	—	—	640,000
May 27, 2000 — issuance of 1,644 shares to individual in exchange for interest Due	1,644	1,644	—	—	—	1,644
Net loss for the year ended May 31, 2000	—	—	—	—	(250,689)	(250,689)
Balance, May 31, 2000	10,183,635	965,891	—	(368,547)	(250,689)	346,655
December 7, 2000 — issuance of 425,000 shares to various investors at $1.00 per share	425,000	425,000	—	—	—	425,000
	—	—	40,000	—	—	40,000

May 31, 2001 — Forgiveness of debt owed to shareholder						
Net loss for the year ended May 31, 2001	—	—	—	—	(553,866)	(553,866)
Balance, May 31, 2001	10,608,635	1,390,891	40,000	(368,547)	(804,555)	257,789

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

PROTALEX, INC.
(A Company in the Development Stage)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY - (continued)

From Inception (September 17, 1999) through May 31, 2009

	Common Stock		Additional Paid in	Common Stock-	Deficit Accumulated During The Development	
	Shares	Amount	Capital	Contra	Stage	Total
August 13, 2001 — Contribution by Shareholders	—	—	143,569	—	—	143,569
November 7, 2001 — issuance of 881,600 Shares at $1.25 per share	881,600	1,102,000	—	—	—	1,102,000
November 26, 2001 — options issued to board member	—	—	133,000	—	—	133,000
Net loss for the year ended May 31, 2002	—	—	—	—	(1,280,465)	(1,280,465)
Balance, May 31, 2002	11,490,235	2,492,891	316,569	(368,547)	(2,085,020)	355,893
July 5, 2002 — issuance of 842,000 shares at $1.50 per share	842,000	1,263,000	—	—	—	1,263,000
July 1, 2002 - May 1, 2003 – purchase of common stock from shareholder at $.70 per share	(130,955)	(91,667)	—	—	—	(91,667)
January 15, 2003 - May 15, 2003 — common stock issued to Company president	41,670	82,841	—	—	—	82,841
May 14, 2003 — common stock issued to employee	5,000	11,250	—	—	—	11,250
June 1, 2002 - May 31, 2003 – compensation related to stock options issued to board members, employees and consultants	—	—	287,343	—	—	287,343
Net loss for the year ended May 31, 2003	—	—	—	—	(1,665,090)	(1,665,090)
Balance, May 31, 2003	12,247,950	3,758,315	603,912	(368,547)	(3,750,110)	243,570
	8,334	16,418	—	—	—	16,418

June 15, 2003, common stock issued to Company president						
June 15, 2003, purchase of common stock from shareholder	(12,093)	(8,333)	—	—	—	(8,333)
September 18, 2003 – issuance of 7,445,646 of common stock issued in private placement At $1.70 per share, net of transaction costs	7,445,646	11,356,063	—	—	—	11,356,063
September 19, 2003 – repurchase and retired 2,994,803 shares for $300,000	(2,994,803)	(300,000)	—	—	—	(300,000)
December 12, 2003 – issuance of 39,399 shares to terminated employees at $2.60 per share	39,399	102,438	—	—	—	102,438
March 1, 2004 – common stock issued to employee at $2.55 per share	50,000	127,500	—	—	—	127,500
May 31, 2004 – reclassify common stock contra to common stock	—	(368,547)	—	368,547	—	—

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

PROTALEX, INC.
(A Company in the Development Stage)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY - (continued)

From Inception (September 17, 1999) through May 31, 2009

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock-Contra	Deficit Accumulated During The Development Stage	Total
June 1, 2003 – May 31, 2004 – compensation related to stock options issued to board members, employees and consultants	—	—	448,096	—	—	448,096
Net loss for the year ended May 31, 2004	—	—	—	—	(2,989,364)	(2,989,364)
Balance, May 31, 2004	16,784,433	$ 14,683,854	$ 1,052,008	—$	(6,739,474)	$ 8,996,388
November 30, 2004 – adjust March 1, 2004 common stock issued to employee		(20,000)	—	—	—	(20,000)
January 13, 2005 – common stock issued to employee at $2.55 per share	15,000	38,250	—	—	—	38,250
February 28, 2005 – Reclass Par Value for Reincorporation into DE as of 12/1/04		(14,701,935)	14,701,935	—	—	0
May 25, 2005 - issuance of 2,593,788 shares of common stock issued in private placement At $1.95 per share, net of transaction costs	2,593,788	25	4,851,168	—	—	4,851,193
June 1, 2004 – May 31, 2005 – compensation related to stock options issued to board members, employees and consultants	—	—	308,711	—	—	308,711
Net loss for the year ended May 31, 2005	—	—	—	—	(5,567,729)	(5,567,729)
Balance, May 31, 2005	19,393,221	$ 194	$ 20,913,822	—$	(12,307,203)	$ 8,606,813
August 23, 2005 – common stock issued to employee	40,000	0	100,000	—	—	100,000
October 19, 2005 – common stock issued to employee	10,000	0	25,000	—	—	25,000
	2,595,132	26	5,510,941	—	—	5,510,967

December 30, 2005 – issuance of 2,595,132 shares of common stock issued in private placement at $2.25 per share, net of transaction costs							
June 1, 2005 – May 31, 2006 – warrants exercised	351,598	4	786,534	—	—	786,538
June 1, 2005– May 31, 2006 – compensation related to stock options issued to board members, employees and consultants	—	—	404,679	—	—	404,679
Net loss for the year ended May 31, 2006	—	—	—	—	(6,104,402)	(6,104,402)
Balance, May 31, 2006	22,389,951	$ 224	$ 27,740,976	—$	(18,411,605)	$ 9,329,595

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

PROTALEX, INC.
(A Company in the Development Stage)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY - (continued)

From Inception (September 17, 1999) through May 31, 2009

	Common Stock Shares	Amount	Additional Paid in Capital	Common Stock-Contra	Deficit Accumulated During The Development Stage	Total
July 7, 2006 – issuance of 6,071,013 shares of common stock issued in private placement at $2.50 per share, net of transaction costs	6,071,013	61	14,217,660	—	—	14,217,721
June 1, 2006 – May 31, 2007 – warrants exercised	133,500	1	300,373	—	—	300,374
June 1, 2006 – May 31, 2007 – stock options exercised	6,000	0	15,200	—	—	15,200
June 1, 2006 – May 31, 2007 – shared-based compensation to board members, employees and consultants	—	—	1,826,850	—	—	1,826,850
Net loss for the year ended May 31, 2007	—	—	—	—	(8,451,942)	(8,451,942)
Balance, May 31, 2007	28,600,464	$ 286	$ 44,101,059	$ —	$ (26,863,547)	$ 17,237,798
June 1, 2007 – May 31, 2008 – shared-based compensation to board members, employees and consultants	—	—	1,011,025	—	—	1,011,025
Net loss for the year ended May 31, 2008	—	—	—	—	(10,490,758)	(10,490,758)
Balance, May 31, 2008	28,600,464	$ 286	$ 45,112,084	$ —	$ (37,354,305)	$ 7,758,065
June 1, 2008 – May 31, 2009 – shared-based compensation to board members, employees and consultants	—	—	753,268	—	—	753,268
Net loss for the year ended May 31, 2009	—	—	—	—	(7,230,206)	(7,230,206)
Balance, May 31, 2009	28,600,464	$ 286	$ 45,865,352	$ —	$ (44,584,511)	$ 1,281,127

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

F-8

PROTALEX, INC.
(A Company in the Development Stage)

STATEMENTS OF CASH FLOWS

For the Years Ended May 31, 2009, 2008 and 2007 and From Inception (September 17, 1999) through May 31, 2009

	Year Ended May 31, 2009	Year Ended May 31, 2008	Year Ended May 31, 2007	From Inception Through May 31, 2009
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (7,230,206)	$ (10,490,758)	$ (8,451,942)	$ (44,584,511)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities				
Gain on disposal of equipment	(78,174)	—	—	(67,594)
Depreciation and amortization	49,799	177,039	169,865	904,702
Share-based compensation	753,268	1,011,025	1,826,850	5,656,668
Non cash expenses	—	—	—	16,644
(Increase) decrease in:				
Prepaid expenses and deposits	235,450	(158,156)	(49,864)	(201,747)
Increase (decrease) in:				
Accounts payable and accrued expenses	(885,764)	344,442	(23,467)	406,791
Payroll and related liabilities	1,150,376	14,601	(46,754)	1,185,638
Other liabilities	(266)	(1,538)	(700)	1,192
Net cash and cash equivalents used in operating activities	(6,005,517)	(9,103,345)	(6,576,012)	(36,682,217)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Acquisition of intellectual technology license – fee portion	—	—	—	(20,000)
Acquisition of equipment	—	—	(403,674)	(905,936)
Excess of amounts paid for public shell over assets acquired to be accounted for as a recapitalization	—	—	—	(250,000)
Proceeds from disposal of equipment	200,000	—	—	206,000
Net cash and cash equivalents provided by/(used) in investing activities	200,000	—	(403,674)	(969,936)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from stock issuance, including options and warrants exercised	—	—	14,533,295	40,658,458
Principal payment on equipment notes payable and capital leases	—	—	—	(295,411)
Contribution by shareholders	—	—	—	183,569
Principal payment on note payable to individuals	—	—	—	(225,717)

Issuance of note payable to individuals	—	—	—	368,546
Acquisition of common stock	—	—	—	(400,000)
Net cash and cash equivalents provided by financing activities	—	—	14,533,295	40,289,445
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	(5,805,517)	(9,103,345)	7,553,609	2,637,292
Cash and cash equivalents, beginning	8,442,809	17,546,154	9,992,545	—
Cash and cash equivalents, end	$ 2,637,292	$ 8,442,809	$ 17,546,154	$ 2,637,292
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:				
Interest paid	$ -	$ -	$ -	$ 66,770
Taxes paid	$ -	$ -	$ -	$ 100

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

PROTALEX, INC.
(A Company in the Development Stage)

NOTES TO FINANCIAL STATEMENTS

From Inception (September 17, 1999) through May 31, 2009

1. ORGANIZATION AND BUSINESS ACTIVITIES

We are a development stage company engaged in developing a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases. We were incorporated on September 17, 1999 in Albuquerque, New Mexico and reincorporated in the State of Delaware on December 1, 2004. Our headquarters are located in New Hope, Pennsylvania. We were formed to take all necessary steps to fully develop and bring to commercial realization certain bioregulatory technology for the treatment of human diseases. Our lead product, PRTX-100, has demonstrated effectiveness in pre-clinical studies in regulating the immune system with persisting effects. However, the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we will see in our clinical trials. We currently have no product on the market and we have no operating revenue. We are targeting the autoimmune diseases rheumatoid arthritis, or RA and idiopathic thrombocytopenic purpura, or ITP.

As of the date of this Report, the Company has no employees and it has insufficient funds to cover future clinical trials and Chemistry, Manufacturing and Control or CMC related expenses beyond the third calendar quarter of 2009. If the Company is unable to raise to sufficient additional funds, it will likely be required to cease further operations. These matters raise substantial doubt about the ability of the Company to continue as a going concern.

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 Company is a development stage enterprise and does not anticipate generating operating revenue for the foreseeable future. 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. LIQUIDITY

Since inception, the Company has incurred an accumulated deficit of $44,584,511 through May 31, 2009. For the years ended May 31, 2009, 2008 and 2007, the Company had losses from operations of $7,230,206, $10,490,758, and $8,451,942 respectively. The Company has used $5,805,517, $9,103,345, and $6,979,686 of cash in operating and investing activities for the years ended May 31, 2009, 2008, and 2007, respectively. As of May 31, 2009, the Company had cash and cash equivalents of $2,637,292 and net working capital of $1,237,428. The Company has incurred negative cash flow from operating activities since its inception. The Company has spent, and with adequate additional financing, expects to continue to spend, substantial amounts in connection with executing its business strategy, including the continued development efforts relating to PRTX-100. As of the date of this Report, the Company has no employees and it has insufficient funds to cover future clinical trials and CMC related expenses beyond the third calendar quarter of 2009. If the Company is unable to raise sufficient additional funds, it will likely be required to suspend or cease further operations of any nature beyond the third calendar quarter of 2009 until such financing is obtained, if ever.. These matters raise substantial doubt about the ability of the Company to continue as a going concern.

Management anticipates that the Company’s capital resources will be adequate to fund its operations into the third calendar quarter of 2009. Additional financing or potential sublicensing of PRTX-100 will be required during the third calendar quarter of 2009, if not sooner in order to continue to fund operations. The most likely sources of additional

financing include the private sale of the Company's equity or debt securities, including bridge loans to the Company from third party lenders.. Additional capital that is required by the Company may not be available on reasonable terms, or at all

..

3. 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 Statement of Financial Accounting Standards No. 128 "Earnings Per Share" (SFAS No. 128) that provides for the calculation of "Basic" and "Diluted" earnings per share. Basic earnings per share include no dilution and is computed by dividing loss to common shareholders 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, 2009, the Company had a total of 7,225,708 potentially dilutive securities comprised of 3,928,896 warrants and 3,296,812 stock options.

Share-Based Compensation

Effective June 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standard No. 123 (revised), Accounting for Share-Based Payment ("SFAS No. 123R") 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 $753,268, $1,011,025 and $1,826,850 for the years ended May 31, 2009, 2008 and 2007, 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 of SFAS No. 123R, 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, 2009 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") No. 107 and No. 110, Share-Based Payments, in connection with the adoption of SFAS No. 123R.

Prior to the adoption of SFAS No. 123R, the Company accounted for stock options granted to employees using the intrinsic value method under the guidance of APB No. 25, and provided pro forma disclosure as required by SFAS No. 123. Stock options issued to non-employees were accounted for as required by SFAS No. 123. Options to non-employees were accounted for using the fair value method, which recognizes the value of the option as an expense over the related service period with a corresponding increase to additional paid-in capital.

The Board of Directors 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 of Directors or the Compensation Committee. There are 4,500,000 shares reserved for grants of options under the plan, of which 1,943,890 have been issued and 4,000 were exercised. The Company has issued 1,358,922 stock options as stand alone grants, of which 2,000 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 of Directors or the Compensation Committee) from the date of the grant. The plan will continue in effect until terminated or amended by the Board of Directors.

SFAS 123(R) 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 Staff Accounting Bulletin No. 107, Share-Based Payments ("SAB No. 107") and as further permitted by Staff Accounting Bulletin No. 110, Share-Based Payments ("SAB No. 110"). 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 our common shares. 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 our stock-based awards.

As of May 31, 2009, there were 3,296,812 stock options outstanding. At May 31, 2009, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model was approximately $1,178,000 (net of estimated forfeitures) will be recognized over a weighted average period of 1.54 years. For the year ended May 31, 2009, the Company granted 1,685,000 stock options, with a fair value of $661,531 (net of estimated forfeitures), and 2,730,606 options were forfeited or expired.

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, 2009	Year Ended May, 31, 2008	Year Ended May, 31, 2007	From Inception Through May 31, 2009
Dividends per year	0	0	0	0
Volatility percentage	96%-112%	94.4%-96.3%	107%	90%-112%
Risk free interest rate	3.11%-3.51%	4.67%-4.87%	3.85%-4.42%	2.07%-5.11%
Expected life (years)	6.25-10	6.25	4	3-10
Weighted Average Fair Value	$ .39	2.00	1.98	1.36

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”).

Property, Equipment, Intellectual Technology Property, Depreciation and Amortization

Property, equipment and leasehold improvements are carried at cost. Depreciation and amortization has been provided by the Company in order to amortize the cost of property and equipment over their estimated useful lives, which are estimated to be over three to five years. The Company uses the straight-line method for all classes of assets for book purposes and accelerated methods for tax purposes. Depreciation expense was $48,779, $176,019, $168,845, and $873,449 for the years ended May 31, 2009, 2008, 2007 and from inception through May 31, 2009, respectively. Depreciation included in research and development expense totaled $31,900, $172,893, $163,724, and $696,900 for the years ended May 31, 2009, 2008 and 2007 and from inception to May 31, 2009, respectively.

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, $1,020 and $9,753 for the years ended May 31, 2009, 2008, 2007 and from inception through May 31, 2009, respectively. The Company reviews the intellectual property for impairment on at least an annual basis in accordance with SFAS No. 142 "Goodwill and Other Intangible Assets"; no impairment charge was recorded as of May 31, 2009. 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.

In July 2006, the FASB issued FASB Interpretation 48, Accounting for Uncertainty in Income Taxes: an interpretation of FASB Statement No. 109. ("FIN 48"), which clarifies Statement 109, 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, FIN 48 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 FIN 48 is to be reported as an adjustment to retained earnings at the beginning of the period in which it is adopted. We adopted FIN 48 effective as of June 1, 2007 and it did not have any impact on our results of operations and financial position.

Other Comprehensive Income

From September 17, 1999 (inception) through May 31, 2009, the Company had no changes in equity which constitute components of other comprehensive income.

Research and Development

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

Fair Value of Financial Instruments

The fair value of the Company's financial instruments, principally cash, approximates their carrying value.

Recent Accounting Pronouncements

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles-a replacement of FASB Statement No.162 ("SFAS 168"). SFAS 168 establishes the FASB Accounting Standards Codification as the single source of authoritative US generally accepted accounting principles recognized by the FASB to be applied to nongovernmental entities. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of SFAS 168 will not have an impact on the Company's financial position, results of operations or cash flow. The Company will update the disclosures for the appropriate FASB codification reference after adoption in the second quarter of fiscal 2010.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events ("SFAS 165"). SFAS 165 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. The Company has evaluated subsequent events after the balance sheet date of May 31,2009 through the date this annual report is filed on August 28, 2009.

In December 2007, the FASB issued SFAS No. 141R (revised 2007) Business Combinations (“SFAS 141R”). SFAS 141R states that all business combinations (whether full, partial or step acquisitions) will result in all assets and liabilities of an acquired business being recorded at their fair values. Certain forms of contingent considerations and certain acquired contingencies will be recorded at fair value at the acquisition date. SFAS 141R also states acquisition costs will generally be expensed as incurred and restructuring costs will be expensed in periods after the acquisition date. This statement is effective for financial statements issued for fiscal years beginning after December 15, 2008. Earlier adoption is prohibited. We are currently evaluating the impact, if any, of SFAS 141R upon adoption on our financial statements.

In December 2007, the FASB ratified the Emerging Issue Task Force (“EITF”) Issue 07-01, Accounting for Collaborative Arrangements (“EITF 07-01”). EITF 07-01 clarifies the accounting for contractual arrangements wherein two or more parties come together to participate in a joint operating activity which is conducted based on provisions of a contract. EITF 07-01 provides guidance on income statement classification of revenues and expenses related to such activities, and specifies disclosures that should be made with respect to such activities. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of EITF 07-01 on its financial statements.

4. 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	$ —	$ —	$ 23,531
Note receivable shareholder	—	118,547	—	118,547
License	20,300	—	—	20,300
Investment in Enerdyne	368,547	—	(368,547)	—
Other current assets	8,212	—	—	8,212
Other current liabilities	(17,555)	—	—	(17,555)
Accounts payable Alex	(40,000)	—	—	(40,000)
Note payable	(368,546)	—	—	(368,546)
Common stock	(25,300)	(833,459)	714,912	(143,847)
Additional paid in capital	—	(1,105,014)	1,105,014	—
Treasury stock	—	430,424	(430,424)	—
Accumulated deficit	30,811	1,389,502	(1,389,502)	30,811
Common stock – contra	—	—	368,547	368,547
	$ —	$ —	$ —	$ —

5. INCOME TAXES

For the years ended May 31, 2009, 2008 and 2007, the components of income tax benefit (expense) consist of the following:

Current:	Year Ended May 31, 2009	Year Ended May 31, 2008	Year Ended May 31, 2007
Federal	$ —	$ —	$ —
State	—	—	—
Deferred:			
Federal	2,584,000	3,797,800	3,354,205
State	456,000	670,200	591,795
Increase in valuation allowance	(3,040,000)	(4,468,000)	(3,946,000)
Income tax benefit	$ —	$ —	$ —

Income tax as a percentage of income for the year ended May 31, 2009, 2008 and 2007 differ from statutory federal income tax rates due to the following:

	Year Ended May 31, 2009	Year Ended May 31, 2008	Year Ended May 31, 2007
Statutory federal income tax rate	(34)%	(34)%	(34)%
State income taxes, net of federal income tax impact	(6)%	(6)%	(6)%
Change in valuation allowance	42%	43%	46%
General business credit/other	(2)%	(3)%	(6)%
	0%	0%	0%

The components of the net deferred tax asset as of May 31, 2009, 2008 and 2007 are as follows:

Assets:	May 31, 2009	May 31, 2008	May 31, 2007

Net operating losses	$ 14,296,000	$ 12,190,000	$ 8,616,000
Vacation accrual	401,000	14,000	8,000
Stock based compensation	2,263,000	1,961,000	1,560,000
Equipment	30,000	38,000	20,000
General business credit	1,852,000	1,599,000	1,130,000
Deferred tax assets	18,842,000	15,802,000	11,334,000
Liability:			
Equipment	—	—	—
Gross deferred tax asset	18,842,000	15,802,000	11,334,000
Less valuation allowance	(18,842,000)	(15,802,000)	(11,334,000)
Deferred tax asset, net of valuation allowance	$ —$	—$	—$ —

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 $35,800,000 as of May 31, 2009 expires beginning in 2020 through 2029. 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. As of May 31, 2009, a portion of the gross deferred tax asset and related valuation allowance is attributable to stock based compensation. To the extent that such assets are realized in the future, the benefit will be applied to equity.

The Company adopted the provisions of FASB Interpretation 48, Accounting for Uncertainty in Income Taxes. Previously, the Company had accounted for tax contingencies in accordance with Statement of Financial Accounting Standards 5, Accounting for Contingencies. As required by Interpretation 48, which clarifies Statement 109, 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. At the adoption date, the Company applied Interpretation 48 to all tax positions for which the statute of limitations remained open. The impact of adopting FIN 48 was not material as of the date of adoption or in subsequent periods. As a result of the implementation of Interpretation 48, the Company did not recognize any change in the liability for unrecognized tax benefits and there was no change to the June 1, 2007 balance of retained earnings.

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

6. RELATED PARTIES

During the years ended May 31, 2009, May 31, 2008 and May 31, 2007, the Company incurred $7,677, $48,633, and $81,352 respectively, of expenses related to air travel to a partnership principally owned by the Chief Executive Officer of the Company.

The Company has an agreement with its Chairman to pay $12,500 per month as a director fee. During the years ended May 31, 2009 the Company incurred $125,000 for this director's fee and during the years ended May 31, 2008 and May 31, 2007, the Company incurred $150,000 in each year for this director's fee.

The Company has an agreement with Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro to pay each $1,667 per month payable on a quarterly basis in arrears as a director fee. During the years ended May 31, 2009, May 31, 2008 and May 31, 2007, the Company incurred $56,678, $60,000, and $60,000 respectively for these directors' fees.

Pursuant to a Cash Waiver & Option Termination Agreement dated April 10, 2009, each of the outside Directors of the Company, G. Kirk Raab, Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro who are currently entitled to a Director's cash fee agreed to waive all such accrued and unpaid Director cash fees and terminate any rights for further cash fees. For Mr. Raab, those cash fees ceased as of April 1, 2009. For the other Directors, those cash fees ceased as of February 1, 2009. In addition, each of these Directors has agreed to terminate immediately all of their existing stock options in the Company (vested and unvested).

As previously disclosed in our Form 10-Q filed on April 14, 2009, Messers. Kane and Rose voluntarily terminated their employment. Messers. Kane and Rose remain the CEO and CFO, respectively, of the Company. As of the date of this report, while Mr. Rose has not accepted full time employment elsewhere, Mr. Kane is now currently also the Chairman and CEO of Patient Safety Technologies, Inc. At May 31, 2009, the Company accrued $845,406 for the Company's severance obligations to Messers. Kane and Rose covering salary, payroll taxes and health benefits. As

also disclosed on our Form 8-K dated July 2, 2009, the Company subsequently entered into a consulting agreement with Mr. Rose providing for consulting fees.

7. STOCK OPTIONS

Prior to January 22, 2004, all options were issued as “stand alone” options. On January 22, 2004, the board of directors of the Company approved the Protalex, Inc. 2003 Stock Option Plan., and on October 25, 2005, the shareholders approved an amendment to the Protalex, Inc. 2003 Stock Option Plan to increase the authorized number of shares under the Plan from 1,500,000 to 4,500,000 which provides for incentive and non-qualified stock options to purchase a total of 4,500,000 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, 2009, options to purchase 3,296,812 shares of the Company’s Common Stock were outstanding, of which 1,943,890 were issued and 4,000 were exercised under the Company’s 2003 Stock Option Plan and the remaining 1,358,922 were issued and 2,000 were exercised as stand alone options. As of May 31, 2009, 2,505,294 are exercisable.

A summary of the common stock option activity for employees, directors, officers and consultants as of May 31, 2009 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, 2006	3,834,625	$ 1.98	7.7
Granted	458,000	$ 2.56	—
Exercised	(6,000)	$ 2.53	—
Forfeited	(112,217)	$ 2.58	—
Expired	(210,546)	$ 2.54	—
Outstanding at May 31, 2007	3,963,862	$ 2.00	6.9
Granted	457,500	$ 1.27	—
Exercised	0	—	—
Forfeited	(48,428)	$ 2.75	—
Expired	(30,516)	$ 2.70	—
Outstanding at May 31, 2008	4,342,418	$ 1.91	6.2
Granted	1,685,000	$ 0.49	—
Exercised	0	—	—
Forfeited	(545,793)	$ 0.53	—
Expired	(2,184,813)	$ 1.67	—
Outstanding at May 31, 2009	3,296,812	$ 1.57	6.0
Exercisable at May 31, 2009	2,505,294	$ 1.79	—

The outstanding and exercisable stock options as of May 31, 2009 had an intrinsic value of $0 and $0, respectively.

The following summarizes certain information regarding stock options at May 31, 2009:

	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 – 0.45	576,876	$ 0.45	9.1	121,676	$ 0.45	9.1
$0.46 – 0.90	150,000	$ 0.85	9.3	37,500	$ 0.85	9.3
$0.91 – 1.35	351,563	$ 1.26	6.7	225,526	$ 1.26	6.7
$1.36 – 1.80	1,256,922	$ 1.50	3.6	1,256,922	$ 1.50	3.6
$1.81 – 2.25	119,166	$ 2.14	5.7	116,103	$ 2.14	5.7
$2.26 – 2.70	560,714	$ 2.49	6.1	495,607	$ 2.52	6.1
$2.70 – 3.15	281,571	$ 2.88	6.9	251,960	$ 2.87	6.9
	3,296,812	$ 1.57	6.0	2,505,294	$ 1.79	6.0

8. COMMITMENTS

The Company leases its office space under a non-cancelable operating lease. The lease term, revised on April 30, 2007 extends through January 31, 2010. Rent expense for the years ended May 31, 2009, May 31, 2008 and May 31, 2007 was $175,997, $170,801, and $166,189, respectively.

In December 2004, the Company entered into a non-cancelable operating lease for a multi-function copier. The lease term is for sixty three months. Rent expense for the years ended May 31, 2009, May 31, 2008 and May 31, 2007 was $6,052, $7,502, and $5,130, respectively.

Future minimum lease payments are as follows:

Year ending May 31,	
2010	$ 122,212

9. SALE AND REPURCHASE OF COMMON STOCK

On September 18, 2003, we raised $12,657,599 through the sale of 7,445,646 shares of our common stock at $1.70 per share, with warrants to purchase an additional 3,164,395 shares of our common stock, at an exercise price of $2.40 per share. The warrants expire 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 2,593,788 shares of our common stock at $1.95 per share, with warrants to purchase an additional 920,121 shares of our common stock, at an exercise price of $2.25 per share. The warrants expire on May 25, 2010. As part of this transaction, the exercise price for the warrants from the September 2003 transaction were lowered from $2.40 per share to $2.25 per share. 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 2,595,132 shares of our common stock at $2.25 per share, with warrants to purchase an additional 648,784 shares of our common stock, at an exercise price of $2.99 per share. We also issued warrants to purchase 227,074 shares of our common stock, at an exercise price of $2.99 per share, to the placement agent. All the warrants expire 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 351,598 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 6,071,013 shares of our common stock at $2.50 per share, with warrants to purchase an additional 1,517,753 shares of our common stock, at an exercise price of $3.85 per share. We also issued warrants to purchase 531,214 shares of our common stock, at an exercise price of $3.85 per share, to the placement agent. All the warrants expire on July 7, 2011.

In the first fiscal quarter of 2007, existing investors and option holders exercised 133,500 warrants and 6,000 options which resulted in $315,574 in cash proceeds.

In December 2006, the FASB issued FASB Staff Position ("FSP") EITF 00-19-02 "Accounting for Registration Payment Arrangements" ("FSP EITF 00-19-02") 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 SFAS No. 5, "Accounting for Contingencies." Adoption of FSP EITF 00-19-02 is required for fiscal years beginning after December 15, 2006. For our 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 is not probable. Accordingly, we adopted FSP EITF 00-19-02 as of June 1, 2007 and as of the adoption date, it did not have any impact on the financial statements.

10. EMPLOYEE BENEFITS

Effective July 1, 2005 until January 31, 2009, we had defined contribution 401(k) retirement plan, pursuant to which employees, with no service requirement, could elect to contribute up to 15% of their compensation on a tax deferred basis up to the maximum amount permitted by the Internal Revenue Code of 1986, as amended. We did not match the participants' deferral at anytime.

11. UNAUDITED QUARTERLY INFORMATION

This table summarizes the unaudited results of operations for each quarter of 2009, 2008 and 2007:

	Quarter Ended			
	August 31	November 30	February 28	May 31
Fiscal 2009				
Revenue	$ —	$ —	$ —	$ —
Net loss	(2,398,932)	(1,520,570)	(1,603,928)	(2,155,932)
Basic and diluted loss per share	(.08)	(.05)	(.06)	(.08)
	August 31	November 30	February 29	May 31
Fiscal 2008				
Revenue	$ —	$ —	$ —	$ —
Net loss	(2,371,680)	(2,814,598)	(2,742,684)	(2,561,795)
Basic and diluted loss per share	(.08)	(.10)	(.10)	(.09)
	August 31	November 30	February 28	May 31

Fiscal 2007				
Revenue	$ —	$ —	$ —	$ —
Net loss	(1,504,529)	(2,430,673)	(2,512,995)	(2,003,745)
Basic and diluted loss per share	(.06)	(.08)	(.09)	(.07)

* Totals may not sum to annual amounts due to rounding at quarterly measurements dates.

EXHIBIT INDEX

2.1	Stock Purchase Agreement among the Company, Don Hanosh and Enerdyne Corporation, dated December 6, 1999	Incorporated by reference, to Exhibit 2.1 to the Company's 10-SB filing on December 6, 1999
2.2	Merger Agreement and Plan of Re-organization between the Company and Enerdyne Corporation	Incorporated by reference, to Exhibit 2.2 to the Company's 10-SB filing on December 6, 1999
2.3	Plan of Merger and Agreement between Protalex, Inc., a New Mexico corporation and Protalex, Inc. a Delaware Corporation	Incorporated by reference, to Exhibit 2.1 to the Company's 8-K filing on December 6, 2004
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	Letter Agreement with Pembroke Financial Ltd. Dated July 9, 2001	Incorporated by reference, to Exhibit 10.9 to the Company's 10-KSB/A filed on September 24, 2003
4.2	Securities Purchase Agreement dated September 18, 2003 between the Company and certain of the Selling Stockholders	Incorporated by reference, to Exhibit 4.3 to the Company's SB-2 filed on October 20, 2003.
4.3	Investor Rights Agreement dated September 18, 2003 between the Company and certain of the Selling Stockholders	Incorporated by reference, to Exhibit 4.3 to the Company's SB-2 filed on October 20, 2003.
4.4	Form of Common Stock Purchase Warrant issued by the Company to the Selling Stockholders	Incorporated by reference, to Exhibit 4.4 to Company's SB-2 filed on October 20, 2003.
4.5	Warrant and Common Stock Purchase Agreement dated May 25, 2005 among the Company and the several purchasers thereunder	Incorporated by reference to Exhibit 4.5 to the Company's Form SB-2 filed on June 16, 2005
4.6	Registration Rights Agreement dated May 25, 2005 among the purchasers under the Warrant and Common Stock Purchase Agreement of even date therewith	Incorporated by reference to Exhibit 4.6 to the Company's Form SB-2 filed on June 16, 2005
4.7	Addendum 1 to Subscription Agreement and Questionnaire of vSpring SBIC, LP dated May 25, 2005	Incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-KSB filed on August 26, 2005
4.8	Warrant and Common Stock Purchase Agreement dated December 22, 2005 among the Company and the several purchasers thereunder	Incorporated by reference, to Exhibit 4.5 to the Company's SB-2 filed on January 27, 2006
4.9	Registration Rights Agreement dated December 22, 2005 among the purchasers under the Warrant and Common Stock Purchase Agreement of even date therewith	Incorporated by reference, to Exhibit 4.6 to the Company's SB-2 filed on January 27, 2006
4.10	Form of Warrant issued by the Company to the Selling Stockholders dated December 22, 2005 of even date therewith	Incorporated by reference, to Exhibit 4.7 to the Company's SB-2 filed on January 27, 2006
4.11	Warrant and Common Stock Purchase Agreement dated June 30, 2006 among the Company and the several purchasers thereunder	Incorporated by reference, to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 10, 2006.
4.12		

	Registration Rights Agreement dated June 30, 2006 among the purchasers under the Warrant and Common Stock Purchase Agreement of even date therewith	Incorporated by reference, to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 10, 2006
4.13	Form of Warrant issued by the Company to the Selling Stockholders dated June 30, 2006 of even date therewith	Incorporated by reference, to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 10, 2006
10.1	Employment offer letter executed by Steven H. Kane	Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-QSB filed on January 13, 2006.
10.2	Board appointment executed by G. Kirk Raab	Incorporated by reference, to Exhibit 10.4 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.3	Form of Option Agreement	Incorporated by reference, to Exhibit 10.6 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003
10.4	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
10.5	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.
10.6	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.
10.7	Stock Redemption Agreement dated August 15, 2003, by and between the Company, Paul L. Mann, Leslie A. McCament-Mann, Gail Stewe and Elizabeth Sarah Anne Wiley	Incorporated by reference, to Exhibit 10.10 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.8	Letter dated August 21, 2003 from Paul L. Mann to the Company	Incorporated by reference, to Exhibit 10.11 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.9	Technology License Agreement dated November 17, 1999, between the Company and Alex, LLC	Incorporated by reference, to Exhibit 10.4 to the Company's Registration of Securities on Form 10-SB filed on December 6, 1999.
10.10	Letter Agreement, dated March 16, 2005, effective October 26, 2004, between the Company and Carleton A. Holstrom	Incorporated by reference, to Exhibit 10.3 to the Company's Quarterly Report on Form 10-QSB/A filed on April 14, 2005.

10.11	Description of the verbal agreement between the Company and Eugene A. Bauer, M.D.	Incorporated by reference to the Company's Current Report on Form 8-K filed on February 22, 2005.
10.12	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.
10.13	Description of the verbal agreement between the Company and Peter G. Tombros	Incorporated by reference to the Company's Current Report on Form 8-K filed on November 14, 2005.
10.14	Modified lease agreement with Union Square LP, dated November 18, 2005	Incorporate by reference to Exhibit 99.1 to the Company's Current Report Form 8-K filed on November 22, 2005.
10.15	Employment offer letter executed by Marc L. Rose, CPA, Vice President, Chief Financial Officer, Treasurer and Corporate Secretary	Incorporated by reference, to Exhibit 10.2 to the Company's Quarterly Report on Form 10-QSB filed on January 14, 2005.
10.16†	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.
10.17	Modified lease agreement with Union Square LP, dated April 30, 2007	Incorporate by reference to Exhibit 99.1 to the Company's Current Report Form 8-K filed on May 3, 2007.
10.18	Settlement Agreement with Steven H. Kane, President, Chief Executive Officer and Director dated April 14, 2009	Filed herewith
10.19	Settlement Agreement with Marc L. Rose, Vice President, Finance, Chief Financial Officer, Secretary and Treasurer dated April 14, 2009	Filed herewith
10.20	Cash Waiver & Option Termination Agreement dated April 10, 2009 with G. Kirk Raab, Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro	Filed herewith
10.21	Indemnification Agreement with Directors and Executive Officers dated August 28, 2009	Filed herewith
23.1	Consent of Grant Thornton 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

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