

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

FORM 10-K

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

For the fiscal year ended May 31, 2016

Commission file number: 000-28385

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

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

91-20033490  
(I.R.S. Employer Identification No.)

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

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

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

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

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes  No

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

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

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

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

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

The approximate aggregate market value of Common Stock held by non-affiliates of the registrant was approximately \$32.3 million as of November 30, 2015, 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 July 15, 2016 was 28,767,582.

DOCUMENTS INCORPORATED BY REFERENCE

None.

PROTALEX, INC.

FORM 10-K

May 31, 2016

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

## PART I

### ITEM 1. BUSINESS

We are focused on the development of a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases including rheumatoid arthritis (RA) and Immune Thrombocytopenia (ITP). Our lead product candidate, PRTX-100, a new generation immunomodulatory therapy, is a highly-purified form of Staphylococcal protein A, which is a bacterial protein known to modify aspects of the human immune system. PRTX-100 has demonstrated effectiveness in animal models of autoimmune diseases and has demonstrated activity on cultured human immune cells at very low concentrations, although the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we would see in future human clinical trials. The safety, tolerability and pharmacokinetics (PK) of PRTX-100 in humans have now been characterized in six clinical studies and was granted Orphan Drug Designation (ODD) in the United States and Europe for the treatment of ITP.

In March 2015, the FDA accepted our Investigational New Drug (IND) application for a Phase I/II open-label, dose-escalating study of PRTX-100 in adults with persistent/chronic ITP (the "PRTX-100-202 Study"). In June 2015, the U.S. Food and Drug Administration (FDA) granted ODD to PRTX-100 for the treatment of ITP. In July 2015, the European Medicines Agency (EMA) granted approval for a Phase 1b open-label, dose-escalating study of PRTX-100 in adult patients with persistent/chronic ITP (the "PRTX-100-203 Study"). In September 2015, the EMA Committee for Orphan Medicinal Products (COMP) issued a positive opinion recommending PRTX-100 for designation as an orphan medicinal product for the treatment of ITP. In November 2015, we enrolled our first patient in the PRTX-100-202 Study in the United States and in January 2016 we enrolled our first patient in the PRTX-100-203 Study in Europe. We do not anticipate generating operating revenue for the foreseeable future and do not currently have any products that are marketable.

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

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

In August 2013, upon completion of the fourth cohort, we expanded the 3.0 microgram, 6.0 microgram, and 12.0 micrograms/kg dose cohorts of the PRTX-100-104 Study. An additional nine patients were enrolled in the expansion cohort that was completed in October 2013. In total, the first four dose-escalating cohorts of the PRTX-100-104 Study, which included these three expanded cohorts, enrolled 41 patients with doses ranging from 1.5 micrograms/kg up to 12.0 micrograms/kg.

In November 2013, we initiated enrollment of the fifth and final cohort (Cohort 5) in the PRTX 100-104 Study. The Cohort 5 sub-study enrolled 20 patients who received five weekly fixed-weight doses of PRTX-100 followed by up to four additional monthly maintenance doses of PRTX-100 in weeks 8, 12, 16, and 20. The primary objective of the Cohort 5 sub-study was to assess safety and tolerability of these doses administered on a modified schedule. In total, 11 out of 20 patients in Cohort 5 completed all study visits by August 2014 per protocol.

In the Cohort 5 sub-study, the amount of PRTX-100 administered and its dosing frequency were varied from Cohorts 1 through 4 to explore effects on safety, tolerability and measures of disease activity. The addition of four monthly maintenance doses after the five weekly doses did not increase the rate or type of Adverse Events (AE), even in those patients who developed anti-drug antibodies (ADAs), nor indicate any apparent correlation between the development of ADAs and effects on measures of RA disease activity. In addition, Cohort 5 patients showed improvement in measures of disease activity, including ACR20 scores, compared to Cohort 1 through 4 patients who did not receive any monthly maintenance doses, suggesting that the addition of monthly maintenance administration of PRTX-100 and weight-based dosing were an important aspect of the dosing protocol and should be considered in future trials of PRTX-100.

A total of 61 patients enrolled across five cohorts in the PRTX 100-104 Study at nine study sites in the United States. For patients in all five cohorts, PRTX-100 appeared safe and well tolerated in all individuals, including those who developed ADAs, and the AE profile was consistent with our prior clinical trial results.

In February 2015, we commenced enrollment, at a single U.S. site, of a Phase I/II open-label, multiple, fixed-dose study (the “PRTX-100-105 Study”) which was open only to PRTX-100-104 Study patients who indicated their desire for additional treatment. The PRTX-100-105 Study was an open-label, single group study with former participants from the 104 Study who were eligible to receive a fixed dose of PRTX-100 over a 6-month period. The primary study endpoint of the 105 Study was the safety and tolerability of a fixed dose of PRTX-100 administered over an extended period. The secondary endpoints included immunogenicity, effects on measures of RA disease activity, evaluation of anti-PRTX-100 antibody presence, and feasibility of joint evaluations with ultrasound and biomarkers as disease markers. A total of eight patients completed all 105 Study visits per protocol.

In the PRTX-100-105 Study, a preliminary interim analysis indicated that for patients who completed per protocol, PRTX-100 exhibited an acceptable safety profile and RA disease activity was improved in a majority of patients at the end of the study as compared to baseline. No serious adverse events (SAEs) were reported. At study day 196, one month after the final dose, patients who completed the study per protocol demonstrated a mean reduction of the DAS28CRP score from 5.25 to 2.52, suggesting a clinically meaningful improvement in disease activity. Additionally, clinical assessment by Ultrasound Power Doppler Joint Counts (UPD), also revealed a reduction in average disease severity by day 196, and the correlation between the UPD and the DAS28CRP was  $r=0.624$  ( $p<.0005$ ).

In November 2015, we commenced enrollment and enrolled our first patient in the PRTX-100-202 Study. The PRTX-100-202 Study may enroll up to 36 patients in as many as six cohorts. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoint of the PRTX-100-202 Study is a platelet response to PRTX-100. Secondary endpoints include safety, immunogenicity, and pharmacokinetics. In February 2016, following a planned interim data review by an Independent Data Safety Monitoring Committee (the “SMC”), enrollment is continuing for patients in the PRTX-100-202 Study at an increased dose.

In January 2016, we commenced enrollment of our first patient in the European based PRTX-100-203 Study. The PRTX-100-203 Study may enroll up to 30 patients in as many as five cohorts at sites in France. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoints of the PRTX-100-203 Study include safety, immunogenicity and pharmacokinetics. Secondary endpoints include platelet response and duration. In May 2016, following a planned interim data review by the SMC, enrollment is continuing for patients in the PRTX-100-203 Study at an increased dose.

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

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

## Change in Control and Incremental Financing Transactions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On October 11, 2013, we issued a Consolidated, Amended and Restated Promissory Note to Niobe in the principal amount of \$9,219,366 (the “Consolidated Note”). The face amount of the Consolidated Note reflects the \$9.0 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on each note from its respective date of issuance. The terms of the Consolidated Note were identical to the Secured Notes except that: (a) the maturity date was September 1, 2015, which is after the latest maturity date of any of the Secured Notes; and (b) it provided for partial mandatory repayment in the event that the Company received aggregate gross proceeds in excess of \$7.5 million from a single or multiple “Liquidity Events” in an amount equal to twenty-five (25%) percent of such gross proceeds (the “Mandatory Repayment”). A “Liquidity Event” means (a) the sale of any of our equity, or equity-linked, securities, and (b) the receipt of proceeds, directly or indirectly related to a development and/or commercialization relationship entered into with an unaffiliated third party. In the Secured Notes, the entire principal amount of each note was due, at Niobe’s election, upon the consummation of an equity financing of \$7.5 million or greater. Consistent with the terms of the Secured Notes and related security agreements entered into, our obligations under the Consolidated Note are secured by a first priority perfected security interest in all of our assets pursuant to a Consolidated, Amended and Restated Security Agreement dated October 11, 2013. Effective as of October 1, 2014, the maturity date of the Consolidated Note was extended until September 1, 2016. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

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

On November 4, 2014, we entered into a new Credit Facility Agreement (the “2014 Credit Facility Agreement”) pursuant to which we may borrow up to an additional \$5 million from Niobe in the form of secured loans of up to \$300,000 on the last day of each calendar month, subject to certain conditions which may be waived by Niobe, at any time prior to the December 31, 2015 expiration date. Each loan made under the 2014 Credit Facility Agreement will be represented by a senior secured promissory note bearing interest at a rate of 3% per annum and maturing on September 1, 2016 (each a “Note”). Our obligations under each Note will be secured by a first priority perfected security interest in all of our assets pursuant to the Second Consolidated, Amended and Restated Security Agreement between us and Niobe, entered into at the same time as the 2014 Credit Facility Agreement (the “Security Agreement”).

In addition, on November 4, 2014, we entered into a Note Modification Agreement (the “Note Modification Agreement”) with Niobe pursuant to which the Consolidated Note, as modified in October 2014, was further amended to increase the threshold amount requiring a Mandatory Prepayment from \$7.5 Million to more than \$10 Million. As a result, partial prepayment will now be triggered in the event of a Liquidity Event in which we receive gross proceeds in excess of \$10 million. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

On December 1, 2015, the 2014 Credit Facility was amended to increase the funds available for loans to us to \$7.5 million and to extend the expiration date of such credit facility to December 31, 2016 pursuant to which we entered into and an Amended and Restated 2014 Credit Facility Agreement (the “Amended and Restated Agreement”). Each loan under the Amended and Restated Agreement has been and will be represented by a senior secured promissory note bearing interest at a rate of 3% per annum which matures on September 1, 2017 (each a “New Note”). Collectively, the Note and the New Note are hereinafter referred to as the “Notes”. In addition, the Security Agreement was also amended and restated to secure our obligations under all the Notes.

As of May 31, 2016, the outstanding principal balance under the 2014 Credit Facility totaled \$7,100,000. During the fiscal year ended May 31, 2016, we borrowed an aggregate of \$3,795,000, \$345,000 on each of July 1, 2015, July 31, 2015, August 31, 2015, October 6, 2015, November 10, 2015, December 1, 2015, January 4, 2016, February 1, 2016, March 4, 2016, April 1, 2016 and May 3, 2016. Payment of the principal and accrued interest on the Notes will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Notes. Our obligations under the Notes are secured by the Security Agreement, as amended.

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

### **About PRTX-100**

PRTX-100 is a proprietary, highly purified form of the Staphylococcal bacterial protein known as Protein A which is a bacterial protein known to modify aspects of the human immune system. PRTX-100 has the ability, at very low concentrations, to bind to human B-lymphocytes and macrophages and to modulate immune processes. Pre-clinical studies also demonstrate that low doses of PRTX-100 have potent therapeutic effects in certain models of immune-mediated inflammatory diseases. Both the PRTX-100-103 and the PRTX-100-104 studies demonstrated that PRTX-100 was generally safe and well tolerated at all dose levels, and at certain higher doses, more patients showed improvement in measures of disease activity than did patients at the lower dose or placebo cohorts.

### **Animal Studies**

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

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

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

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

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

## Clinical Trials

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

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

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

In February 2015, we commenced enrollment, at a single U.S. site, of a Phase I/II open-label, multiple, fixed-dose study (the "PRTX-100-105 Study") which was open only to PRTX-100-104 Study patients who indicated their desire for additional treatment. The PRTX-100-105 Study was an open-label, single group study with former participants from the 104 Study who were eligible to receive a fixed dose of PRTX-100 over a 6-month period. The primary study endpoint of the 105 Study was the safety and tolerability of a fixed dose of PRTX-100 administered over an extended period. The secondary endpoints included immunogenicity, effects on measures of RA disease activity, evaluation of anti-PRTX-100 antibody presence, and feasibility of joint evaluations with ultrasound and biomarkers as disease markers. A total of eight patients completed all 105 Study visits per protocol.

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

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

In March 2015, the FDA accepted our IND application for a Phase I/II open-label, dose-escalating study of PRTX-100 in adults with persistent/chronic ITP (the “PRTX-100-202 Study”). In June 2015, the FDA granted ODD to PRTX-100 for the treatment of ITP. In July 2015, the EMA granted approval for a Phase 1b open-label, dose-escalating study of PRTX-100 in adult patients with persistent/chronic ITP (the “PRTX-100-203 Study”). In September 2015, COMP issued a positive opinion recommending PRTX-100 for designation as an orphan medicinal product for the treatment of ITP. In November 2015, we enrolled our first patient in the PRTX-100-202 Study in the United States and in January 2016 enrolled our first patient in the PRTX 100-203 Study in Europe.

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

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

### **The PRTX-100-103 Study**

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

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

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

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

## **The PRTX-100-104 Study**

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

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

In November 2013, following completion of the Cohort 4 expansion cohorts, we initiated enrollment of the fifth and final cohort (Cohort 5) in the PRTX 100-104 Study. The Cohort 5 sub-study enrolled 20 patients who received five weekly fixed-weight doses of PRTX-100 followed by up to four additional monthly maintenance doses of PRTX-100 in weeks 8, 12, 16, and 20. The primary objective of the Cohort 5 sub-study was to assess safety and tolerability of these doses administered on a modified schedule. Secondary objectives included determining the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the PK parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety, PK and efficacy parameters. In total, 11 out of 20 patients in Cohort 5 completed all study visits by August 2014 per protocol.

In November 2014, we announced final data from Cohorts 1 through 4 and an interim analysis of pooled data from Cohort 5 of the 104 Study. For patients in all five cohorts of the 104 Study, PRTX-100 appeared safe and well tolerated in all individuals, including those who developed ADAs, and the AE profile was consistent with our prior clinical trial results.

In the Cohort 5 sub-study, the amount of PRTX-100 administered and its dosing frequency were varied from Cohorts 1 through 4 to explore effects on safety, tolerability and measures of disease activity. In total, twenty patients were randomized to 420 µg PRTX-100 (12 patients), 240 µg PRTX-100 (3 patients) or placebo (5 patients). The addition of four monthly maintenance doses after the five weekly doses did not increase the rate or type of AEs, even in those patients who developed ADAs nor indicate any apparent correlation between the development of ADAs and effects on measures of RA disease activity.

In addition, Cohort 5 patients showed improvement in measures of disease activity, including ACR20 scores, compared to Cohort 1 through 4 patients who did not receive any monthly maintenance doses, suggesting that the addition of monthly maintenance administration of PRTX-100 and weight-based dosing were an important aspect of the dosing protocol and should be considered in future trials of PRTX-100. A total of 61 patients enrolled across the five cohorts in the PRTX 100-104 Study at nine study sites in the United States

## **The PRTX-100-105 Study**

In February 2015, we commenced enrollment, at a single U.S. site, of a Phase I/II open-label, multiple, fixed-dose study (the “PRTX-100-105 Study”) which was open only to PRTX-100-104 Study patients who indicated their desire for additional treatment. The PRTX-100-105 Study was an open-label, single group study with former participants from the 104 Study who were eligible to receive a fixed dose of PRTX-100 over a 6-month period. The primary study endpoint of the 105 Study was the safety and tolerability of a fixed dose of PRTX-100 administered over an extended period. The secondary endpoints included immunogenicity, effects on measures of RA disease activity, evaluation of anti-PRTX-100 antibody presence, and feasibility of joint evaluations with ultrasound and biomarkers as disease markers. A total of eight patients completed all 105 Study visits per protocol.

In the PRTX-100-105 Study, a preliminary interim analysis indicated that for patients who completed per protocol, PRTX-100 exhibited an acceptable safety profile and RA disease activity was improved in a majority of patients at the end of the study as compared to baseline. No SAEs were reported. At study day 196, one month after the final dose, patients who completed the study per protocol demonstrated a mean reduction of the DAS28CRP score from 5.25 to 2.52, suggesting a clinically meaningful improvement in disease activity. Additionally, clinical assessment by UPD, also revealed a reduction in average disease severity by day 196, and the correlation between the UPD and the DAS28CRP was  $r=0.624$  ( $p<.0005$ ).

#### **The PRTX-100-202 Study**

In November 2015, we commenced enrollment and enrolled our first patient in the PRTX-100-202 Study. The PRTX-100-202 Study may enroll up to 36 patients in as many as six cohorts. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoint of the PRTX-100-202 Study is a platelet response to PRTX-100. Secondary endpoints include safety, immunogenicity, and pharmacokinetics. In February 2016, following a planned interim data review by the SMC, enrollment is continuing for patients in the PRTX-100-202 Study at an increased dose.

#### **The PRTX-100-203 Study**

In January 2016, we commenced enrollment of our first patient in the European based PRTX-100-203 Study. The PRTX-100-203 Study may enroll up to 30 patients in as many as five cohorts at sites in France. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoints of the PRTX-100-203 Study include safety, immunogenicity and pharmacokinetics. Secondary endpoints include platelet response and duration. In May 2016, following a planned interim data review by the SMC, enrollment is continuing for patients in the PRTX-100-203 study at an increased dose.

#### **Manufacturing**

We currently contract the manufacturing of our lead drug substance PRTX-100 to Eurogentec S.A. in Belgium where it is produced under Current Good Manufacturing Practice, or cGMP, conditions. In July 2014, we contracted with Eurogentec for the manufacture of additional bulk drug substance (our “active pharmaceutical ingredients”) (“API”), which we believe will be sufficient supply for completion of our current clinical studies. The stability testing and packaging of the final drug product for clinical supplies is performed by Eurogentec. The packaging of the final drug product is conducted at separate FDA-approved facilities. These companies, in the aggregate, have provided the drug product for both toxicological testing and clinical supplies. We believe that this entire process is scaleable to commercial production but will require additional manufacturing resources. The original three clinical trials of PRTX-100 were conducted with a liquid formulation and all subsequent studies have utilized a newer lyophilized formulation designed to achieve better stability and longer product shelf-life. Compared to therapeutic doses of other biologic products used to treat RA and ITP, we believe the overall costs for these proposed therapeutic doses of PRTX-100 are significantly less due to the low dose and the simplicity of drug substance manufacture.

#### **Markets**

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

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

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

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

ITP has no known cure, and relapses may occur years after seemingly successful medical or surgical management. If the patient's condition does not improve with the use of prednisone, a corticosteroid drug that is the first line therapy for ITP, other treatments may include: danazol (Danocrine), a drug taken by mouth; infusions of high-dose gamma globulin (an immune factor); drugs that suppress the immune system; anti-RhD therapy for people with certain blood types; and newer agents like romiplostim (Nplate) and eltrombopag (Promacta) that stimulate the bone marrow to make more platelets. Global sales of Nplate and Promacta were approximately \$525 million and \$400 million, respectively, in 2015. Neither romiplostim nor eltrombopag impact the principal pathological mechanism of ITP, namely immune-mediated platelet destruction, and we believe that PRTX-100 may have a more direct impact on ITP disease processes. Thus, we believe that PRTX-100 may complement or reduce the use of thrombopoietic agents in adult patients with ITP.

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

Our long-term strategy contemplates the pursuit of FDA approval of PRTX-100 to treat other autoimmune and inflammatory diseases in addition to RA and ITP.

## **Competition**

We believe, based on the pre-clinical trials and the results to date of our five Phase I RA clinical studies, that PRTX-100 has a potential competitive advantage as it may be safer and more efficacious than existing RA therapies, and may cost less to manufacture than competing biologic-based therapies. Current RA treatments are characterized by complex manufacturing methods and, in 2015, resulted in an average annual retail cost of approximately \$13,000 to \$30,000 per patient, if the newer disease-modifying anti-rheumatic drugs approved in the last 20 years were used. The cost can increase according to the size/weight of a patient and the number of doses required. Additionally, patients are faced with the cost of the infusion itself and blood tests which are often not included in those cost estimates. A number of pharmaceutical agents are currently being used, with varying degrees of success, to control the signs and symptoms of RA and slow its progression. Available treatment options include:

- Analgesic/anti-inflammatory preparations, ranging from simple aspirin to the COX-2 inhibitors;
- Immunosuppressive/antineoplastic drugs, including azathioprine and methotrexate;
- TNF (Tumor Necrosis Factor) inhibitors, also known as anti-TNF therapy, currently represented by etanercept (Enbrel®), infliximab (Remicade®), and adalimumab (Humira®) and the newer entries, certolizumab (Cimzia®) and golimumab (Simponi®);
- Soluble Interleukin-1 (IL-1) Receptor Therapy, Anakinra (Kineret®) and (IL-6) tocilizumab (Actemra®);
- Costimulatory molecule inhibitor abatacept (Orencia®);
- Anti CD20 B-cell-directed therapy, rituximab (Rituxan®); and
- Janus Kinase (JAK) inhibitor, tofacitinib citrate (Xeljanz).

Many large and small pharmaceutical companies are active in this market, with Amgen Corporation (with Pfizer), Johnson & Johnson, Inc. (with Merck) and Abbott Laboratories dominating the market for biologic therapies with their respective products, Enbrel®, Remicade® and Humira®. According to each company's 2015 annual reports, Enbrel generated revenues of approximately \$8.7 billion combined for Amgen and Pfizer, Remicade generated revenues of more than \$9.3 billion combined for Johnson & Johnson and Merck, and AbbVie reported generated revenues of \$14 billion for Humira. For other TNF inhibitors, Cimzia generated revenues of \$1.2 billion for UCB; Simponi generated revenues of \$2 billion for Johnson & Johnson and Merck; and Orencia generated revenues of \$1.9 billion for Bristol Myers Squibb. Kineret generated revenues of \$94 million in sales for SOBI, which acquired from Amgen the rights to develop and commercialize Kineret in 2014. Actemra generated revenues of \$1.5 billion and Rituxan \$5.6 billion, respectively, for Roche. Xeljanz earned \$523 million for Pfizer in 2015. Revenue figures above reflect the use of these drugs for RA, other indications and off label uses.

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

### **Government Regulation and Product Approval**

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

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

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice or GLP regulations and other regulations;
- submission to the FDA of an IND application which must become effective before clinical trials may begin;
- performance of multiple adequate and well-controlled clinical trials meeting FDA requirements to establish the safety and efficacy of the product candidate for each proposed indication;
- submission of a Biological License Application or BLA to the FDA;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product candidate is produced, and potentially other involved facilities as well, to assess compliance with cGMP, regulations and other applicable regulations; and
- the FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the drug.

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

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

### ***Clinical Trials***

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

- *Phase I clinical trials* are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. In some cases, particularly in cancer trials, a sponsor may decide to conduct what is referred to as a “Phase 1b” evaluation, which is a second safety-focused Phase I clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently FDA-approved drugs.
- *Phase II clinical trials* are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine an optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some cases, a sponsor may decide to conduct what is referred to as a “Phase IIb” evaluation, which is a second, confirmatory Phase II clinical trial that could, if positive and accepted by the FDA, serve as a pivotal clinical trial in the approval of a drug candidate.
- *Phase III clinical trials* are commonly referred to as pivotal trials. When Phase II clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

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

### ***Biological License Application***

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

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

### ***Fast Track Designation***

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

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

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

- *Priority Review.* As explained above, a drug candidate may be eligible for a six-month priority review. The FDA assigns priority review status to an application if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track drug would ordinarily meet the FDA's criteria for priority review, but may also be assigned a standard review. We do not know whether any of our drug candidates will be assigned priority review status or, if priority review status is assigned, whether that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately approve the drug.
- *Accelerated Approval.* Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and efficacy in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival or irreversible morbidity. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies with due diligence, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, may cause the FDA to seek to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

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

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

### ***Regulatory Requirements***

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

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

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

In June 2015, the FDA granted Orphan Drug Designation to PRTX-100 in the treatment for ITP. In September 2015, COMP issued a positive opinion recommending PRTX-100 for designation as an orphan medicinal product for ITP. Based upon study data to date, we believe that PRTX-100 may be effective in the treatment of ITP, as well as other orphan immunological diseases.

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

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

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

We retained the consulting services of Coté Orphan Consulting, LLC (Coté) to submit the application for Orphan Drug Designation in the EU for PRTX-100 as Protalex, Inc. does not maintain a European subsidiary. On October 9, 2015, PRTX-100 was granted Orphan Drug Designation in EU as EU/3/15/1562 (EMA/OD/111/15) for the treatment of Immune Thrombocytopenia. Coté Orphan Consulting UK Limited, a subsidiary of Coté Orphan Consulting, LLC, is identified as the sponsor of the designation for PRTX-100 in the EU. Under our agreement with Coté, we retain all ownership in the Orphan Drug Designation for PRTX-100 in the EU.

### ***Foreign Regulation***

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

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

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

### **Patents, Trademarks, and Proprietary Technology**

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

Our success will depend on our ability to maintain our trade secrets and proprietary technology in the United States and in other countries.

The table below provides a list of our issued patents:

<u>Patent Title</u>	<u>Number</u>	<u>Expiration Date</u>
Protein A Compositions and Methods of Use	U.S. Patent No. 7,211,258	Nov. 6, 2022
Protein A Methods of Use	U.S. Patent No. 7,425,331	Nov. 6, 2022
Protein A Compositions and Methods of Use	U.S. Patent No. 7,807,170	April 10, 2022
Protein A Compositions and Methods of Use	U.S. Patent No. 8,168,189	June 16, 2022
Protein A Compositions and Methods of Use	U.S. Patent No. 8,603,486	April 10, 2022
Protein A Compositions and Methods of Use	European Patent No. 2570136	March 6, 2023
Protein A Composition and Method of Use	Japanese Patent No. 5523796	March 6, 2023
Protein A Compositions and Methods of Use	U.S. Patent No. 9,370,552	April 10, 2022

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

### **Employees**

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

### **Properties**

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

### **Legal Proceedings**

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

## ITEM 1A. RISK FACTORS

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

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

### **Risks relating to our Business**

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

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

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

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

- slow enrollment of qualified patients;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials
- slower than expected rates of patient recruitment
- inability to monitor patients adequately or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

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

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

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

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

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

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

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

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

***We could lose orphan market exclusivity.***

Orphan drug exclusive marketing rights may be lost if the FDA, EMA or other regulatory body later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Although obtaining approval to market a product with orphan drug exclusivity may be advantageous, we cannot be certain that:

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

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

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

We have tried to protect our proprietary position by filing U.S. and international patent applications related to PRTX-100 in Canada, Japan, Hong Kong and the European Union. 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.

Patent applications in the United States are maintained in secrecy and not published if either: i) the application is a provisional application or, ii) the application is filed and we request no publication, and certify that the invention disclosed “has not and will not” be the subject of a published foreign application. Otherwise, U.S. applications or foreign counterparts, if any, publish 18 months after the priority application has been filed. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we were the first creator of inventions covered by pending patent applications or that we were the first to file patent applications for such inventions. There can be no assurance that our patents, if issued, would be held valid or enforceable by a court or that a competitor’s technology or product would be found to infringe such patents.

Moreover, we may be subject to third party preissuance submissions of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Further, patents generally expire, regardless of their date of issue, 20 years from the earliest claimed nonprovisional filing date. As a result, the time required to obtain regulatory approval for a product candidate may consume part or all of the patent term. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Risks Related to Our Dependence on Third Parties**

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

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

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

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

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

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

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

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

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

We will remain responsible for ensuring that our PRTX-100-202 and 203 Studies and each of our future clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA will require us to comply with cGTPs with respect to any clinical trials conducted in connection with a submission to the FDA, including an IND, and will require that we record and report clinical trial results to assure that data and reported results are credible and accurate and that the rights and safety are protected. We will also be required to register ongoing FDA-regulated clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and could devote fewer resources to our product candidates than we expect them to;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of our product or products;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate or repeat or conduct new clinical trials;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

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

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

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

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

In their report on our May 31, 2016 financial statements, our auditors expressed substantial doubt as to our ability to continue as a going concern. A going concern qualification could impair our ability to finance our operations through the sale of debt or equity securities. Our ability to continue as a going concern will depend, in large part, on our ability to obtain additional financing and generate positive cash flow from operations, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

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

We are a clinical stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by similarly situated companies. We have generated net losses in all periods since our inception in September 1999 including losses of approximately \$9.4 million and \$11.6 million for the years ended May 31, 2016 and 2015, respectively and as of May 31, 2016 we had an accumulated deficit of approximately \$94.6 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

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

Our operations have consumed substantial amounts of cash since inception. During the years ended May 31, 2016 and 2015, we incurred research and development expenses of approximately \$3.1 million and \$3.0 million, respectively. As of May 31, 2016, we had cash and cash equivalents of approximately \$444,000 and negative net working capital of approximately \$107,000. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. We currently have no agreements relating to any of these types of transactions and we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

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

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

## **Risks Associated with our Capital Stock**

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

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

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

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

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

As of June 30, 2016, our directors and executive officers and their affiliates beneficially own approximately 80% of the outstanding shares of our common stock, with one such affiliate, Niobe Ventures LLC, beneficially owns approximately 78% of our outstanding common stock. As a result, this stockholder is able to exercise control over matters requiring stockholder approval, including the election of directors, and the approval of mergers, consolidations and sales of all or substantially all of our assets.

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

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

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

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

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

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

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

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

***The price of our common stock may be volatile.***

The trading price of our common stock may fluctuate substantially. The price of our common stock that will prevail in the market may be higher or lower than the price you have paid, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock. Those factors that could cause fluctuations include, but are not limited to, the following:

- the actual number of shares of our common stock that trade;
- sales of potential sales of large blocks of our stock;
- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events, conditions or developments relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- departures of key personnel;
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
- changes in the regulatory status of our immunotherapies;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- events affecting existing or future collaborators including licensors and manufacturers;
- announcements of new products or technologies, commercial relationships, results of clinical trials, regulatory approvals, new product introductions or other relevant events by us or our competitors;
- legislative and/or regulatory developments in the United States and other countries;
- failure of our common stock or warrants to be listed or quoted on the NASDAQ Capital Market or other national market systems;
- changes in accounting principles; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

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

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

***Sales of additional equity securities may adversely affect the market price of our common stock and your rights may be reduced.***

We expect to continue to incur drug development and selling, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our common stock or other equity securities in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

***Additional authorized shares of common stock available for issuance may adversely affect the market price of our securities.***

We are currently authorized to issue 100,000,000 shares of common stock. As of May 31, 2016, we had 28,767,582 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding options. To the extent the shares of common stock are issued or options are exercised, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. As of May 31, 2016, we had outstanding options to purchase 4,582,543 shares of our common stock at a weighted average exercise price of approximately \$4.22 per share.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

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

**ITEM 3. LEGAL PROCEEDINGS**

None.

**ITEM 4. MINE SAFETY DISCLOSURE**

Not applicable.

## PART II

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

(a) *Market Information.* Our common stock is traded on the OTC Markets under the symbol "PRTX". The following table sets forth, for the periods indicated and as reported on the OTC Markets, the high and low bid prices for our common stock. Such quotations reflect inter-dealer prices, without retail mark-up, markdown or commission and may not necessarily represent actual transactions.

	<u>High</u>	<u>Low</u>
<b>2016*</b>		
First Quarter	\$ 5.93	\$ 4.51
Second Quarter	5.75	3.45
Third Quarter	5.45	3.00
Fourth Quarter	4.80	2.30
<b>2015*</b>		
First Quarter	\$ 9.00	\$ 5.60
Second Quarter	7.00	3.70
Third Quarter	7.75	4.00
Fourth Quarter	6.00	4.80

\* The prices for the fiscal years ended May 31, 2016 and 2015 are actual sale prices because the bid price information was not available.

(b) *Holder.* As of June 30, 2016, there were approximately 252 holders of record, and approximately 800 beneficial holders of our common stock.

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

#### Unregistered Sale of Equity Securities

During the year ended May 31, 2016 we granted non-qualified stock options for an aggregate of 800,000 shares of our common stock to four consultants, one officer/director, and one director. All of these options have a five-year term with an exercise price of \$5.41 per share, and were issued in reliance upon the exemptions from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act.

### ITEM 6. SELECTED FINANCIAL DATA

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

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

*This discussion, which refers to our historical results of operations and financial condition, should be read in conjunction with the other sections of this Annual Report, including "Risk Factors," "Business" and the consolidated financial statements and other consolidated financial information included in this Annual Report. The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this Annual Report. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially. You should read this Management's Discussion and Analysis of Financial Condition and Results of Operations in conjunction with our 2016 financial statements and accompanying notes included elsewhere in this Annual Report. The matters addressed in this Management's Discussion and Analysis of Financial Condition and Results of Operations, may contain certain forward-looking statements involving risks and uncertainties.*

## Overview

We are focused on the development of a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases including rheumatoid arthritis (RA) and Immune Thrombocytopenia (ITP). Our lead product candidate, PRTX-100, a new generation immunomodulatory therapy, is a highly-purified form of Staphylococcal protein A, which is a bacterial protein known to modify aspects of the human immune system. PRTX-100 has demonstrated effectiveness in animal models of autoimmune diseases and has demonstrated activity on cultured human immune cells at very low concentrations, although the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we would see in future human clinical trials. The safety, tolerability and pharmacokinetics (PK) of PRTX-100 in humans have now been characterized in six clinical studies and was granted Orphan Drug Designation (ODD) in the United States and Europe for the treatment of ITP.

In March 2015, the FDA accepted our Investigational New Drug (IND) application for a Phase I/II open-label, dose-escalating study of PRTX-100 in adults with persistent/chronic ITP (the "PRTX-100-202 Study"). In June 2015, the U.S. Food and Drug Administration (FDA) granted ODD to PRTX-100 for the treatment of ITP. In July 2015, the European Medicines Agency (EMA) granted approval for a Phase 1b open-label, dose-escalating study of PRTX-100 in adult patients with persistent/chronic ITP (the "PRTX-100-203 Study"). In September 2015, the EMA Committee for Orphan Medicinal Products (COMP) issued a positive opinion recommending PRTX-100 for designation as an orphan medicinal product for the treatment of ITP. In November 2015, we enrolled our first patient in the PRTX-100-202 Study in the United States and in January 2016 we enrolled our first patient in the PRTX-100-203 Study in Europe. We do not anticipate generating operating revenue for the foreseeable future and do not currently have any products that are marketable.

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

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

In August 2013, upon completion of the fourth cohort, we expanded the 3.0 microgram, 6.0 microgram, and 12.0 micrograms/kg dose cohorts of the PRTX-100-104 Study. An additional nine patients were enrolled in the expansion cohort that was completed in October 2013. In total, the first four dose-escalating cohorts of the PRTX-100-104 Study, which included these three expanded cohorts, enrolled 41 patients with doses ranging from 1.5 micrograms/kg up to 12.0 micrograms/kg.

In November 2013, we initiated enrollment of the fifth and final cohort (Cohort 5) in the PRTX 100-104 Study. The Cohort 5 sub-study enrolled 20 patients who received five weekly fixed-weight doses of PRTX-100 followed by up to four additional monthly maintenance doses of PRTX-100 in weeks 8, 12, 16, and 20. The primary objective of the Cohort 5 sub-study was to assess safety and tolerability of these doses administered on a modified schedule. In total, 11 out of 20 patients in Cohort 5 completed all study visits by August 2014 per protocol.

In the Cohort 5 sub-study, the amount of PRTX-100 administered and its dosing frequency were varied from Cohorts 1 through 4 to explore effects on safety, tolerability and measures of disease activity. The addition of four monthly maintenance doses after the five weekly doses did not increase the rate or type of Adverse Event (AE), even in those patients who developed anti-drug antibodies (ADAs), nor indicate any apparent correlation between the development of ADAs and effects on measures of RA disease activity. In addition, Cohort 5 patients showed improvement in measures of disease activity, including ACR20 scores, compared to Cohort 1 through 4 patients who did not receive any monthly maintenance doses, suggesting that the addition of monthly maintenance administration of PRTX-100 and weight-based dosing were an important aspect of the dosing protocol and should be considered in future trials of PRTX-100.

A total of 61 patients enrolled across five cohorts in the PRTX 100-104 Study at nine study sites in the United States. For patients in all five cohorts, PRTX-100 appeared safe and well tolerated in all individuals, including those who developed ADAs, and the AE profile was consistent with our prior clinical trial results.

In February 2015, we commenced enrollment, at a single U.S. site, of a Phase I/II open-label, multiple, fixed-dose study (the “PRTX-100-105 Study”) which was open only to PRTX-100-104 Study patients who indicated their desire for additional treatment. The PRTX-100-105 Study was an open-label, single group study with former participants from the 104 Study who were eligible to receive a fixed dose of PRTX-100 over a 6-month period. The primary study endpoint of the 105 Study was the safety and tolerability of a fixed dose of PRTX-100 administered over an extended period. The secondary endpoints included immunogenicity, effects on measures of RA disease activity, evaluation of anti-PRTX-100 antibody presence, and feasibility of joint evaluations with ultrasound and biomarkers as disease markers. A total of eight patients completed all 105 Study visits per protocol.

In the PRTX-100-105 Study, a preliminary interim analysis indicated that for patients who completed per protocol, PRTX-100 exhibited an acceptable safety profile and RA disease activity was improved in a majority of patients at the end of the study as compared to baseline. No serious adverse events (SAEs) were reported. At study day 196, one month after the final dose, patients who completed the study per protocol demonstrated a mean reduction of the DAS28CRP score from 5.25 to 2.52, suggesting a clinically meaningful improvement in disease activity. Additionally, clinical assessment by Ultrasound Power Doppler Joint Counts (UPD), also revealed a reduction in average disease severity by day 196, and the correlation between the UPD and the DAS28CRP was  $r=0.624$  ( $p<.0005$ ).

In November 2015, we commenced enrollment and enrolled our first patient in the PRTX-100-202 Study. The PRTX-100-202 Study may enroll up to 36 patients in as many as six cohorts. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoint of the PRTX-100-202 Study is a platelet response to PRTX-100. Secondary endpoints include safety, immunogenicity, and pharmacokinetics. In February 2016, following a planned interim data review by an Independent Data Safety Monitoring Committee (the “SMC”), enrollment is continuing for patients in the PRTX-100-202 Study at an increased dose.

In January 2016, we commenced enrollment of our first patient in the European based PRTX-100-203 Study. The PRTX-100-203 Study may enroll up to 30 patients in as many as five cohorts at sites in France. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoints of the PRTX-100-203 Study include safety, immunogenicity and pharmacokinetics. Secondary endpoints include platelet response and duration. In May 2016, following a planned interim data review by the SMC, enrollment is continuing for patients in the PRTX-100-203 Study at an increased dose.

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

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

## Change in Control and Incremental Financing Transactions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On October 11, 2013, we issued a Consolidated, Amended and Restated Promissory Note to Niobe in the principal amount of \$9,219,366 (the “Consolidated Note”). The face amount of the Consolidated Note reflects the \$9.0 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on each note from its respective date of issuance. The terms of the Consolidated Note were identical to the Secured Notes except that: (a) the maturity date was September 1, 2015, which is after the latest maturity date of any of the Secured Notes; and (b) it provided for partial mandatory repayment in the event that the Company received aggregate gross proceeds in excess of \$7.5 million from a single or multiple “Liquidity Events” in an amount equal to twenty-five (25%) percent of such gross proceeds (the “Mandatory Repayment”). A “Liquidity Event” means (a) the sale of any of our equity, or equity-linked, securities, and (b) the receipt of proceeds, directly or indirectly related to a development and/or commercialization relationship entered into with an unaffiliated third party. In the Secured Notes, the entire principal amount of each note was due, at Niobe’s election, upon the consummation of an equity financing of \$7.5 million or greater. Consistent with the terms of the Secured Notes and related security agreements entered into, our obligations under the Consolidated Note are secured by a first priority perfected security interest in all of our assets pursuant to a Consolidated, Amended and Restated Security Agreement dated October 11, 2013. Effective as of October 1, 2014, the maturity date of the Consolidated Note was extended until September 1, 2016. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

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

On November 4, 2014, we entered into a new Credit Facility Agreement (the “2014 Credit Facility Agreement”) pursuant to which we may borrow up to an additional \$5.0 million from Niobe in the form of secured loans in accordance with the 2014 Credit Facility Agreement, at any time prior to the December 31, 2015 expiration date. Each loan made under the 2014 Credit Facility Agreement will be represented by a senior secured promissory note bearing interest at a rate of 3% per annum and maturing on September 1, 2016 (each a “Note”). Our obligations under each Note will be secured by a first priority perfected security interest in all of our assets pursuant to the Second Consolidated, Amended and Restated Security Agreement between us and Niobe, entered into at the same time as the 2014 Credit Facility Agreement (the “Security Agreement”).

In addition, on November 4, 2014, we entered into a Note Modification Agreement (the “Note Modification Agreement”) with Niobe pursuant to which the Consolidated Note, as modified in October 2014, was further amended to increase the threshold amount requiring a Mandatory Prepayment from \$7.5 Million to more than \$10 Million. As a result, partial prepayment will now be triggered in the event of a Liquidity Event in which we receive gross proceeds in excess of \$10 million. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

On December 1, 2015, the 2014 Credit Facility was amended to increase the funds available for loans to us to \$7.5 million and to extend the expiration date of such credit facility to December 31, 2016 pursuant to which we entered into and an Amended and Restated 2014 Credit Facility Agreement (the “Amended and Restated Agreement”). Each loan under the Amended and Restated Agreement has been and will be represented by a senior secured promissory note bearing interest at a rate of 3% per annum which matures on September 1, 2017 (each a “New Note”). Collectively, the Note and the New Note are hereinafter referred to as the “Notes”. In addition, the Security Agreement was also amended and restated to secure the Company’s obligations under all the Notes.

As of May 31, 2016, the outstanding principal balance under the 2014 Credit Facility totaled \$7,100,000. During the fiscal year ended May 31, 2016, we borrowed an aggregate of \$3,795,000, \$345,000 on each of July 1, 2015, July 31, 2015, August 31, 2015, October 6, 2015, November 10, 2015, December 1, 2015, January 4, 2016, February 1, 2016, March 4, 2016, April 1, 2016 and May 3, 2016. Payment of the principal and accrued interest on the Notes will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Notes. Our obligations under the Notes are secured by the Security Agreement, as amended.

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

### **Critical Accounting Policies**

Our financial statements are prepared in conformity with accounting principles generally accepted in the United States of America. Note 4 to the financial statements for the years ended May 31, 2016 and 2015, describe the significant accounting policies and methods used in the preparation of our financial statements.

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

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

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

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

### **Results of Operations**

#### **Fiscal year ended May 31, 2016 compared to fiscal year ended May 31, 2015**

Research and Development Expenses – Research and Development expenses increased from \$2,989,311 in our 2015 fiscal year to \$3,136,800 in our 2016 fiscal year. The increase of \$147,489, or 5%, was the result of a slight increase in the expenses associated with the formulation and production of our bulk drug substance and drug product.

Administrative Expenses - Administrative expenses decreased to \$5,160,468 in our 2016 fiscal year from \$7,785,086 in our 2015 fiscal year. The decrease of \$2.6 million was related almost solely to a decrease in non-cash stock compensation.

Professional Fees - Professional fees increased from \$523,613 in our 2015 fiscal year to \$682,853 in our 2016 fiscal year. The increase of \$159,240, or 30%, was due to increases in consulting and legal expenses.

Interest Expense – Interest expense increased from \$320,769 in our 2015 fiscal year to \$434,312 in our 2016 fiscal year. The increase was attributable to the increased level of borrowing during 2016 as described above.

### **Net Loss Outlook**

We have not generated any product sales revenues, have incurred operating losses since inception and have not achieved profitable operations. Our accumulated deficit from inception through May 31, 2016 was \$94,622,528 and we expect to continue to incur substantial losses in future periods. We expect that our operating losses in future periods will be the result of continued research and development expenses relating to PRTX-100, as well as costs incurred in preparation for the potential commercialization of PRTX-100.

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

### **Liquidity and Capital Resources**

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

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

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

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

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

Effective as of October 1, 2014, we entered into a Note Modification Agreement with Niobe, pursuant to which the maturity date of the Consolidated Note was extended until September 1, 2016. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

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

On November 4, 2014, we entered into the 2014 Credit Facility Agreement pursuant to which we may borrow up to an additional \$5 million from Niobe, in the form of secured loans, in accordance with the 2014 Credit Facility Agreement at any time prior to the December 31, 2015 expiration date. Each loan made under the 2014 Credit Facility Agreement is represented by a Note and secured by a first priority perfected security interest in all of our assets.

In addition, on November 4, 2014, the Consolidated Note was further amended to increase the threshold amount requiring a Mandatory Prepayment from \$7.5 million to more than \$10 million. As a result, partial prepayment will now be triggered in the event of a Liquidity Event in which we receive gross proceeds in excess of \$10 million. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

On December 1, 2015, the 2014 Credit Facility was amended to increase the funds available for loans to us to \$7.5 million and to extend the expiration date of such credit facility to December 31, 2016 pursuant to which we entered into the Amended and Restated Agreement. Each loan under the Amended and Restated Agreement has been and will be represented by a New Note. In addition, the Security Agreement was also amended and restated to secure our obligations under all the Notes.

As of May 31, 2016, the outstanding principal balance under the 2014 Credit Facility totaled \$7,100,000. During the year ended May 31, 2016, we borrowed an aggregate \$3,795,000 pursuant to which we issued eleven Notes in the principal amount of \$345,000 each (for an aggregate of \$3,795,000). Payment of the principal and accrued interest on the Notes will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Notes. Our obligations under the Notes are secured by the Security Agreement, as amended.

#### **Subsequent Event**

On June 1, 2016, we borrowed an additional \$345,000 from Niobe under the 2014 Credit Facility and issued a them a New Note in that amount.

On June 30, 2016, the 2014 Credit Facility was amended to increase the funds available for loans to us to \$9.0 million (the "Second Amended and Restated Agreement"). Each loan under the Second Amended and Restated Agreement will be represented by a New Note. In addition, the Security Agreement was also amended and restated to secure our obligations under all the Notes including the New Notes to be issued under the Second Amended and Restated Agreement.

On July 1, 2016, we borrowed an additional \$375,000 from Niobe under the 2014 Credit Facility pursuant to the Second Amended and Restated Agreement and issued a them a New Note in that amount.

On July 15, 2016, we entered into an agreement with Niobe pursuant to which Niobe agreed to exchange all Notes outstanding, which as of May 31, 2016 had an aggregate outstanding principal balance of \$16,319,366, for shares of our common stock, at the price per share that our common stock is sold to public investors in a qualified public offering. The agreement defines a "qualified public offering" to mean a public offering of our common stock yielding gross proceeds to us of at least \$7.0 million which is consummated on or before October 31, 2016. The agreement further provided that 50% of accrued but unpaid interest would also be converted into common stock and 50% would be paid out of the proceeds of the qualified public offering.

#### **Net Cash Used in Operating Activities and Operating Cash Flow Requirements Outlook**

Our operating cash outflows for the fiscal years ended May 31, 2016 and 2015 have resulted primarily from research and development expenditures associated for PRTX-100 and administrative purposes. We expect to continue to use cash resources to fund operating losses and expect to continue to incur operating losses in fiscal 2017 and beyond due to continuing research and development activities.

#### **Net Cash Used in Investing Activities and Investing Requirements Outlook**

We do not expect to be required to make any significant investments in information technology and laboratory equipment to support our future research and development activities.

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

## **Off-Balance Sheet Arrangements**

As of May 31, 2016 we had no off-balance sheet arrangements such as guarantees, retained or contingent interest in assets transferred, obligation under a derivative instrument and obligation arising out of or a variable interest in an unconsolidated entity.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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

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

Not applicable.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **(a) Evaluation of Disclosure Controls and Procedures**

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

Our management, including our president and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, management’s evaluation of controls and procedures can only provide reasonable assurance that all control issues and instances of fraud, if any, within Protalex have been detected.

### **(b) Management’s Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of May 31, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework as adopted in 1992. Our management has concluded that, as of May 31, 2016, our internal control over financial reporting is effective based on these criteria.

### **(c) Changes in Internal Control over Financial Reporting**

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

## ITEM 9B. OTHER INFORMATION

None.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth information concerning our officers and directors as of June 30, 2016:

Name	Age	Title
Arnold P. Kling	58	President and Director
Kirk M. Warshaw	58	Chief Financial Officer, Secretary and Director
Marco M. Elser	57	Director

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

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

**Marco M. Elser.** Mr. Elser has served as a director since February 2014. Since June 2015, Mr. Elser has been a partner with Lonsin Capital Ltd., an entity regulated by the Financial Conduct Authority of the United Kingdom and the fund manager of Lousin Global Credit Fund, a distressed debt fund registered in the Cayman Islands. From January 2002 until June, 2015, Mr. Elser was a partner with AdviCorp Plc, a London-based investment banking firm. From 1994 to 2001, Mr. Elser served as International Vice President of Northeast Securities, managing distressed funds for family offices and small institutions. Prior to that, from 1985 through 1994, he served as a First Vice President of Merrill Lynch Capital Markets in Rome and London. Mr. Elser is presently a director (since 2002) of North Hills Signal Processing Corporation, a technology company, a director (since 2012) of Trans-Lux Corporation, a designer and manufacturer of digital signage display solutions, and a director (since 2016) of Scooterino srl, a Rome-based two-wheel ride sharing company. From 2002 to 2014, Mr. Elser was the president of the Harvard Club of Italy, an association he founded with other alumni in Italy where he has been living since 1984. He received his BA in Economics from Harvard College in 1981. Mr. Elser's extensive knowledge of international finance and commerce allows him to make valuable contributions as one of our directors.

#### Scientific Advisory Board

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

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

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

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

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

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

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

### **Third-Party Consultants**

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

### **Family Relationships**

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

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who beneficially own more than ten percent of our common stock (collectively, the "Reporting Persons") to report their ownership of and transactions in our common stock to the SEC. Copies of these reports are also required to be supplied to us. To our knowledge, during the fiscal year ended May 31, 2016 the Reporting Persons complied with all applicable Section 16(a) reporting requirements.

### **Code of Ethics**

Our Board has adopted a Code of Ethics and Business Conduct Code of Ethics and Business Conduct, or the Code, that applies to all directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, and contains the general guidelines for conducting our business. The overall purpose of the Code is to ensure compliance of general guidelines for conducting our business consistent with the understanding of our standards of ethical business practices. The Code includes provisions relating to compliance with all laws and regulations governing its operations, compliance with Regulation FD, professional and personal use of our information systems, our commitment to providing a safe, orderly, diverse and tolerant work environment that is free of any discrimination or harassment, and the Company's employment practices regarding alcohol, drugs and violence prevention. All of our directors, officers and employees are expected to be familiar with the Code and to adhere to those principles and procedures set forth in the Code that apply to them. The Code, and any amendments to the Code, as well as any waivers that are required to be disclosed by the rules of the SEC, is available on our web site at [www.protalex.com](http://www.protalex.com). A copy of the Code will also be provided to any person requesting same without charge. To request a copy, please make written request to Corporate Secretary c/o Protalex, Inc., 131 Columbia Turnpike, Suite 1, Florham Park, NJ 07932.

### **Board Composition and Election of Directors**

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

### **Board Committees**

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

### **Audit Committee Financial Expert**

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

## Stockholder Communications

As of the date of this Annual Report, we do not yet have a defined process for security holders to send communications to the Board. Security holders that wish to communicate with the Board are encouraged to contact us at our principal executive offices by letter or telephone.

## ITEM 11. EXECUTIVE COMPENSATION

### Executive Compensation

#### *Compensation Discussion and Analysis.*

We are in the process of assembling a compensation committee to evaluate and define the annual compensation for our executive officers and directors. The objectives approved by the compensation committee will be designed to attract and retain qualified, effective managers with the experience necessary to manage our business effectively. Our financial performance will be a major factor in the compensation of key employees as well as their individual contributions. Stock options are expected to comprise a portion of total compensation. Stock options will be properly accounted for under ASC 718 and will be either “incentive stock options” (as defined in the Internal Revenue Code and federal tax regulations) or non-incentive options. ASC 718 will require us to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award (with limited exceptions). That cost will be recognized over the period during which an employee is required to provide service in exchange for any award the requisite service period (usually the vesting period). The compensation amounts disclosed in the following compensation table reflects executive compensation prior to the existence of the compensation committee, but were nonetheless determined by factors that we believe were in the best interests of our stockholders.

The compensation paid to our named executive officers for fiscal 2016 is not necessarily indicative of how we will compensate our named executive officers in the future and we anticipate our compensation programs, as developed and implemented by our compensation committee, will vary significantly from our historical practices.

### Summary of Compensation

For the fiscal year 2016, total compensation paid to Arnold Kling, our president, was \$72,000, all of which constituted salary paid in cash. Total compensation paid to Kirk Warshaw, our chief financial officer in fiscal 2016, was \$1,368,146, which included cash of \$72,000 and stock options valued at \$1,296,146. Neither Mr. Kling nor Mr. Warshaw has an employment agreement.

The primary objective of our executive compensation program is to attract and retain qualified, energetic managers who are enthusiastic about our mission and culture. A further objective of the compensation program is to provide incentives and reward each manager for their contribution. In addition, we strive to promote an ownership mentality among key leadership and the board of directors.

It is our intention to set total executive cash compensation at levels sufficient to attract and retain a strongly motivated leadership team. Each executive’s current and prior compensation will be considered in setting future compensation. In addition, we intend to review the compensation practices of other similarly situated companies. To some extent, our compensation plan is based on the market and the companies we compete against for executive management. We expect that the elements of our proposed compensation plan, base salary, bonus and stock options, will be similar to the elements of compensation used by many companies.

### Summary Compensation Table

The following table sets forth, for the fiscal years ended May 31, 2016 and 2015, the information as to compensation paid to or earned by our then principal executive officer and our two other most highly compensated executive officers, other than the principal executive officer, whose total compensation exceeded \$100,000 during the fiscal year ended May 31, 2016. These individuals are referred to in this Annual Report as our named executive officers. As none of our named executive officers received non-equity incentive plan compensation or nonqualified deferred compensation earnings during the fiscal years ended May 31, 2016 and 2015, we have omitted those columns from the table.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)(1)</b>	<b>Option Awards (\$)(1)</b>	<b>Total (\$)</b>
Arnold P. Kling, President	2016	\$ 72,000	0	\$ 72,000
	2015	\$ 72,000	0	\$ 72,000
Kirk M. Warshaw, Chief Financial Officer	2016	\$ 72,000	\$ 1,296,146	\$ 1,368,146
	2015	\$ 72,000	\$ 625,000	\$ 697,000

(1) Reflects the value of stock options that was charged to income as reported in our financial statements and calculated using the provisions of FASB ASC 718 "Share-based Payments." The assumptions underlying the valuation of equity awards are set forth in Note 7 of our financial statements for the fiscal years ended May 31, 2016 and 2015, included elsewhere in this report.

### **Employment Contracts**

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

### **Indemnification Agreements**

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

### Outstanding Equity Awards at Fiscal Year End

The table below summarizes the outstanding equity awards to our named executive officers as of the fiscal year ended May 31, 2016:

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Kirk M. Warshaw, Chief Financial Officer	750,543	0	\$ 0.25	12/29/2019
	250,000	0	\$ 1.01	10/31/2021
	350,000	0	\$ 1.05	05/22/2023
	100,000	0	\$ 6.00	11/04/2019
	125,000	125,000	\$ 5.41	6/30/2020

### Compensation of Directors

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

The table below summarizes the compensation paid to our independent director for the fiscal year ended May 31, 2016:

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
Marco M. Elser	\$ 0	\$ 249,996	\$ 0	\$ 249,996

- (1) Reflects the value of stock options that was charged to income as reported in our financial statements and calculated using the provisions of FASB ASC 718 “Share-based Payments.” The assumptions underlying the valuation of equity awards are set forth in Note 7 of our financial statements, included elsewhere in this report. At May 31, 2016, Mr. Elser held options exercisable for an aggregate of 350,000 shares at exercise prices ranging from \$6.00 to \$9.00 per share. The number of shares to be acquired upon exercise assumes that the options are fully-vested.

### Employee Benefit Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate qualified personnel and service providers, and encourages them to devote their best efforts to our business and financial success. The material terms of our equity incentive plans are described below.

### **Limitations of Directors' Liability and Indemnification**

Our certificate of incorporation provides that a director will not be personally liable to us or to our stockholders for monetary damages for breach of their fiduciary duty of care as a director, including breaches which constitute gross negligence. This provision does not eliminate or limit the liability of a director:

- for any breach of the director's duty of loyalty to us or our stockholders,
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, or
- for any transaction from which the director derived an improper personal benefit.

Our certificate of incorporation also provides that we indemnify and hold harmless each of our directors and officers, to the fullest extent authorized by law, against all expense, liability and loss (including attorney's fees, judgments, fines, ERISA excise taxes or penalties and amounts paid or to be paid in settlement), reasonably incurred or suffered by such person in connection their service as our director or officer.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons pursuant to our certificate of incorporation, bylaws or Delaware law, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 30, 2016 of:

- each person who is known by us to be the beneficial owner of more than 5% of our outstanding common stock;
- each of our directors;
- each of our named executive officers and current executive officers; and
- all of our current directors and executive officers as a group.

As used in the table below and elsewhere in this Annual Report, the term beneficial ownership with respect to our common stock consists of sole or shared voting power (which includes the power to vote, or to direct the voting of shares of our common stock) or sole or shared investment power (which includes the power to dispose, or direct the disposition of, shares of our common stock) through any contract, arrangement, understanding, relationship or otherwise, including a right to acquire such power(s). Unless otherwise indicated in the footnotes to this table, and subject to community property laws where applicable, we believe each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Unless otherwise indicated, the address for each of the individuals and entities listed in this table is c/o Protalex, Inc. at 131 Columbia Turnpike, Suite 1, Florham Park, NJ 07932.

Name and Title	Shares Beneficially Owned(1)	
	Number	Percent (2)
Arnold P. Kling, president and director (3)	22,581,149	78.5%
Kirk M. Warshaw, CFO, secretary and director (4)	1,700,543	5.6%
Marco M. Elser, director (5)	384,000	1.3%
Officers and Directors as a group (3 persons) (6)	24,665,692	80.0%
<b>5% Beneficial Owners</b>		
Niobe Ventures LLC 410 Park Avenue – Suite 1710 New York, NY 10022	22,576,087	78.5%

- (1) Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned by them. A person is deemed to be the beneficial owner of securities which may be acquired by such person within 60 days from the date indicated above upon the exercise of options, warrants or convertible securities. Each beneficial owner's percentage ownership is determined by assuming that options, warrants or convertible securities that are held by such person (but not those held by any other person) and which are exercisable within 60 days of the date indicated above, have been exercised.
- (2) Based on 28,767,582 shares of common stock issued and outstanding as of June 30, 2016.
- (3) Arnold P. Kling, our president and a director, possesses sole voting and dispositive control over the securities owned by Niobe Ventures, LLC and therefore is deemed to be the beneficial owner of the securities held by that entity.
- (4) Our chief financial officer and secretary and a director. Shares beneficially owned consist of options to purchase: 750,543 shares of common stock at an exercise price of \$0.25 per share; 250,000 shares of common stock at an exercise price of \$1.01 per share; 350,000 shares of common stock at an exercise price of \$1.05 per share; 100,000 shares of common stock at an exercise price of \$6.00 per share and 250,000 shares of common stock at an exercise price of \$5.41 per share.
- (5) A director. Shares beneficially owned include options to purchase: 250,000 shares of common stock at an exercise price of \$9.00 per share and 100,000 shares of common stock at an exercise price of \$6.00 per share.
- (6) Includes 2,050,543 shares of common stock underlying options to purchase shares of common stock beneficially owned.

## Securities Authorized for Issuance under Equity Compensation Plans

### Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders – 2003 Stock Option Plan	2,000	\$ 10.75	0
Equity compensation plans not approved by security holders – Stand Alone Option Grants	4,580,543	\$ 4.22	Not applicable
<b>Total</b>	<b>4,582,543</b>	<b>\$ 4.22</b>	<b>0</b>

During the fiscal year ended May 31, 2016, options for an aggregate of 800,000 shares of our common stock were granted under Equity Compensation Plans Not Approved by Security Holders as compensation for consulting services. These options are five year options with an exercise price of \$ 5.41 per share and were 50% vested on the date of grant with the remaining 50% vesting on the first anniversary of the date of grant.

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

Our policy is to not enter into transactions with related parties unless the terms, on the whole, are no more favorable, or no less favorable, than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all of the transactions described below met this policy standard at the time they occurred.

As described herein above, from November 2014 through May 31, 2016 we borrowed an aggregate of \$7,100,000 from Niobe pursuant to the 2014 Credit Facility.

On June 1, 2016 and July 1, 2016, we borrowed an additional \$345,000 and \$375,000, respectively, from Niobe under the 2014 Credit Facility and issued a them a New Note for each loan in such amount.

On June 30, 2016, we entered into the Second Amended and Restated Agreement with Niobe, which increased the funds available for loans to us to \$9.0 million. Each loan under the Second Amended and Restated Agreement will be represented by a New Note. In addition, the Security Agreement was also amended and restated to secure our obligations under all the Notes including the New Notes to be issued under the Second Amended and Restated Agreement.

On July 15, 2016, we entered into an agreement with Niobe pursuant to which Niobe agreed to exchange all Notes outstanding, which as of May 31, 2016 had an aggregate outstanding principal balance of \$16,319,366, for shares of our common stock, at the price per share that our common stock is sold to public investors in a qualified public offering. The agreement defines a “qualified public offering” to mean a public offering of our common stock yielding gross proceeds to us of at least \$7.0 million which is consummated on or before October 31, 2016. The agreement further provided that 50% of accrued but unpaid interest would also be converted into common stock and 50% would be paid out of the proceeds of the qualified public offering.

Currently, we do not have written policies and procedures for the review, approval or ratification of related person transactions. However, given our small size, senior management and the audit committee (or full Board) are able to review all transactions consistent with applicable securities rules governing our transactions and proposed transactions exceeding the lesser of \$120,000 or one percent of the average of our total assets as of May 31, 2016 and 2015 in which a related person has a direct or indirect material interest. Our Board reviews related person transactions and has approval authority with respect to whether a related person transaction is within our best interest.

## Director Independence

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

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The aggregate fees billed by our principal accounting firm, Liggett & Webb P.A. (formerly Liggett, Vogt & Webb P.A.) in the fiscal years ended May 31, 2015 and 2016 are as follows:

	2015	2016
Audit fees*	\$ 36,500	\$ 36,500
Audit related fees	0	0
Tax fees	4,500	4,500
All other fees**	0	18,850
Total fees	\$ 41,000	\$ 59,850

\*Includes fees for professional services rendered for the audit of our annual financial statements and the review of financial statements included in our report on Form 10-Qs or services that are normally provided in connection with statutory and regulatory filings.

\*\*Includes fees for professional services rendered in connection with the preparation and filing of our Registration Statement on Form S-1 and S-1/A filed on July 31, 2015 and June 3, 2016, respectively.

## Pre-Approval of Audit and Permissible Non-Audit Services

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

## PART IV

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

### (a) 1. Financial Statements

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

### 2. Financial Statement Schedules

None.

### (b) Exhibits

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

#### EXHIBIT INDEX

3.1	Certificate of Incorporation of the Company	Incorporated by reference to Exhibit 3.1 to the Company's 8-K filing on December 6, 2004.
3.2	Bylaws of the Company	Incorporated by reference to Exhibit 3.2 to the Company's 8-K filing on December 6, 2004.
3.3	State of Delaware, Certificate of Amendment of Certificate of Incorporation	Incorporated by reference to Exhibit 3.3 to the Company 10-QSB filed on January 13, 2006.
3.4	Certificate of Amendment of Certificate of Incorporation of the Company, effective as of December 8, 2010	Filed herewith.
4.1	Consolidated, Amended and Restated Promissory Note in the principal amount of \$9,219,366, dated October 11, 2013	Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on October 11, 2013.
4.2	Final form of Securities Purchase Agreement dated as of January 22, 2014 between the Company and certain accredited investors pursuant to which such investors were granted piggy back registration rights	Incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K filed on August 5, 2014.
4.3	Secured Promissory Note issued to Niobe in the principal amount of \$300,000 dated November 4, 2014	Incorporated by reference to Exhibit 4.1 to the Company's 8-K filing on November 7, 2014.
4.4	Secured Promissory Note issued to Niobe in the principal amount of \$430,000 dated November 24, 2014	Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on January 9, 2015.
4.5	Secured Promissory Note issued to Niobe in the principal amount of \$645,000 dated January 9, 2015	Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on April 10, 2015.
4.6	Secured Promissory Note issued to Niobe in the principal amount of \$545,000 dated February 4, 2015	Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on April 10, 2015.
4.7	Secured Promissory Note issued to Niobe in the principal amount of \$395,000 dated March 9, 2015	Incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed on April 10, 2015.
4.8	Secured Promissory Note issued to Niobe in the principal amount of \$300,000 dated April 1, 2015	Incorporated by reference to Exhibit 4.4 to the Company's Quarterly Report on Form 10-Q filed on April 10, 2015.
4.9	Secured Promissory Note issued to Niobe in the principal amount of \$345,000 dated May 1, 2015	Incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-K filed on July 14, 2015.
4.10	Secured Promissory Note issued to Niobe in the principal amount of \$345,000 dated May 29, 2015	Incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-K filed on July 14, 2015.
4.11	Secured Promissory Note issued to Niobe in the principal amount of \$345,000 dated July 1, 2015	Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on October 13, 2015.
4.12	Secured Promissory Note issued to Niobe in the principal amount of \$345,000 dated July 30, 2015	Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on October 13, 2015.
4.13	Secured Promissory Note issued to Niobe in the principal amount of \$345,000 dated August 31, 2015	Incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed on October 13, 2015.
4.14	Final Form of Secured Promissory Note issued to Niobe on October 6, 2015 and on November 10, 2015	Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on January 7, 2016.
4.15	Final Form of Secured Promissory Note issued to Niobe pursuant to the Amended and Restated 2014 Credit Facility Agreement between the Company and Niobe dated as of December 1, 2015	Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on January 7, 2016.
4.16	Final Form of Secured Promissory Note issued to Niobe pursuant to the Second Amended and Restated 2014 Credit Facility Agreement between the Company and Niobe dated as of June 30, 2016	Filed herewith.

10.1	Frame Contract between the Company and Eurogentec S.A.	Incorporated by reference to Exhibit 10.5 to the Company's 10-KSB/A filed on September 24, 2003.
10.2	Assignment of Intellectual Property from Alex LLC to the Company	Incorporated by reference to Exhibit 10.8 to the Company's 10-KSB/A filed on September 24, 2003.
10.3	Assignment of Intellectual Property from Dr. Paul Mann to the Company	Incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.4	Protalex, Inc. 2003 Stock Option Plan Amended and Restated as of July 29, 2005	Incorporated by reference to Appendix B to the Company's Proxy Statement filed on September 23, 2005.
10.5†	Service Contract with AAIPharma Inc., dated January 29, 2007	Incorporated by reference to Exhibit 10.18 to the Company's Quarterly Report on Form 10-QSB filed on April 13, 2007.
10.6	Indemnification Agreement with Directors and Executive Officers dated August 28, 2009	Incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on August 28, 2009.
10.7**	Final Form of Indemnification Agreement with current Directors, Executive Officers and the members of the Scientific Advisory Board	Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 13, 2010.
10.8**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw December 29, 2009	Incorporate by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on January 8, 2010.
10.9**	Form of Non-Qualified Stock Option Agreement with each of William Gannon, Edward Bernton and Valerie Jackson	Incorporated by reference to Exhibit 4.9 to the Company's Annual Report on Form 10-K filed on August 27, 2010.
10.10**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw dated November 1, 2011	Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed on August 29, 2012.
10.11**	Form of Non-Qualified Stock Option Agreement with each of Edward Bernton and Valerie Jackson, dated November 1, 2011	Incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed on August 29, 2012.
10.12**	Form of Non-Qualified Stock Option Agreement with Marco M. Elser dated February 4, 2014	Incorporate by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on February 20, 2014.
10.13**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw dated May 22, 2013	Incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on February 20, 2014.
10.14	Final Form of Consolidated Note Modification Agreement effective as of October 1, 2014, between the Company and Niobe	Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on October 8, 2014.
10.15	Consolidated, Amended and Restated Security Agreement dated October 11, 2013, between the Company and Niobe Ventures, LLC	Incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on February 20, 2014.
10.16	Final Form of Consolidated Note Modification Agreement between the Company and Niobe dated November 4, 2014	Incorporated by reference to Exhibit 10.1 to the Company's 8-K filing on November 7, 2014.
10.17	Final Form of the 2014 Million Credit Facility Agreement between the Company and Niobe dated as of November 4, 2014	Incorporated by reference to Exhibit 10.2 to the Company's 8-K filing on November 7, 2014.
10.18	Final Form of Second Consolidated, Amended and Restated Security Agreement between the Company and Niobe dated as of November 4, 2014	Incorporated by reference to Exhibit 10.3 to the Company's 8-K filing on November 7, 2014.
10.19**	Form of Non-Qualified Stock Option Agreement with each of Kirk M. Warshaw and Marco Elser dated November 4, 2014	Incorporated by reference, to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on January 9, 2015.

10.20**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw dated July 1, 2015	Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on October 13, 2015.
10.21	Final Form of the Amended and Restated 2014 Credit Facility Agreement between the Company and Niobe dated as of December 1, 2015	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 7, 2015.
10.22	Final Form of the Third Consolidated, Amended and Restated Security Agreement between the Company and Niobe dated as of December 1, 2015	Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 7, 2015.
10.23	Final Form of the Second Amended and Restated 2014 Credit Facility Agreement between the Company and Niobe dated as of June 30, 2016	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 7, 2016.
10.24	Final Form of the Fourth Consolidated, Amended and Restated Security Agreement between the Company and Niobe dated as of June 30, 2016	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 7, 2016.
10.25	Exchange Agreement, dated June 3, 2016, between the Company and Niobe	Incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed on June 3, 2016.
10.26	Amended and Restated Exchange Agreement, dated July 15, 2016, between the Company and Niobe	Filed herewith.
23.1	Consent of Liggett & Webb, P.A.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act	Filed herewith.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith in accordance with Item 601 (32)(ii) of Regulation S-K.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith in accordance with Item 601 (32)(ii) of Regulation S-K.
101.INS	<i>XBRL Instance Document</i>	Filed herewith.
101.SCH	<i>XBRL Taxonomy Extension Schema Document</i>	Filed herewith.
101.CAL	<i>XBRL Taxonomy Extension Calculation Linkbase Document</i>	Filed herewith.
101.LAB	<i>XBRL Taxonomy Extension Label Linkbase Document</i>	Filed herewith.
101.PRE	<i>XBRL Taxonomy Extension Presentation Linkbase Document</i>	Filed herewith.
101.DEF	<i>XBRL Taxonomy Extension Definition Linkbase Document</i>	Filed herewith.

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

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

## SIGNATURES

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

Protalex Inc.

Date: July 15, 2016

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

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

Date: July 15, 2016

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

Date: July 15, 2016

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

Date: July 15, 2016

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

**PROTALEX, INC.**

**INDEX TO FINANCIAL STATEMENTS**

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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Protalex, Inc. as of May 31, 2016 and 2015, and the related statements of operations, changes in stockholders' (deficit), and cash flows for each of the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our 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, 2016 and 2015 and the results of its operations and its cash flows for each of the years ended, in conformity with accounting principles generally accepted in the United States of America.

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

/s/ Liggett & Webb, P.A.

New York, NY  
July 14, 2016

**PROTALEX, INC.**  
**BALANCE SHEETS**

	2016	May 31, 2015
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 444,179	\$ 928,279
Prepaid expenses	55,687	56,431
Total current assets	499,866	984,710
<b>OTHER ASSETS:</b>		
Intellectual technology property, net of accumulated amortization of \$16,128 and \$15,108 as of May 31, 2016 and May 31, 2015, respectively	3,407	4,427
Total other assets	3,407	4,427
Total Assets	\$ 503,273	\$ 989,137
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT)</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 561,683	\$ 494,954
Accrued expenses	45,572	59,701
Total current liabilities	607,255	554,655
<b>LONG TERM LIABILITIES:</b>		
Senior Secured Note – related party	16,319,366	12,524,366
Senior Secured Note Accrued Interest – related party	932,882	498,570
Total liabilities	17,859,503	13,577,591
<b>STOCKHOLDERS' (DEFICIT)</b>		
Preferred stock, par value \$0.00001, 1,000,000 shares authorized; none issued and outstanding	-	-
Common stock, par value \$0.00001, 100,000,000 shares authorized; 28,767,582 and 28,767,582 shares issued and outstanding, respectively	288	288
Additional paid in capital	77,266,010	72,618,336
Accumulated deficit	(94,622,528)	(85,207,078)
Total stockholders' (deficit)	(17,356,230)	(12,588,454)
Total liabilities and stockholders' (deficit)	\$ 503,273	\$ 989,137

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

**PROTALEX, INC.**

**STATEMENTS OF OPERATIONS**  
**For The Years Ended May 31,**

	<b>2016</b>	<b>2015</b>
Revenues	\$ -	\$ -
Operating Expenses		
Research and development	3,136,800	2,989,311
Administrative	5,160,468	7,785,086
Professional fees	682,853	523,613
Depreciation and amortization	1,020	1,020
Operating loss	(8,981,141)	(11,299,030)
Other income (expense)		
Interest income	3	3
Interest expense	(434,312)	(320,769)
Loss before income taxes	(9,415,450)	(11,619,796)
Provision for income taxes	-	-
Net loss	\$ (9,415,450)	\$ (11,619,796)
Weighted average number of common shares outstanding – basic and diluted	<b>28,767,582</b>	<b>28,767,582</b>
Loss per common share – basic and diluted	\$ (0.33)	\$ (0.40)

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

**PROTALEX, INC.**

**STATEMENT OF CHANGES IN STOCKHOLDERS' (DEFICIT)**

For the Years Ended May 31, 2015 and May 31, 2016

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, May 31, 2014	28,767,582	\$ 288	\$ 65,402,505	\$ (73,587,282)	\$ (8,184,489)
Stock based compensation	-	-	7,215,831	-	7,215,831
Net loss	-	-	-	(11,619,796)	(11,619,796)
Balance, May 31, 2015	28,767,582	288	72,618,336	(85,207,078)	(12,588,454)
Stock based compensation	-	-	4,647,674	-	4,647,674
Net loss	-	-	-	(9,415,450)	(9,415,450)
Balance, May 31, 2016	28,767,582	\$ 288	\$ 77,266,010	\$ (94,622,528)	\$ (17,356,230)

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

**PROTALEX, INC.**

**STATEMENTS OF CASH FLOWS**  
**For The Years Ended May 31,**

	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (9,415,450)	\$ (11,619,796)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities		
Depreciation and amortization	1,020	1,020
Stock based compensation	4,647,674	7,215,831
(Increase)/decrease in:		
Prepaid expenses and deposits	744	(11,104)
Increase in:		
Accounts payable and accrued expenses	52,600	101,801
Accrued interest payable	434,312	320,769
Net cash and cash equivalents used in operating activities	(4,279,100)	(3,991,479)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
	-	-
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Issuance of note payable to related party	3,795,000	3,305,000
Net cash and cash equivalents provided by financing activities	3,795,000	3,305,000
<b>NET (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(484,100)	(686,479)
Cash and cash equivalents, beginning of year	928,279	1,614,758
Cash and cash equivalents, end of year	\$ 444,179	\$ 928,279
<b>SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:</b>		
Interest paid	\$ 0	\$ 0
Taxes paid	\$ 0	\$ 0

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

PROTALEX, INC.  
**NOTES TO FINANCIAL STATEMENTS**  
For The Years Ended May 31, 2016 and 2015

**1. ORGANIZATION AND BUSINESS ACTIVITIES**

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

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

In April 2009, the Company ceased all operations and terminated all employees in light of insufficient funds to continue its clinical trials and related product development. The Company's business was dormant until new management took control of its operations in November 2009. Since then the Company has been actively pursuing the commercial development of PRTX-100 for the treatment of RA.

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

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

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

**2. CHANGE OF OWNERSHIP TRANSACTION**

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

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

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

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

During the period February 1, 2012 to August 27, 2013 the Company raised a total of \$9,000,000 in principal through the issuance of several varying amounts of loans from Niobe and are hereinafter referred to as the "Secured Notes." These Secured Notes bore an interest rate of 3% and had maturity dates ranging from February 1, 2014 to August 27, 2015.

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

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

On November 4, 2014, the Company entered into a new Credit Facility Agreement (the "2014 Credit Facility Agreement") pursuant to which it may borrow up to an additional \$5 million from Niobe in the form of secured loans of up to \$300,000 on the last day of each calendar month, subject to certain conditions which may be waived by Niobe, at any time prior to the December 31, 2015 expiration date (the "2014 Credit Facility"). Each loan made under the 2014 Credit Facility Agreement will be represented by a senior secured promissory note bearing interest at a rate of 3% per annum and maturing on September 1, 2016 (each an "Original Note"). The Company's obligations under each Note will be secured by a first priority perfected security interest in all of its assets pursuant to the Second Consolidated, Amended and Restated Security Agreement between the Company and Niobe, entered into at the same time as the 2014 Credit Facility Agreement (the "Security Agreement").

In addition, on November 4, 2014, the Company entered into a Note Modification Agreement (the “Note Modification Agreement”) with Niobe pursuant to which the Consolidated Note, as modified in October 2014, was further amended to increase the threshold amount requiring a Mandatory Prepayment from \$7.5 Million to more than \$10 Million. As a result, partial prepayment will now be triggered in the event of a Liquidity Event in which the Company receives gross proceeds in excess of \$10 million. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

In October 2015, the Company entered into an agreement with Niobe pursuant to which Niobe agreed to convert all notes outstanding into shares of Common Stock, at the offering price in a “qualified public offering” consummated by the Company. The agreement defines a “qualified public offering” to mean a public offering of Common Stock yielding gross proceeds to the Company of at least \$7 million, which is consummated on or before February 29, 2016. The agreement further provided that accrued interest would be paid out of the proceeds of the qualified public offering. On December 1, 2015, the agreement expired pursuant its own terms.

On December 1, 2015, the 2014 Credit Facility was amended to increase the funds available for loans to the Company to \$7.5 million and to extend the expiration date of such credit facility to December 31, 2016 pursuant to which the Company and Niobe entered into and an Amended and Restated 2014 Credit Facility Agreement (the “Amended and Restated Agreement”). Each loan under the Amended and Restated Agreement has been and will be represented by a senior secured promissory note bearing interest at a rate of 3% per annum which matures on September 1, 2017 (each a “New Note”). Collectively, the Original Note and the New Note are hereinafter referred to as the “Notes”. In addition, the Security Agreement was also amended and restated to secure the Company’s obligations under all the Notes.

Pursuant to the terms and condition of the Amended and Restated Agreement, as of May 31, 2016, the Company borrowed an aggregate of \$7,100,000. Payment of the principal and accrued interest on the Notes will, at Niobe’s election, automatically become immediately due and payable if the Company undertakes certain Fundamental Transactions or upon an Event of Default, both as defined in the Notes. The Company’s obligations under the Notes are secured by the Security Agreement.

### **3. GOING CONCERN**

There is substantial doubt about the Company’s ability to continue as a going concern. From inception through May 31, 2016, the Company has incurred an accumulated deficit of \$94,622,528. For the years ended May 31, 2016 and 2015, the Company had net losses of \$9,415,450 and \$11,619,796, respectively. The Company utilized \$4,279,100 and \$3,991,479 of cash for operating activities for the years ended May 31, 2016 and 2015, respectively. As of May 31, 2016, the Company had cash and cash equivalents of \$444,179 and negative net working capital of \$107,389. The Company has incurred negative cash flow from operating activities since its inception. The Company has spent, and subject to obtaining additional financing, expects to continue to spend, substantial amounts in connection with executing its business strategy, including continued development efforts relating to PRTX-100.

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

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

#### 4. BASIS OF ACCOUNTING AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

##### Estimates

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

##### Loss per Common Share

The Financial Accounting Standards Board (FASB) has issued accounting guidance “Earnings Per Share” that provides for the calculation of “Basic” and “Diluted” earnings per share. Basic earnings per share include no dilution and is computed by dividing the loss to common stockholders by the weighted average number of common shares outstanding for the period. All potentially dilutive securities have been excluded from the computations since they would be antidilutive. However, these dilutive securities could potentially dilute earnings per share in the future. As of May 31, 2016 and 2015, the Company had a total of 3,982,543 shares and 3,524,209 shares, respectively, of potentially dilutive securities comprised solely of shares of Common Stock underlying stock options.

##### Share-Based Compensation

Effective June 1, 2006, the Company adopted the FASB accounting guidance for fair value recognition provisions of the “Accounting for Share-Based Payment”. This standard requires the Company to measure the cost of employee services received in exchange for equity share options granted based on the grant-date fair value of the options. The cost is recognized as compensation expense over the vesting period of the options. The fair value of compensation costs attributed to equity rights issued was \$4,647,674 and \$7,215,831 and is included in operating expenses for the years ended May 31, 2016 and May 31, 2015, respectively. These amounts included both the compensation cost of stock options granted prior to but not yet vested as of June 1, 2006 and compensation cost for all options granted subsequent to May 31, 2006. In accordance with the modified prospective application transition method, prior period results are not restated. Incremental compensation cost for a modification of the terms or conditions of an award is measured by comparing the fair value of the modified award with the fair value of the award immediately before the modification. No tax benefit was recorded as of May 31, 2016 and 2015 in connection with these compensation costs due to the uncertainty regarding ultimate realization of certain net operating loss carryforwards. The Company has also implemented the SEC interpretations in Staff Accounting Bulletin (“SAB”) for “Share-Based Payments,” in connection with the adoption of FASB accounting guidance.

As of May 31, 2016, there were 4,582,543 stock options outstanding. At May 31, 2016, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model, was approximately \$180,333 (net of estimated forfeitures) will be recognized over a weighted average period of eighteen months. During the year ended May 31, 2016, the Company granted an aggregate of 800,000 stock options to four consultants and one officer/director, all of which have a five year term and have an exercise price of \$5.41 per share. 25,000 options expired during the year ended May 31, 2016.

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

	Year Ended May 31, 2016	Year Ended May 31, 2015
Dividends per year	0	0
Volatility percentage	606%	570%
Risk free interest rate	4.00%	1.60%
Expected life (years)	5	5
Weighted Average Fair Value	\$ 5.41	\$ 6.74

## **Cash and Cash Equivalents**

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

## **Intellectual Technology Property, Amortization**

The Company’s intellectual technology property was originally licensed from a former related party. This intellectual technology property was then assigned to the Company upon the dissolution of the related party. The cost of the intellectual technology property is being amortized over a 20-year period. Amortization expense is \$1,020 and \$1,020 for the years ended May 31, 2016 and 2015, respectively. The Company reviews the intellectual property for impairment on at least an annual basis in accordance with the accounting guidance for “Goodwill and Other Intangible Assets”; no impairment charge was recorded as of May 31, 2016. Amortization expense for the intellectual property will be \$1,020 for each of the next three years with the remaining balance written off in the fourth year.

## **Income Taxes**

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

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

## **Research and Development**

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

## **Financial Instruments**

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

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

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

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

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

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

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

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

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

### **New Accounting Pronouncements**

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

On June 19, 2014, the Company adopted the amendment to (Topic 718) *Stock Compensation: Accounting for Share-Based Payments* when the terms of an award provide that a performance target could be achieved after the requisite service period. The amendment for accounting for share based payments, when an award provides that a performance target that affects vesting could be achieved after an employee completes the requisite service period shall be accounted for as a performance condition. The performance target shall not be reflected in estimating the fair value of the award at the grant date, and compensation cost shall be recognized in the period in which it becomes probable that the performance target will be achieved and will represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost shall be recognized prospectively over the remaining requisite service period. The total amount of compensation cost recognized during and after the requisite service period shall reflect the number of awards that are expected to vest and shall be adjusted to reflect the awards that ultimately vest. The Company does not believe the accounting standards currently adopted will have a material effect on the accompanying financial statements.

In August 2014, FASB issued ASU 2014-15, "Presentation of Financial Statements Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". Currently, there is no guidance in U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in this ASU provide that guidance. In doing so, the amendments are intended to reduce diversity in the timing and content of footnote disclosures. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this ASU are effective for public and nonpublic entities for annual periods ending after December 15, 2016. Early adoption is permitted. The Company does not believe the accounting standards currently adopted will have a material effect on the accompanying financial statements.

## 5. SENIOR SECURED NOTE – RELATED PARTY AND OTHER

### RELATED PARTY TRANSACTIONS

#### Senior Secured Note – Related Party

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

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

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

During the period February 1, 2012 to August 27, 2013 the Company raised a total of \$9,000,000 in principal through the issuance of several varying amounts of loans from Niobe and are hereinafter referred to as the “Secured Notes.” These Secured Notes bore an interest rate of 3% and had maturity dates ranging from February 1, 2014 to August 27, 2015.

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

On November 4, 2014, the Company entered into a new Credit Facility Agreement (the “2014 Credit Facility Agreement”) pursuant to which it may borrow up to an additional \$5 million from Niobe in the form of secured loans of up to \$300,000 on the last day of each calendar month, subject to certain conditions which may be waived by Niobe, at any time prior to the December 31, 2015 expiration date (the “2014 Credit Facility”). Each loan made under the 2014 Credit Facility Agreement will be represented by a senior secured promissory note bearing interest at a rate of 3% per annum and maturing on September 1, 2016 (each an “Original Note”). The Company’s obligations under each Note will be secured by a first priority perfected security interest in all of its assets pursuant to the Second Consolidated, Amended and Restated Security Agreement between the Company and Niobe, entered into at the same time as the 2014 Credit Facility Agreement (the “Security Agreement”).

In addition, on November 4, 2014, the Company entered into a Note Modification Agreement (the “Note Modification Agreement”) with Niobe pursuant to which the Consolidated Note, as modified in October 2014, was further amended to increase the threshold amount requiring a Mandatory Prepayment from \$7.5 Million to more than \$10 Million. As a result, partial prepayment will now be triggered in the event of a Liquidity Event in which the Company receives gross proceeds in excess of \$10 million. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

In October 2015, the Company entered into an agreement with Niobe pursuant to which Niobe agreed to convert all notes outstanding into shares of Common Stock, at the offering price in a “qualified public offering” consummated by the Company. The agreement defines a “qualified public offering” to mean a public offering of Common Stock yielding gross proceeds to the Company of at least \$7 million, which is consummated on or before February 29, 2016. The agreement further provided that accrued interest would be paid out of the proceeds of the qualified public offering. On December 1, 2015, the agreement expired pursuant its own terms.

On December 1, 2015, the 2014 Credit Facility was amended to increase the funds available for loans to the Company to \$7.5 million and to extend the expiration date of such credit facility to December 31, 2016 pursuant to which the Company and Niobe entered into and an Amended and Restated 2014 Credit Facility Agreement (the “Amended and Restated Agreement”). Each loan under the Amended and Restated Agreement has been and will be represented by a senior secured promissory note bearing interest at a rate of 3% per annum which matures on September 1, 2017 (each a “New Note”). Collectively, the Original Note and the New Note are hereinafter referred to as the “Notes”. In addition, the Security Agreement was also amended and restated to secure the Company’s obligations under all the Notes.

Pursuant to the terms and condition of the Amended and Restated Agreement, as of May 31, 2016, the Company borrowed an aggregate of \$7,100,000. Payment of the principal and accrued interest on the Notes will, at Niobe’s election, automatically become immediately due and payable if the Company undertakes certain Fundamental Transactions or upon an Event of Default, both as defined in the Notes. The Company’s obligations under the Notes are secured by the Security Agreement. All of the securities issued in the aforementioned financings were issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the “Act”) pursuant to Section 4(a)(5) and Rule 506 of Regulation D thereof. The offer, sale and issuance of such securities were made without general solicitation or advertising. The securities were offered and issued only to “accredited investors” as such term is defined in Rule 501 under the Act.

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

#### **Other Related Party Transactions**

During the fiscal year ended May 31, 2015, the Company issued an additional option for an aggregate of 100,000 shares of Common Stock to Mr. Elser. This option has a five year term, an exercise price of \$6.00 per share and fully vested on the date of issuance. This option has been valued at \$625,000 for which \$625,000 of compensation expense has been recorded.

During the fiscal year ended May 31, 2015, the Company issued an option for an aggregate of 100,000 shares of Common Stock to Kirk Warshaw, the CFO and a director of the Company. This option has a five year term, an exercise price of \$6.00 per share and fully vested on the date of issuance. This option has been valued at \$625,000 for which \$625,000 of compensation expense has been recorded.

During the fiscal year ended May 31, 2016, the Company issued an option for an aggregate of 250,000 shares of Common Stock to Kirk Warshaw, the CFO and a director of the Company. This option has a five year term, an exercise price of \$5.41 per share and vested 50% on the date of issuance and 50% on the one year anniversary. This option has been valued at \$1,352,500 of which \$1,296,146 of compensation expense has been recorded.

## 6. STOCK OPTIONS

Prior to January 22, 2004, all options were issued as “stand alone” options. On January 22, 2004, the Board approved the Protalex, Inc. 2003 Stock Option Plan, and on October 25, 2005, the stockholders approved an amendment to the Protalex, Inc. 2003 Stock Option Plan to increase the authorized number of shares under the Plan from 300,000 to 900,000 which provides for incentive and non-qualified stock options to purchase a total of 900,000 shares of Common Stock. Under the terms of the plan, incentive options may not be granted at exercise prices less than the fair market value of the Common Stock at the date of the grant and non-qualified options shall not be granted at exercise prices equal to less than 85% of the fair market value of Common Stock at the date of the grant. Beginning January 1, 2005, all stock options are granted at fair market value. Vesting generally occurs ratably over forty eight months and is exercisable over a period no longer than ten years after the grant date. As of May 31, 2016, options to purchase 4,582,543 shares of Common Stock were outstanding, of which 2,000 were issued and 800 were exercised under the Company’s 2003 Stock Option Plan and the remaining 4,580,543 were issued and 400 were exercised as standalone options. As of May 31, 2016, options to purchase 3,982,543 shares of Common Stock are exercisable.

The 800,000 options issued during the year ended May 31, 2016 are five year options all with an exercise price of \$5.41 per share. The options vested 50% upon issuance and the remainder vest on their one year anniversary. The options issued during the year ended May 31, 2016 have been valued at \$4,328,000 for which \$4,147,667 of compensation expense has been recorded. The balance of the option expense recorded during the year ended May 31, 2016 is related to options issued in prior years.

A summary of the Common Stock option activity for employees, directors, officers and consultants as of May 31, 2016 and for the two years then ended is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at May 31, 2014	4,317,543	\$ 3.26	6.67
Granted	600,000	6.74	4.00
Exercised	-	-	-
Forfeited	(1,110,000)	2.46	-
Expired	-	-	-
Outstanding at May 31, 2015	3,807,543	\$ 4.04	5.76
Granted	800,000	\$ 5.41	4.08
Exercised	-	-	-
Expired	(25,000)	14.26	-
Outstanding at May 31, 2016	4,582,543	\$ 4.22	4.75
Exercisable at May 31, 2016	3,982,543		

The outstanding and exercisable stock options as of May 31, 2016 and 2015 had an intrinsic value of \$19,367,636 and \$9,043,243, respectively.

The 800,000 options issued during the year were issued at an exercise price that was equal to the market price at the time the options were granted.

The following summarizes certain information regarding stock options at May 31, 2016:

Exercise Price Range	Total			Exercisable		
	Number	Weighted Average Exercise Price	Weighted Average Remaining Life (years)	Number	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
\$0.00 – 1.00	930,543	\$ 0.36	4.17	930,543	\$ 0.36	4.17
\$1.01 – 5.00	1,150,000	\$ 1.11	5.88	1,150,000	\$ 1.11	5.88
\$5.01 – 10.00	2,500,000	\$ 7.09	4.31	1,900,000	\$ 7.09	4.31
\$10.01 – 15.00	2,000	\$ 10.75	.36	2,000	\$ 10.75	.36
	4,582,543	\$ 4.22	4.75	3,982,543	\$ 3.74	4.75

The following summarizes certain information regarding stock options at May 31, 2015:

Exercise Price Range	Total			Exercisable		
	Number	Weighted Average Exercise Price	Weighted Average Remaining Life (years)	Number	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
\$0.00 – 1.00	930,543	\$ 0.36	5.17	930,543	\$ 0.36	5.17
\$1.01 – 5.00	1,150,000	\$ 1.11	6.88	1,150,000	\$ 1.11	6.88
\$5.01 – 10.00	1,700,000	\$ 7.89	5.40	1,416,667	\$ 7.89	6.05
\$10.01 – 15.00	27,000	\$ 14.19	.89	27,000	\$ 14.19	.89
	3,807,543	\$ 4.04	5.76	3,524,209	\$ 3.74	4.75

## 7. STOCKHOLDERS DEFICIT

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

On December 8, 2010, the Company authorized one million shares of a “blank check” class of preferred stock.

## 8. INCOME TAXES

For the years ended May 31, 2016 and 2015, the components of income tax benefit (expense) consist of the following:

	Year Ended May 31, 2016	Year Ended May 31, 2015
<b>Current:</b>		
Federal	\$ 0	\$ 0
State	0	0
<b>Deferred:</b>		
Federal	3,201,000	3,951,000
State	565,000	697,000
Tax credits	188,000	219,000
Permanent timing difference	(2,448,000)	(2,997,000)
Increase in valuation allowance	(1,506,000)	(1,870,000)
<b>Income tax benefit</b>	<b>\$ 0</b>	<b>\$ 0</b>

Income tax as a percentage of income for the year ended May 31, 2016 and 2015 differ from statutory federal income tax rates due to the following:

	Year Ended May 31, 2016	Year Ended May 31, 2015
Statutory federal income tax rate	(34)%	(34)%
State income taxes, net of federal income tax impact	(6)%	(6)%
Change in valuation allowance	16%	16%
Permanent timing differences	26%	26%
General business credit/other	(2)%	(2)%
	<u>0%</u>	<u>0%</u>

The components of the net deferred tax asset as of May 31, 2016 and 2015 are as follows:

	May 31, 2016	May 31, 2015
<b>Assets:</b>		
Net operating losses	\$ 24,518,000	\$ 23,200,000
General business credit	2,947,000	2,759,000
Deferred tax assets	27,465,000	25,959,000
<b>Liability:</b>		
Gross deferred tax asset	27,465,000	25,959,000
Less valuation allowance	(27,465,000)	(25,959,000)
Deferred tax asset, net of valuation allowance	<u>\$ -</u>	<u>\$ -</u>

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

Internal Revenue Code Section 382 places a limitation on the amount of taxable income that can be offset by carryforwards after a change in control. As a result of these provisions, utilization of the NOL and tax credit carryforwards may be limited. Most of the deferred tax asset of net operating loss carryforwards and tax credits are subject to a Section 382 limitation on the amount to be utilized in a given year. The years May 31, 2012 through 2016 remain subject to examination by the relevant tax authorities.

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

## 9. COMMITMENTS AND CONTINGENCIES

The Company leases space on a month to month basis. Rent expense for the year ended May 31, 2016 and 2015, was \$2,400 and \$2,200, respectively.

## 10. SUBSEQUENT EVENTS

On June 1, 2016 and July 1, 2016 the Company borrowed \$345,000 and \$375,000, respectively, under the terms of the 2014 Credit Facility and issued Niobe a New Note for each borrowing in the same principal amount of each loan.

On June 30, 2016, the 2014 Credit Facility was amended to increase the funds available for loans to the Company to \$9.0 million (the “Second Amended and Restated Agreement”). Each loan under the Second Amended and Restated Agreement will be represented by a New Note. In addition, the Security Agreement was also amended and restated to secure the Company’s obligations under all the Notes including the New Notes to be issued under the Second Amended and Restated Agreement.

On July 15, 2016, the Company entered into an agreement with Niobe pursuant to which it agreed to exchange all Notes outstanding, which as of May 31, 2016 had an aggregate outstanding principal balance of \$16,319,366, for shares of Common Stock, at the price per share that Common Stock is sold to public investors in a qualified public offering. The agreement defines a “qualified public offering” to mean a public offering of Common Stock yielding gross proceeds to the Company of at least \$7.0 million which is consummated on or before October 31, 2016. The agreement further provided that 50% of accrued but unpaid interest would also be converted into Common Stock and 50% would be paid out of the proceeds of the qualified public offering.

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

**CERTIFICATE OF AMENDMENT  
OF CERTIFICATE OF INCORPORATION  
OF PROTALEX, INC.**

Pursuant to Section 242 of the General Corporation Law of the State of Delaware, Protalex, Inc. a corporation organized and existing under the General Corporation Law of the State of Delaware, does hereby certifies and set forth as follows:

1. The name of the corporation is Protalex, Inc. (the "Corporation").
2. Resolutions were duly adopted by the Board of Directors of the Corporation setting forth proposed amendments to the Corporation's Charter (the "Certificate of Amendment"), and declaring such Certificate of Amendment advisable and in the best interests of the Corporation and its stockholders.
3. Pursuant to the recommendation of the Board of Directors of the Corporation, the Certificate of Amendment was consented to in writing by the stockholders of the Corporation in accordance with Section 228 of the General Corporation Law of the State of Delaware.
4. The Corporation's Charter is hereby amended by amending and restating Article V thereof to read as follows:

The total number of shares which the Corporation shall have the authority to issue is 100,000,000 shares, of which 99,000,000 shares shall be common stock, with a par value of \$0.00001 per share (the "Common Stock") and 1,000,000 shares shall be preferred stock, with a par value of \$0.00001 per share (the "Preferred Stock").

The Preferred Stock may be issued from time to time in one or more series with such designations, preferences and relative participating, optional or other special rights and qualifications, limitations or restrictions thereof, as shall be stated in the resolutions adopted by the Board of Directors of the Corporation (the "Board") providing for the issuance of such Preferred Stock or series thereof; and the Board is hereby vested with authority to fix such designations, preferences and relative participating, optional or other special rights or qualifications, limitations, or restrictions for each series, including, but not by way of limitation, the power to fix the redemption and liquidation preferences, the rate of dividends payable and the time for and the priority of payment thereof and to determine whether such dividends shall be cumulative or not and to provide for and fix the terms of conversion of such Preferred Stock or any series thereof into Common Stock of the Corporation and fix the voting Power, if any, of shares of Preferred Stock or any series thereof.

This Certificate of Amendment shall be effective as of 9:00 a.m. eastern time on December 8, 2010 (the "Effective Date"). On the Effective Date each five shares of Common Stock then issued, which are the only voting securities of the Corporation issued, shall be automatically reclassified into one share of Common Stock (the "Reverse Stock-Split"). Any fractional interests resulting from such reclassification shall be rounded-up to the nearest full share.

On and after the Effective Date, the amount of capital represented by the Common Stock shall be the same as the amount of capital represented by such shares immediately prior to the Effective Date, until thereafter reduced or increased in accordance with applicable law; the par value of a share of Common Stock shall remain unchanged after the Reverse Stock Split at \$0.00001 per share; and the total number of shares of all classes of capital stock which the Corporation shall have authority to issue shall remain unchanged.

5. This Certificate of Amendment will be effective on the Effective Date.

IN WITNESS WHEREOF, Protalex, Inc. has caused this Certificate of Amendment to be signed on this 3rd day of December 2010.

Protalex, Inc.

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

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## SECURED PROMISSORY NOTE

\$ \_\_\_\_\_

\_\_\_\_\_, 2016  
New York, New York

FOR VALUE RECEIVED, PROTALEX, INC., a Delaware corporation (“Protalex”), having an address at 131 Columbia Turnpike, Suite 1, Florham Park, NJ 07932 (the “Company”), unconditionally promise to pay to the order of NIOBE VENTURES, LLC, a Delaware limited liability company (hereinafter referred to as the “Holder”), at the offices of Morse, Zelnick, Rose & Lander LLP, 825 Third Avenue, 16th floor, New York, New York 10022, or at such other place as Holder may designate in writing, the principal sum of \_\_\_\_\_ and 00/100 Dollars (\$ \_\_\_\_\_) (the “Principal Sum”), with interest thereon computed from the date hereof until maturity, whether on the Maturity Date (as hereinafter defined), by acceleration, or otherwise, at the rate of three percent (3.00%) per annum (the “Interest Rate”), and thereafter, in accordance with the terms of this Note, at the Default Rate (as hereinafter defined and governed), together with any costs, expenses and attorneys’ fees incurred by Holder pursuant to the provisions hereof. Any amounts that remain unpaid after the Maturity Date shall thereafter bear interest at the rate of twelve percent (12%) per annum (the “Default Rate”). Interest as aforesaid shall be calculated on the basis of actual number of days elapsed over a year of 360 days.

The Principal Sum and all accrued interest on this Note shall be due on September 1, 2017, or such earlier date as provided for in Section 5 hereof (the “Maturity Date”). The Maturity Date is subject to acceleration in accordance with Section 4 hereof.

Section 1. Promissory Note. This Note is a direct debt obligation of the Company and, pursuant to the Fourth Consolidated, Amended and Restated Security Agreement dated as of June 30, 2016 (the “A/R Security Agreement”) all of the Company’s obligations hereunder are secured by a first priority perfected security interest in all of the assets of the Company (the “Security”) for the benefit of the Holder.

Section 2. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Note the following terms shall have the following meanings:

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

“Event of Default” shall have the meaning set forth in Section 6.

“Fundamental Transaction” shall have the meaning set forth in Section 4.

“Liquidity Event” shall have the meaning set forth in Section 5.

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

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

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

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Section 3. Registration of Transfers and Exchanges.

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

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

Section 4. Acceleration of Maturity Date. If, at any time while this Note is outstanding: (A) the Company effects any merger or consolidation of the Company with or into another Person, (B) the Company effects any sale of all or substantially all of its assets in one or a series of related transactions, (C) any tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to tender or exchange their shares for other securities, cash or property, or (D) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (in any such case, a "Fundamental Transaction"), then, immediately prior to the occurrence of such Fundamental Transaction the Principal Sum and all accrued but unpaid interest payable hereunder shall automatically become, at the Holder's election, immediately due and payable in cash.

Section 5. Mandatory Prepayment, Partial Prepayment. If, at any time while this Note is outstanding, the Company receives in the aggregate, from a single or multiple "Liquidity Events" (as defined below), gross proceeds in excess of \$10,000,000 ("Gross Proceeds"), then, in such event, a payment, in the aggregate (each, a "Mandatory Prepayment Amount"), in reduction of the amount then outstanding under this Note and any other note from the Company to the Holder shall immediately be due and payable in an amount equal to twenty-five (25%) percent of the Gross Proceeds received (each, a "Mandatory Prepayment Event"). The Mandatory Prepayment Amount shall be allocated pro rata to reduce the amount then outstanding under this Note and any other note from the Company to the Holder. A "Liquidity Event" shall mean each of (a) the sale of any of the Company's equity, or equity-linked, securities, and (b) the receipt of proceeds, directly or indirectly related to a development and/or commercialization relationship entered into with an unaffiliated third party.

Section 6. Events of Default.

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

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

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

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

#### Section 7. Miscellaneous.

a) Priority of Payment. Payments under this Note shall be applied first to accrued and unpaid interest and then to the Principal Sum outstanding. All amounts due under this Note shall be payable without setoff, counterclaim or any other deduction whatsoever.

b) Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder shall be in writing and delivered personally, by facsimile, sent by a nationally recognized overnight courier service, addressed to the Company, at 131 Columbia Turnpike, Suite 1, Florham Park, NJ 07932, attention: Chief Financial Officer, or such other address or facsimile number as the Company may specify for such purposes by notice to the Holder delivered in accordance with this Section. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile, sent by a nationally recognized overnight courier service addressed to the Holder at the facsimile, telephone number or address of such Holder appearing on the books of the Company, or if no such facsimile telephone number or address appears, at the principal place of business of the Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile telephone number specified in this Section prior to 5:30 p.m. (New York City time), (ii) the date after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile telephone number specified in this Section later than 5:30 p.m. (New York City time) on any date and earlier than 11:59 p.m. (New York City time) on such date, (iii) the second Business Day following the date of mailing, if sent by nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

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

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

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Note, and any claim, controversy or dispute arising under or related to this Note, the relationship of the parties, and/or the interpretation and enforcement of the rights and duties of the parties hereunder shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations or enforcement of this Note (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state or federal courts sitting in the City of New York, Borough of Manhattan (the "New York Courts"). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, or such New York Courts are improper or inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Note and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Note or the transactions contemplated hereby. If either party shall commence an action or proceeding to enforce any provisions of this Note, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

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

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

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

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

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

**PROTALEX, INC.**

By: \_\_\_\_\_

**Kirk M. Warshaw, Chief Financial Officer**

Protalex, Inc.  
131 Columbia Turnpike, Suite 1  
Florham Park, New Jersey 07392

July 15, 2016

Niobe Ventures, LLC  
410 Park Ave  
New York, NY 10022

Re: Agreement to Exchange Outstanding Debt

Gentlemen:

This will confirm the agreement we have reached with respect to the outstanding debt due and owing from Protalex, Inc. ("Protalex") to Niobe Ventures, LLC ("Niobe") as evidenced by promissory notes issued by Protalex to Niobe (the "Notes").

Simultaneous with the effectiveness of the Company's Registration Statement on Form S-1 (SEC File No. 333-206008) with respect to a "Qualified Public Offering", the Company and Niobe hereby unconditionally agree to exchange, concurrently with the closing of such Qualified Public Offering, the full principal amount of the Notes and fifty (50%) percent of the accrued and unpaid interest due under the Notes for shares of Protalex common stock, par value \$.00001 per share ("Common Stock"), at the price per share that Common Stock is sold to the public investors in a Qualified Public Offering. Upon such exchange, the outstanding indebtedness represented by the Notes and all of the rights, duties and obligations of all parties to the credit facility agreements relating to the Notes, the Notes and the related security agreements shall immediately terminate, other than Niobe's right to the payment in cash of accrued and unpaid interest under the Notes as provided for below.

A "Qualified Public Offering" shall mean a public offering of Protalex Common Stock yielding gross proceeds to Protalex of at least \$7.0 million.

Within five business days following the closing of a Qualified Public Offering, fifty (50%) percent all accrued and unpaid interest due under the Notes shall be paid to Niobe in cash.

Niobe agrees and acknowledges that the shares of Common Stock to be issued to Niobe upon conversion of the Notes as contemplated by this letter agreement (the "Shares") will be "restricted securities" and that the Shares have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or any applicable state securities law and that it is acquiring the Shares as principal for its own account and not with a view to or for distributing or reselling such Shares or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Shares in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Shares in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Purchaser's right to sell the Shares otherwise in compliance with applicable federal and state securities laws). Niobe further agrees to enter into a customary lockup agreement covering all such Shares in favor of the underwriter of the Qualified Public Offering on the same terms as shall apply to the Company and its officers and directors.

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Upon issuance of the Shares as contemplated by this letter agreement, the Shares shall be duly authorized, full paid and nonassessable shares of Common Stock.

In furtherance of the transactions contemplated by this letter agreement, each of Protalex and Niobe, at any time or from time to time after the date hereof, agree to cooperate with each other, and at the request of the other party, to execute and deliver any further instruments or documents and to take all such further action as the other party or any underwriter of such Qualified Public Offering may reasonably request in order to evidence or effectuate the consummation of the transactions contemplated hereby and to otherwise carry out the intent of the parties hereto.

In the event that a Qualified Public Offering is not consummated on or before October 31, 2016 as contemplated by the related underwriting agreement, then this letter agreement and the rights and obligations hereunder shall be null and void, *ab initio*.

This agreement amends and restates the Agreement to Exchange Outstanding Debt entered into between the parties hereto on June 3, 2016 and supersedes that agreement in all respects.

Sincerely,

PROTALEX, INC.

By: /s/ Kirk Warshaw  
Kirk Warshaw  
Chief Financial Officer

AGREED TO AND ACCEPTED:

NIOBE VENTURES, LLC

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

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Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (SEC File No.s. 333-130998, 333-130997, 333-125919) of Protalex, Inc. (the "Company") of our report dated July 14, 2016, with respect to the financial statements as of and at the year ended May 31, 2016 and 2015, which appear in the Annual Report of the Company on Form 10-K for the year ended May 31, 2016. Our report includes an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern

/s/ Liggett & Webb, P.A.

New York, NY  
July 15, 2016

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## CERTIFICATION

I, Arnold P. Kling, certify that:

1. I have reviewed this annual report on Form 10-K of Protalex, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 15, 2016

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

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## CERTIFICATION

I, Kirk M. Warshaw, certify that:

1. I have reviewed this annual report on Form 10-K of Protalex, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 15, 2016

/s/ Kirk M. Warshaw  
Kirk M. Warshaw  
Chief Financial Officer  
(Principal Financial Officer)

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CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Protalex, Inc. (the "Company") on Form 10-K for the period ending May 31, 2016 as filed with the Securities and Exchange Commission (the "Report"), I, Arnold P. Kling, President of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: July 15, 2016

/s/ Arnold P. Kling

Arnold P. Kling

President

(Principal Executive Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Protalex, Inc. (the "Company") on Form 10-K for the period ending May 31, 2016 as filed with the Securities and Exchange Commission (the "Report"), I, Kirk M. Warsaw, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: July 15, 2016

/s/ Kirk M. Warsaw

Kirk M. Warsaw

Chief Financial Officer

(Principal Financial Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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