As filed with the Securities and Exchange Commission on June 3, 2016.

Registration No. 333-206008

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

AMENDMENT NO. 1
TO

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

PROTALEX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**8731**	**91-2003490**
(State or other jurisdiction of incorporation or organization)	(Primary standard industrial classification code number)	(I.R.S. employer identification number)

131 Columbia Turnpike, Suite 1,
Florham Park NJ 07932
(215) 862-9720

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Arnold P. Kling
President
Protalex, Inc.
131 Columbia Turnpike, Suite 1,
Florham Park NJ 07932
(215) 862-9720

(Name, address, including zip code, and telephone number, including area code, of agent for service)
Copies to:

Kenneth S. Rose, Esq.	**Mitchell S. Nussbaum, Esq.**
Morse, Zelnick, Rose & Lander, LLP	**Loeb & Loeb LLP**
825 Third Avenue	**345 Park Avenue**
New York, NY 10022	**New York, NY 10154**
Tel. No.: 212-838-1177	**Tel. No.: 212-407-4000**
Fax No.: 212-208-6809	**Fax No.: 212-407-4990**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☒

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is deemed effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION** **DATED JUNE 3, 2016**

_____ Shares of Common Stock
and
Warrants to Purchase _____ Shares of Common Stock

We are offering _____ shares of our common stock and warrants to purchase up to an aggregate of _____ shares of our common stock. The warrants will have an exercise price of $_____ per share, ___% of public offering price of the common stock. The warrants are exercisable immediately and will expire five years from the date of issuance. The common stock and warrants are immediately separable but can only be purchased together in this Offering. It is currently contemplated that the per share offering price will be between $___ and $___ per share and the warrant offering price will be $___ per warrant.

Our common stock trades on the OTC Markets (*OTCQB*)under the symbol "PTRX." We have applied to list our common stock on the NASDAQ Capital Market under the symbol "PRTX". We expect that our common stock will begin trading on The NASDAQ Capital Market simultaneously with the effective date of this offering. On June 2, 2016, the last reported sale price for our common stock on the OTCQB was $3.50 per share. We have not applied to list the warrants on any trading market and do not expect any active trading market to develop for the warrants.

Our business and an investment in our securities involve a high degree of risk. See "Risk Factors" beginning on page 8 of this prospectus for a discussion of information that you should consider before investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Per Share	Per Warrant	Total
Public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds, before expenses, to us	$	$

(1) We have agreed to reimburse the underwriters for certain expenses and the underwriters will receive compensation in addition to underwriting discounts and commissions. See the section titled "Underwriting" for additional disclosure regarding underwriter compensation and offering expenses.

The underwriters may also purchase up to an additional _____ shares of common stock and _____ warrants from us at the public offering price for each such security, less the underwriting discount, within 45 days from the date of this prospectus to cover over-allotments, if any.

The underwriters expect to deliver the shares and warrants against payment therefor on or about _____, 2016.

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_____ __, 2016

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

Our logo and some of our trademarks and tradenames are used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks, tradenames and service marks referred to in this prospectus may appear without the ®, ™ and SM symbols, but those references are not intended to indicate in any way that we will not assert to the fullest extent under applicable law our rights or the rights of the applicable licensor to these trademarks, tradenames and service marks.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in each case included elsewhere in this prospectus. Unless otherwise stated or the context requires otherwise, references in this prospectus to "Protalex," "we," "us," or "our" refer to Protalex, Inc.

Business 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 PTRX-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 Orphan Drug Designation (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 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 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 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 anti-drug antibodies (ADAs), and the Adverse Event (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.

Business Strategy

Short-Term Strategic Goals and Objectives

During the next 12 months, our strategic goals and objectives include the following:

- Continue enrollment in PRTX-202 and 203 Studies;
- Design clinical trial protocol for a Phase 2 RA clinical study;
- Expand pre-clinical research and development activities for both auto-immune and non-autoimmune orphan indications; and
- Evaluate biomarker strategy for PRTX-100 in the treatment of RA.

Risks

We are a development stage company and have generated minimal revenues to date. Since our inception, we have incurred substantial losses. Our business and our ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our securities. In particular, you should carefully consider the following risks, which are discussed more fully in "Risk Factors" beginning on page 8 of this prospectus.

- If we are unable to enroll enough patients to complete our clinical trials, our applications may never be submitted or approved.
- If clinical trials don't provide positive results, we may be required to abandon the clinical trials.
- If we fail to obtain regulatory approvals for drugs we develop, we will not be able to generate revenues from the commercialization or sale of those drugs.
- Our products, if approved, may fail to achieve market acceptance.
- We may never obtain market exclusivity for any orphan disease indication, and if approved, we could lose orphan market exclusivity if another drug is approved first using the same method of action or demonstrates clinical superiority.
- 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.
- 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.
- We may become involved in lawsuits to protect or enforce our patents that would be expensive and time consuming.
- We may not be able to manufacture our products in commercial quantities, or we may be delayed, which would prevent us from marketing our products.
- We have no experience selling, marketing or distributing our products and no internal capability to do so.
- Competition in the pharmaceutical industry is intense; if we fail to compete effectively, our financial results will suffer.
- If we are unable to hire additional qualified scientific, sales and marketing, and other personnel, we will not be able to achieve our goals.
- Even if we obtain marketing approval, PRTX-100 will be subject to ongoing regulatory review.
- Market acceptance of PRTX-100 will be limited if users are unable to obtain adequate reimbursement from third-party payors.
- We may be required to defend lawsuits or pay damages in connection with the alleged or actual harm caused by our products.
- Developments by competitors may render our products obsolete or non-competitive.

- The loss of one or more key members of our management team or Scientific Advisory Board could adversely affect our business.
- 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.
- 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.
- The implementation of the healthcare reform law in the United States may adversely affect our business.
- 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 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 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.
- If we are not able to establish collaborations, we may have to alter our development and commercialization plans.
- Our auditors have doubt as to our ability to continue in business.
- 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 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.
- 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.
- 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.
- Our affiliates control the majority of our shares of common stock and one shareholder holds a controlling interest.
- 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.
- If our common stock becomes subject to the penny stock rules, this may make it more difficult to sell our shares.
- The price of our common stock may be volatile.
- A limited public trading market may cause volatility in the price of our common stock.
- Speculative nature of warrants.
- If we fail to remain current with our reporting requirements or satisfy the other continued listing criteria, we could be delisted from the Nasdaq Capital Market, which would limit your ability to sell our securities in the secondary market.
- Sales of additional equity securities may adversely affect the market price of our common stock and your rights in us may be reduced.
- Additional authorized shares of common stock available for issuance may adversely affect the market price of our securities.
- We do not intend to pay cash dividends.
- Our management will have broad discretion over the use of the net proceeds from this offering and we may use the net proceeds in ways with which you disagree or which do not produce beneficial results.
- You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future as we do further financings and transactions.

Recent Developments

In June 2016, we entered into an agreement with the holder of our outstanding indebtedness 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 our common stock, at the offering price set forth on the cover of this prospectus (the "Debt-for-Equity Exchange"). Accrued interest ($932,883 as of May 31, 2016) will be paid out of the proceeds of this offering.

Corporate Information

We were originally incorporated in the State of Delaware on March 23, 2004. Our principal executive offices are located at 131 Columbia Turnpike, Suite 1, Florham Park, New Jersey 07392 and our telephone number is (215) 862-9720. We maintain a website at www.protalex.com which contains descriptions of our technology, our drugs and the trial status of each drug. The information on our website is not incorporated into this prospectus.

THE OFFERING

Securities offered by us	_____ shares of common stock and warrants to purchase up to an aggregate of _____ shares of common stock.
Proposed price range	$____ to $____ per share of common stock and $___ per warrant.
Description of warrants	The warrants will have a per share exercise price equal to $___, ___% of public offering price of the common stock. The warrants are exercisable immediately and expire five years from the date of issuance.
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to an additional _____ shares of our common stock and/or warrants at the public offering price for each such security less the underwriting discount and commission to cover over-allotments, if any.
Common stock to be outstanding immediately after this offering	_____ shares of common stock (_____ if the warrants are exercised in full). If the underwriters' over-allotment option is exercised in full, the total number of shares of common stock outstanding immediately after this offering would be _____ (_____ if the warrants and overallotment warrants are exercised in full).
Use of proceeds	We estimate that the net proceeds from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $____ million (or $____ million if the underwriters' over-allotment option is exercised in full), assuming a public offering price per share of $____, the midpoint of the proposed price range per share set forth on the cover page of this prospectus. We intend to use the net proceeds received from this offering to fund our research and development activities, to pay interest on outstanding notes, and for working capital and general corporate purposes. See "Use of Proceeds" on page 25.
Risk factors	See "Risk Factors" beginning on page 8 and the other information included in this prospectus for a discussion of factors you should carefully consider before investing in our securities.
Proposed Nasdaq Symbol and Listing	Common stock – PRTX. The warrants will not be listed.

Unless we indicate otherwise, all information in this prospectus:

- is based on 28,767,582 shares of common stock issued and outstanding as of May 31, 2016;
- assumes no exercise by the underwriters of their option to purchase up to an additional _____ shares of common stock and/or warrants to purchase _____ additional shares of common stock to cover over-allotments, if any;
- excludes 4,582,543 shares of our common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $4.30 per share as of May 31, 2016; and
- reflects the issuance of _____ shares of our common stock in the Debt-for-Equity Exchange.

SUMMARY FINANCIAL DATA

The following tables set forth our summary statement of operations and balance sheet data for the fiscal years ended May 31, 2015 and 2014 and the nine months ended February 29, 2016 and February 28, 2015.

Statement of Operations Data:

	Year Ended May 31,		Nine Months Ended February 29,	
	2015	2014	2016	2015
Revenue	$	$	$	$
Research and development expenses	2,989,311	3,232,321	2,409,183	2,302,983
Loss from operations	11,299,030	11,568,513	7,341,909	9,822,201
Net interest expense	320,766	283,716	313,343	225,683
Net loss	11,619,796	11,852,229	7,655,252	10,047,884
Net loss per share, basic and diluted	$ 0.40	$ 0.45	$ 0.27	$ 0.35
Weighted average number of shares outstanding, basic and diluted	28,767,582	26,222,563	28,767,582	28,767,582

Balance Sheet Data:

	As of February 29, 2016	
	Actual	Pro Forma, As Adjusted[(1)]
Cash and cash equivalents	$ 594,701	$ _____
Total assets	686,199	_____
Total liabilities	16,885,734	_____
Total shareholders' equity (deficit)	(16,199,535)	_____

(1) Pro forma, as adjusted amounts give effect to (i) issuance of _____ shares of our common stock in the Debt-for-Equity Exchange; and (ii) the sale of _____ shares of our common stock and warrants to acquire _____ shares of our common stock in this offering at the public offering price of $___ per share, the midpoint of the proposed price range per share set forth on the cover page of this prospectus, and $___ per warrant, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

RISK FACTORS

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

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

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

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

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

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

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

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

We 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 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 U.S. 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, 2015 financial statements, our auditors expressed substantial doubt as to our ability to continue as a going concern. A going concern qualification could impair our ability to finance our operations through the sale of debt or equity securities. Our ability to continue as a going concern will depend, in large part, on our ability to obtain additional financing and generate positive cash flow from operations, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

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

We are a clinical stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by similarly situated companies. We have generated net losses in all periods since our inception in September 1999 including losses of approximately $11.6 million and $11.9 million for the years ended May 31, 2015 and 2014, respectively and as of February 29, 2016 we had an accumulated deficit of approximately $92.9 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, 2015 and 2014, we incurred research and development expenses of approximately $3.0 million and $3.2 million, respectively. As of February 29, 2016, we had cash and cash equivalents of approximately $595,000 and 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.

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 May 31, 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. Following the consummation of this offering and the Debt-for-Equity Exchange, Niobe Ventures LLC will beneficially own approximately __% of our 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 Securities and Exchange Commission has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). If the price of our common stock drops below $5.00, our securities will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore security holders may have difficulty selling their shares.

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 after this offering 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.

A limited public trading market may cause volatility in the price of our common stock and warrants.

The quotation of our common stock on The NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market will develop, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our stockholders could suffer losses or be unable to liquidate their holdings. Also there are large blocks of restricted stock that have met the holding requirements under Rule 144 that may be sold without restriction. Our stock is thinly traded due to the limited number of shares available for trading on the market thus causing large swings in price. In addition, there is no established trading market for the warrants being offered in this offering. Even if our common stock is listed on The NASDAQ Capital Market, no assurance can be given that the price of our common stock will be less volatile or that the price of the warrants will not be volatile.

Speculative nature of warrants.

The warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of $_.00 per share, ___% of public offering price of the common stock, prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

If we fail to remain current with our reporting requirements or satisfy the other continued listing requirements, we could be delisted from The* NASDAQ Capital Market*, which would limit your ability to sell our securities in the secondary market.

Companies trading on the NASDAQ Capital Market must be reporting issuers under Section 12 of the Exchange Act, as amended, and must be current in their reports under Section 13 and satisfy a number of other continued listing criteria, in order to maintain quotation privileges. If we fail to remain current on our reporting requirements or the trading price of a share of our common stock falls below $1.00 and remains below that threshold for 30 days or more, or we fail to satisfy the other continued listing requirements, we could be delisted from The NASDAQ Capital Market. As a result, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

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 $4.30 per share.

We do not intend to pay cash dividends.

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

Our management will have broad discretion over the use of the net proceeds from this offering and we may use the net proceeds in ways with which you disagree or which do not produce beneficial results.

We currently intend to use the net proceeds from this offering to fund our research and development activities and for working capital and general corporate purposes and payment of interest on certain outstanding debt (see "Use of Proceeds"). Other than as specified under "Use of Proceeds," we have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us or our stockholders. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, and results of operation.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future as we do further financings and transactions.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the Debt-for-Equity Exchange and the sale by us of _____ shares of common stock and warrants to purchase up to an aggregate of _____ shares of common stock offered in this offering at a public offering price of $____ per share, the midpoint of the proposed price range per share set forth on the cover page of this prospectus, and $___ per warrant, and after deducting the underwriters' discount and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of $____ per share. In addition, in the past, we issued options and warrants to acquire shares of common stock. To the extent these options or warrants are ultimately exercised, you will sustain further future dilution.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

Various statements made in this prospectus 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 the Risk Factors section of this prospectus and discussed in our other Securities and Exchange Commission (“SEC”) filings, which discloses all material factors known to us that we believe could cause actual results to differ materially from those expressed or implied by forward-looking statements.

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

This prospectus also includes industry data that we obtained from industry publications and surveys and internal company sources. The industry publications and industry data contained in this prospectus have been obtained from sources believed to be reliable.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of the common stock and warrants offered pursuant to this prospectus will be approximately $___ million (or approximately $___ million if the underwriters exercise in full their option to purchase additional shares of common stock and additional warrants) at an assumed public offering price of $___ per share of common stock, the midpoint of the proposed price range per share set forth on the cover page of this prospectus, and a public offering price of $___ per warrant, and after deducting the underwriting discount and the estimated offering expenses that are payable by us.

We currently intend to use the net proceeds from this Offering (including proceeds resulting from the exercise of warrants, if any) on (i) accrued interest on outstanding notes ($932,883 at May 31, 2016), (ii) clinical development related to lead product candidate PRTX-100, including continued enrollment in our PRTX-202 and 203 studies, and (iii) other general corporate purposes, including satisfying accounts payable. The table below reflects our current planned use of the net proceeds from this Offering, assuming no exercise of the warrants and no exercise of the underwriters' option to purchase additional shares and warrants. Each of these amounts is an estimate only, and is subject to change at any time before or after closing of the Offering.

	Amounts in $000
Gross proceeds	$
Underwriting discounts, commissions and other expenses of the Offering	$ ( )
Net proceeds	$
Payment of accrued interest on outstanding notes	
Clinical development of PRTX-100 in ITP	$
General and administrative, working capital and other general corporate purposes, including payment of accounts payable	$
	$

Although we expect net proceeds from this Offering to provide sufficient funding for our operations through the completion of our PRTX-202 and 203 studies, anticipated in the _____ quarter of _____, the net proceeds from the Offering will not be sufficient to complete the commercialization of PRTX-100 in ITP. Assuming no exercise of the warrants acquired in this Offering and no exercise of the underwriters' option to purchase additional shares and warrants, we believe an additional $_____ million to $_____ million will be required prior to the end of the _____ quarter of _____ in order to commercialize PRTX-100 in ITP. No assurances can be provided that such additional capital will be available to us when necessary, on reasonable terms, or at all. In the event we are unable to raise such additional capital, our operations will be negatively and materially affected.

Other than described above, we have not yet determined the amount of the remaining net proceeds to be used specifically for any purposes. Accordingly, our management will have significant discretion and flexibility in applying the majority of the net proceeds from this offering. Pending any use as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

PRICE RANGE OF COMMON STOCK

Our common stock trades on the OTCQB under the symbol “PRTX”. The following table shows the reported high and low closing bid quotations per share for our common stock based on information provided by the OTCQB Marketplace. Such over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly because our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market.

Fiscal 2016	**High**	**Low**
Fourth Quarter	$ 4.65	$ 2.50
Third Quarter	$ 5.35	$ 3.00
Second Quarter	$ 5.60	$ 3.45
First Quarter	$ 5.93	$ 4.91

Fiscal 2015	**High**	**Low**
Fourth Quarter	$ 6.00	$ 4.80
Third Quarter	$ 7.75	$ 4.00
Second Quarter	$ 7.00	$ 3.70
First Quarter	$ 9.00	$ 5.60

Fiscal 2014	**High**	**Low**
Fourth Quarter	$ 9.05	$ 3.76
Third Quarter	$ 9.50	$ 7.78
Second Quarter	$ 10.00	$ 3.11
First Quarter	$ 4.00	$ 1.31

The closing price of our common stock on the OTCQB Marketplace on June 2, 2016 was $3.50 per share.

As of May 31, 2016, we had approximately 100 stockholders of record and approximately 800 beneficial owners of our common stock. We have received approval from Nasdaq for the listing of our common stock on The Nasdaq Capital Market under the symbol “PRTX” simultaneously with the effective date of this offering.

DIVIDEND POLICY

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

DILUTION

If you invest in our securities, your interest will be immediately and substantially diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after giving effect to this offering.

Our net tangible book value as of February 29, 2016 was $(_____) or $(____) per share of common stock.

After giving effect to (i) the sale of the _____ shares and warrants to acquire _____shares in this offering at the public offering price of $___ per share, the midpoint of the proposed price range per share set forth on the cover page of this prospectus and $___ per warrant, (ii) the Debt-for-Equity Exchange; and (iii) after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at February 29, 2016 would have been approximately $_____, or $___ per share. This represents an immediate increase in pro forma net tangible book value of approximately $___ per share to our existing stockholders, and an immediate dilution of $___ per share to investors purchasing securities in the offering.

Dilution in pro forma net tangible book value per share represents the difference between the amount per share paid by purchasers of our common stock in this offering and the pro forma net tangible book value per share of our common stock immediately after this offering.

The following table illustrates the per share dilution to investors purchasing shares in the offering:

Public offering price per share		$ ____
Pro forma net tangible book value per share as of February 29, 2016	$ ____	
Increase in net tangible book value per share attributable to this offering	$ ___	
Pro forma as adjusted net tangible book value per share after this offering		$ ___
Amount of dilution in net tangible book value per share to new investors in this offering		$ ___

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to $___ per share, representing an immediate increase to existing stockholders of $____ per share and an immediate dilution of $_____ per share to new investors. If any shares are issued upon exercise of outstanding options, warrants, or convertible notes, new investors will experience further dilution.

CAPITALIZATION

The following table sets forth our capitalization, as of February 29, 2016:

- on an actual basis;
- Pro forma, as adjusted amounts give effect to (i) issuance of _____ shares of our common stock in Debt-for-Equity Exchange; and (ii) the sale of _____ shares of our common stock and warrants to acquire _____ shares of our common stock in this offering at the public offering price of $____ per share, the midpoint of the proposed price range per share set forth on the cover page of this prospectus, and $___ per warrant, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

You should consider this table in conjunction with our financial statements and the notes to those financial statements included elsewhere in this prospectus.

	As of February 29, 2016	
	Actual	Pro Forma, As Adjusted
Notes payable	$ 16,096,283	$ -
Current liabilities	789,451	_____
Total liabilities	16,885,734	_____
Stockholders' equity (deficit):		
Preferred stock, $0.00001 par value; 1,000,000 shares authorized; no shares issued and /or outstanding actual, pro forma or pro forma as adjusted	-	-
Common stock, $0.00001 par value: 100,000,000 shares authorized, 28,767,582 shares issued and outstanding actual, and 33,857,441 shares issued and outstanding pro forma, as adjusted	288	_____
Additional paid-in capital	76,662,507	_____
Deficit accumulated during the development stage	(92,862,330)	_____
Total stockholders' equity (deficit)	(16,199,535)	_____
Total liabilities and stockholders' equity (deficit)	$ 686,199	$ _____

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 prospectus, including "Risk Factors," "Business" and the consolidated financial statements and other consolidated financial information included in this prospectus. 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 prospectus. See "Cautionary Note Regarding Forward-Looking Statements and Industry Data." 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 2015 financial statements and accompanying notes included elsewhere in this prospectus. 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 PTRX-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 Orphan Drug Designation (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 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 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 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 anti-drug antibodies (ADAs), and the Adverse Event (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 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.

As of February 29, 2016, the outstanding principal balance under the 2014 Credit Facility totaled $6,065,000. During the nine months ended February 29, 2016, we borrowed an aggregate of $2,760,000, $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, and February 1, 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.

During the quarter ended May 31, 2016, we borrowed an additional $1,035,000 in three tranches under the terms of the Amended and Restated Credit Facility Agreement and issued Niobe New Notes in the same principal amount.

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, 2015 and 2014 and Note 3 to the financial statements for the nine month periods ended February 29, 2016 and February 28, 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 prospectus 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.

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, 2015 compared to fiscal year ended May 31, 2014

Research and Development Expenses – Research and Development expenses decreased from $3,232,321 in our 2014 fiscal year to $2,989,311 in our 2015 fiscal year. The decrease of $243,010, or 7.5%, was the result of increased activity associated with our clinical study in the United States, as disclosed above but a significant decline in the expenses associated with the formulation and production of our bulk drug substance, drug product, and placebo. During such period, we engaged more consultants and incurred other clinical study-related expenses as we enrolled patients and analyzed study data.

Administrative Expenses - The increase of approximately $34,000 was related to a general increase in the cost of goods and services used by the Company in its operation. Equity based compensation is $7,215,831 of the administrative expenses during the year, which approximated the same amount for the prior year.

Professional Fees - Professional fees decreased from $584,585 in fiscal year 2014 to $523,613 in fiscal year 2015. The decrease of $60,972, or 10.4%, was due primarily to decreases in consulting and legal expenses.

Interest Expense – Interest expense increased from $283,720 in fiscal year 2014 to $320,769 in fiscal year 2015. The increase was attributable to interest expense from the increase in borrowings pursuant to the 2014 Credit Facility Agreement.

Nine months ended February 29, 2016 compared to nine months ended February 28, 2015

Research and Development Expenses - R&D Expenses were $2,409,183 and $2,302,983 for the nine months ended February 29, 2016 and February 28, 2015, respectively. The increase in R&D Expenses for the nine month period ended February 29, 2016 compared to the nine month period ended February 28, 2015 was primarily the result of an increase in the activities associated with our clinical study activities partially offset by a decrease in the activities associated with the manufacturing of PRTX-100.

There are significant risks and uncertainties inherent in the preclinical and clinical studies associated with our research and development program. These studies may yield varying results that could delay, limit or prevent a program's advancement through the various stages of product development and significantly impact the costs to be incurred, and time involved, in bringing a program to completion. As a result, the costs to complete such programs, as well as the period in which net cash outflows from such programs are expected to be incurred, are not reasonably estimable.

Administrative Expenses - Administrative expenses were $4,395,245 and $7,144,472 for the nine months ended February 29, 2016 and February 28, 2015, respectively. The decrease in administrative expenses for the nine month period ended February 29, 2016 compared to the same prior year period was due to a decrease in stock compensation expense.

Professional Fees - Professional expenses were $536,716 and $373,981 for the nine months ended February 29, 2016 and February 28, 2015, respectively. The increase for the nine month period ended February 29, 2016 was principally due to an increase in professional fees related to the preparation and filing of a Registration Statement on Form S-1 with the SEC during the first fiscal quarter ended August 31, 2015.

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 February 29, 2016 was $92,862,330 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 and 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 the Company's obligations under all the Notes.

As of February 29, 2016, the outstanding principal balance under the 2014 Credit Facility totaled $6,065,000. During the nine months ended February 29, 2016, we borrowed an aggregate $2,760,000 pursuant to which we issued eight Notes in the principal amount of $345,000 each (for an aggregate of $2,760,000). 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.

Fourth Quarter Events

During the quarter ended May 31, 2016, we borrowed an additional $1,035,000 in three tranches under the terms of the Amended and Restated Credit Facility Agreement and issued Niobe New Notes in the same principal amount.

In June 2016, we entered into an agreement with Niobe pursuant to which Niobe agreed to effect the Debt-for-Equity Exchange. The agreement defines a "qualified public offering" to mean a public offering of 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 accrued interest 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 nine months ended February 29, 2016 and February 28, 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 this fiscal year 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 February 29, 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.

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 PTRX-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 Orphan Drug Designation (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 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 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 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 anti-drug antibodies (ADAs), and the Adverse Event (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 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.

As of February 29, 2016, the outstanding principal balance under the 2014 Credit Facility totaled $6,065,000. During the nine months ended February 29, 2016, we borrowed an aggregate of $2,760,000, $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, and February 1, 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.

During the quarter ended May 31, 2016, we borrowed an additional $1,035,000 in three tranches under the terms of the Amended and Restated Credit Facility Agreement and issued Niobe New Notes in the same principal amount.

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 three clinical trials and are in the process of completing a fourth clinical trial under this IND. Our first Phase I single-dose clinical trial commenced in December 2005 and was completed in March 2006. This trial was performed in healthy volunteers and was designed primarily to assess the safety and tolerability of a single intravenous dose of PRTX-100. This study demonstrated that PRTX-100 appears safe and well-tolerated at the doses administered. There were no deaths or serious adverse events. The PK profile was determined and found consistent with that projected from pre-clinical models.

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

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

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

In November 2013, following completion of the Cohort 4 expansion cohorts, we initiated enrollment of the fifth and final cohort (Cohort 5) in the PRTX 100-104 Study. The Cohort 5 sub-study enrolled 20 patients who 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 anti-drug antibodies (ADAs), and the Adverse Event (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 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 $r=0.624$ ($p<.0005$).

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 an Independent Data Safety Monitoring Committee (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 several planned future 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 $469 million and $263 million, respectively, in 2014. Neither romiplostim nor eltrombopag impact the principal pathological mechanism of ITP, namely immune-mediated plated destruction, and we believe that PRTX-100 may have a more direct impact on ITP disease processes. Thus, we believe that PRTX-100 may complement or reduce the use of thrombopoeitic agents in 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 autoimmune and inflammatory diseases other than RA and ITP.

Competition

We believe, based on the pre-clinical trials and the results to date of our five Phase I 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 2014, 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-l (IL-I) Receptor Therapy, Anakinra (Kineret®) and (Il-6) tocilizumab (Actemra®);
- Costimulatory molecule inhibitor abatacept (Orencia®);
- Anti CD20 B-cell-directed therapy, rituximab (Rituxan®); and
- Janus Kinase (JAK) inhibitor, tofacitinib citrate (Xeljanz).

Many large and small pharmaceutical companies are active in this market, with Amgen Corporation (with Pfizer), Johnson & Johnson, Inc. (with Merck) and Abbott Laboratories dominating the market for biologic therapies with their respective products, Enbrel®, Remicade® and Humira®. According to each company's 2014 annual reports, Enbrel generated revenues of approximately $8.5 billion combined for Amgen and Pfizer, Remicade generated revenues of more than $9.2 billion combined for Johnson & Johnson and Merck, and AbbVie reported generated revenues of $12.5 billion for Humira. For other TNF inhibitors, Cimzia generated revenues of $904 million for UCB; Astellas, Simponi generated revenues of $1.9 billion for Johnson & Johnson and Merck; and Orencia generated revenues of $1.7 billion for Bristol Myers Squibb. Kineret generated revenues of $75 million in sales for SOBI, which acquired from Amgen the rights to develop and commercialize Kineret in 2014. Actemra and Rituxan generated revenues of $1.34 billion and and Rituxan $7.5 billion, respectively, for Roche. Xeljanz earned forgenerated revenues of Pfizer $308 million for Pfizer in 2014. 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 serious adverse events (SAEs). Products which inhibit the action of TNF-alpha, being the longest on the market and the most studied, have demonstrated an increased incidence of certain SAEs. Due to suppression of the immune system by these products, these SAEs include serious and opportunistic infections such as tuberculosis, fungal infections, and listeria infection, and increased risk of lymphomas. Transient neutropenia and other blood dyscrasias have been reported. TNF inhibitors are also not recommended in patients with demyelinating disease or with congestive heart failure. Rituxan (anti-CD20) use increases the potential for Hep B reactivation and multifocal leukoencephalopathy, a fatal viral disease. Kineret (IL-1) also shows an increased the risk of infection. Actemra (IL-6) use has led to increased liver enzyme levels, hypertension, transient neutropenia, and an increase in cholesterol levels. Orencia (T cell inhibition) also works by weakening the immune system, therefore can increase the risk of infections. Patients using Orencia have developed lymphoma and lung cancer. Xeljanz (JAK) is the newest RA treatment to enter the market. It has demonstrated similar side effects to TNF inhibitors, including invasive and opportunistic infections and the reactivation of tuberculosis. Lymphomas and other malignancies have been observed in patients treated with Xeljanz. In a study by a Swedish research group published in November 2012 by the American College of Rheumatology entitled, “Mortality Rates in Patients with Rheumatoid Arthritis Treated with Tumor Necrosis Factor Inhibitors”, following treatment of RA with either of the TNF inhibitors Enbrel, Humira or Remicade, mortality rates were on average approximately one death per 30 patients treated in the first three years of treatment. Findings such as these and the long list of serious adverse events for all of the currently marketed treatments indicate that new and safer treatments for autoimmune diseases such as RA are needed.

Government Regulation and Product Approval

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

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

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

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

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, the EMA Committee for Orphan Medicinal Products (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:

Patent Title	Number	Expiration Date
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

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.

MANAGEMENT

The following table sets forth information concerning our officers and directors as of May 31, 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
Ralph H. Isham	60	Director Nominee
Doron Steger	69	Director Nominee

Arnold P. Kling. Mr. Kling has served as our president and director since November 2009. For the past 15 years, Mr. Kling has been the senior managing partner for a group of private equity investment funds that invest and manage early stage companies whose technologies have the potential to disrupt their targeted markets. From 1993 to 1995 he was a senior executive and general counsel of a Nasdaq listed licensing and multimedia company. From 1990 through 1993, Mr. Kling was an associate and partner in the corporate and financial services department of Tannenbaum, Helpern, Syracuse & Hirschtritt LLP, a mid-size New York law firm. Mr. Kling received a Bachelor of Science degree from New York University in International Business in 1980 and a Juris Doctor degree from Benjamin Cardozo School of Law in 1983. Mr. Kling'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. For over five years, Mr. Elser has been a partner with AdviCorp Plc, a London-based investment banking firm. From 1994 to 2001, Mr. Elser served as International Vice President of Northeast Securities, managing distressed funds for family offices and small institutions. Prior to that, from 1985 through 1994, he served as a First Vice President of Merrill Lynch Capital Markets in Rome and London. Mr. Elser served on the Board of Directors of Pine Brook Capital, a Shelton, CT-based engineering company from 2007 to 2012 and was its Chairman from 2009 through 2012. He is presently a director (since 2002) of North Hills Signal Processing Corporation, a technology company and a director (since 2012) of Trans-Lux Corporation, a designer and manufacturer of digital signage display solutions. From 2002 to 2014, Mr. Elser was also the president of the Harvard Club of Italy, an association he founded with other alumni in Italy where he has been living since 1984. He received his BA in Economics from Harvard College in 1981. Mr. Elser's extensive knowledge of international finance and commerce allows him to make valuable contributions as one of our directors.

Ralph H. Isham. Mr. Isham will become a director on the date of this prospectus**.** For the past 25 years, Mr. Isham has been an active investment banker and investor focused in growth equity principally in the sectors of clean and alternative technology, telecommunications and transportation (aviation) services. He is currently the Managing Partner of GH Venture Partners LLC ("GHVP"), a financial advisory and investment firm originally established by former Schroder Bank executives. Before joining GHVP, Mr. Isham worked as a consultant to corporate management with The Boston Consulting Group (BCG) and with Strategic Planning Associates (Mercer Consulting acquiree). In addition, Mr. Isham worked at the American Stock Exchange (AMEX) as a Director. Mr. Isham graduated from Yale University with a BA Degree in Political Science in 1979 and earned an MBA at Harvard Business School in 1983. Mr. Isham is Chair (US) of the Institute for War and Peace Reporting (IWPR) headquartered in London and Washington, DC. He also is a former Director on the Research Committee of the American Association of Neurological Surgeons (AANS).

Doron Steger Mr. Steger will become a director on the date of this prospectus. Mr. Steger presently serves as the Chairman, President and CEO of DZS Software Solutions, Inc. ("DZS"), a company that develops and licenses software products used by over 60 pharmaceutical and biotech companies, enabling them to monitor clinical trials and capture, clean, code and analyze the research data. DZS also provides services conducting clinical trials and collecting and summarizing the trial results. Mr. Steger was the Chairman, President and CEO of DZS Computer Solutions, Inc. from its founding in 1984 through its sale in 2009 and Chairman and CEO of ClinPro, Inc., from 2001 through its sale in 2009. These companies provided services conducting clinical trials and collecting and summarizing the trial results. Earlier in his career, Mr. Steger was employed by Sandoz Pharmaceuticals, Inc. and Hoechst-Roussel Pharmaceuticals Inc. Mr. Steger earned MS degrees in physics and computer science from Rutgers University.

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*. 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. On the date of this prospectus, we will 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").

Director Independence

When we become a "listed company" under SEC rules, we will be required to have a board comprising 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 each of Marco M. Elser, Ralph H. Isham and Doron Steger meet the independence standard of the Nasdaq Rules.

Board Committees

Our Board has, effective on the date of this prospectus, established an Audit Committee, a Compensation Committee and a Governance and Nominations Committee as required by the Nasdaq Rules. We intend to publish the respective charters of each of those committees on our web site. Following is a general description of what we expect will be the make-up and functions of these committees.

Audit Committee

The primary functions of the Audit Committee are to: (a) review the financial reports and other financial information prepared by us for submission to any governmental or regulatory body or the public and monitor the integrity of such financial reports; (b) review our systems of internal controls established for finance, accounting, legal compliance and ethics; (c) review our accounting and financial reporting processes generally and the audits of our financial statements; (d) monitor compliance with legal regulatory requirements; (e) monitor the independence and performance of our registered independent public accounting firm; and (f) provide effective communication between the Board, senior and financial management and our registered independent public accounting firm.

The members of our Audit Committee are Marco M. Elser (Chair), Ralph H. Isham and Doron Steger. Our Board has determined that each committee member meets the independence criteria for directors set forth under the Nasdaq Rules and the additional independence criteria for members of audit committees specified in the Nasdaq Rules and Rule 10A-3 under the Exchange Act of 1934.

Our Board has determined that Marco M. Elser qualifies as an "audit committee financial expert," as such term is defined by SEC rules.

Compensation Committee

The members of our Board's Compensation Committee are Ralph H. Isham (Chairman), Marco M. Elser and Doron Steger, each of whom is "independent" as required by the Nasdaq Rules and in accordance with the requirements of Section 952 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Each member of the Committee qualifies as an outside director within the meaning of Section 162(m) of the Internal Revenue Code of 1986, as amended.

Our executive compensation program is administered by the Compensation Committee. The primary functions of the Compensation Committee are to: review and recommend to the Board of Directors, or the Board, appropriate executive compensation policies, compensation of the directors and officers, and executive and employee benefit plans and programs, and oversee such policies, compensation, plans and programs approved by the Board and, where appropriate, by the shareholders.

Compensation of our President and is determined, or recommended to the Board for determination, by the Compensation Committee comprised solely of independent directors. Our President is not present during voting or deliberations. Compensation for all other officers is determined, or recommended to the Board for determination, by the Compensation Committee comprised solely of independent directors.

Under the Compensation Committee Charter, our President may recommend to the Compensation Committee individual compensation awards for our officers. The Compensation Committee would then have to review the recommendation and make its own recommendation to the Board.

Governance and Nominations Committee

The members of our Board's Governance and Nominations Committee are Doron Steger (Chairman), Marco M. Elser and Ralph H. Isham, each of whom is "independent" as required by the Nasdaq Rules.

The primary functions of the Governance and Nominations Committee are to: review and make recommendations on the range of skills and expertise which should be represented on the Board, and the eligibility criteria for individual Board and Committee membership; review and recommend to the Board the appropriate structure of the Board; identify individuals qualified to become Board members and recommend to the Board the nominees for election to the Board at the next Annual Meeting of Stockholders; implement a policy and procedures with regard to consideration of any director candidate recommended by stockholders; retain and terminate any search firm to be used to identify director candidates, and to approve the search firm, fees and other retention terms; and review and recommend to the Board the appropriate structure of Board Committees, Committee assignments and the Board Committee chairman.

Among the factors the Governance and Nominations Committee considers when determining persons to be nominated include whether such individuals are actively engaged in business endeavors, have an understanding of financial statements, corporate budgeting and capital structure, are familiar with the requirements of a publicly traded company, are familiar with industries relevant to our business endeavors, are willing to devote significant time to the oversight duties of the Board of Directors of a public company, and are able to promote a diversity of views based on the person's education, experience and professional employment. The Governance and Nominations Committee evaluates each individual in the context of the board as a whole, with the objective of recommending a group of persons that can best implement our business plan, perpetuate our business and represent stockholder interests. The Governance and Nominations Committee may require certain skills or attributes, such as financial or accounting experience, to meet specific board needs that arise from time to time.

We are of the view that the continuing service of qualified incumbents promotes stability and continuity in the board room, contributing to the ability of the Board of Directors to work as a collective body, while giving us the benefit of the familiarity and insight into our affairs that its directors have accumulated during their tenure. Accordingly, the process of the Governance and Nominations Committee for identifying nominees reflects our practice of re-nominating incumbent directors who continue to satisfy the Governance and Nominations Committee's criteria for membership on the Board of Directors, whom the Governance and Nominations Committee believes continue to make important contributions to the Board of Directors and who consent to continue their service on the Board of Directors. The Governance and Nominations Committee will identify and/or solicit recommendations for new candidates when there is no qualified and available incumbent.

The Governance and Nominations Committee will consider nominees recommended by stockholders. There are no differences in the manner in which the committee evaluates nominees for director based on whether the nominee is recommended by a stockholder. Stockholders who would like to have our Governance and Nominations Committee consider their recommendations for nominees for the position of director, should submit their recommendations, in accordance with the procedures set forth below, in writing to: Corporate Secretary, Protalex, Inc., 131 Columbia Turnpike, Suite 1, Florham Park, NJ 07932.

For nominations, a stockholder's notice must include: (i) as to each person whom the stockholder proposes to nominate for election as a director, (A) the name, age, business address and residential address of such person, (B) the principal occupation or employment of such person, (C) the class and number of shares of stock of Protalex that are beneficially owned by such person, (D) any other information relating to such person that is required to be disclosed in solicitations of proxies for election of directors or is otherwise required by the rules and regulations of the SEC promulgated under the Exchange Act, and (E) the written consent of the nominee to be named in the proxy statement as a nominee and to serve as a director if elected and (ii) as to the stockholder giving the notice, (A) the name, business address, and residential address, as they appear on our stock transfer books, of the nominating stockholder, (B) a representation that the nominating stockholder is a stockholder of record and intends to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice, (C) the class and number of shares of stock of Protalex beneficially owned by the nominating stockholder and (D) a description of all arrangements or understandings between the nominating stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nomination or nominations are to be made by the nominating stockholder.

Stockholder Communications

As of the date of this prospectus, 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.

EXECUTIVE AND DIRECTOR 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 following completion of our initial public offering. 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 2015 is not necessarily indicative of how we will compensate our named executive officers after this offering and we anticipate our compensation programs following the offering, 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 $1,311,792, which included cash of $72,000 and stock options valued at $1,239,792. 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 the information as to compensation paid to or earned by our then Chief Executive Officer and our two other most highly compensated executive officers during the fiscal years ended May 31, 2016 and 2015. These individuals are referred to in this proxy statement 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.

Name and Principal Position	Year	Salary ($) (1)	Option Awards ($) (1)	Total ($)
Arnold P. Kling,	2016	$ 72,000	-	$ 72,000
President	2015	$ 72,000	-	$ 72,000
Kirk M. Warshaw,	2016	$ 72,000	$ 1,239,792	$ 1,311,792
Chief Financial Officer	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 prospectus.

Employment Contracts

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

Indemnification Agreements

As of the date of this prospectus, 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 summaries 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
	250,000	0	$ 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 summaries the compensation paid to our independent director for the fiscal year ended May 31, 2016:

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

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.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders – 2003 Stock Option Plan	**2,000**	**$ 10.75**	**0**
Equity compensation plans not approved by security holders – Stand Alone Option Grants	**4,580,543**	**$ 4.30**	**Not applicable**
Total	**4,582,543**	**$ 4.30**	**0**

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 are fully-vested on the date of grant.

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.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of May 31, 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 prospectus, 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.

	SHARES BENEFICIALLY OWNED[1]			
	Prior to Offering[2]		After Offering[3]	
Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Class	Number of Shares Beneficially Owned	Percent of Class
Executive Officers and Directors:				
Arnold P. Kling[4]	22,581,149	78.5%	_____	____%
Kirk M. Warshaw[5]	1,700,543	5.6%	1,700,543	____%
Marco Elser[6]	384,000	1.3%	384,000	*
Officers and directors as a group (3 persons)[7]	24,665,692	80.0%	_____	____%
5% Beneficial Owners:				
Niobe Ventures LLC[4]	22,576,087	78.5%	_____	____%

*less than 1%

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

(2) Based on 28,767,582 shares of common stock issued and outstanding as of May 31, 2016.

(3) Based on _____ shares of common stock issued and outstanding immediately after this offering including _____ shares of common stock issued in this offering and _____ shares of common stock to be issued to the holder of outstanding notes upon conversion thereof, assuming conversion at $____ per share, the midpoint of the proposed price range per share set forth on the cover page of this prospectus.

(4) 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.

(5) 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.

(6) 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.

(7) Includes 2,050,543 shares of common stock underlying options to purchase shares of common stock beneficially owned.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

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, during the years ended May 31, 2014 and May 31, 2015, we raised an aggregate of $4,305,000 of working capital from six separate loans, in varying principal amounts, from Niobe and issued to Niobe the Secured Notes.

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

From November 2014 through May 31, 2016, pursuant to the 2014 Credit Facility Agreement, we borrowed an aggregate of $16,319,366 from Niobe and issued a Note to Niobe for each loan.

In June 2016, we entered into an agreement with the holder of our outstanding indebtedness pursuant to which it agreed to effect the Debt-for-Equity Exchange. Accrued interest ($932,883 as of May 31, 2016) will be paid out of the proceeds of this 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, 2015 and 2014 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.

DESCRIPTION OF SECURITIES

General

At the date hereof, we are authorized by our certificate of incorporation to issue an aggregate of 100,000,000 shares of common stock, par value $0.00001 per share, and 1,000,000 shares of "blank check" preferred stock, par value $0.00001 per share. As of May 31, 2016, we had 28,767,582 shares of common stock and no shares of preferred stock outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. Holders of our common stock do not have cumulative voting rights, which means that the holders of more than one half of the outstanding shares of common stock, subject to the rights of the holders of the preferred stock, if any, can elect all of our directors, if they choose to do so. In this event, the holders of the remaining shares of common stock would not be able to elect any directors. Except as otherwise required by Delaware law, and subject to the rights of the holders of preferred stock, if any, all stockholder action is taken by the vote of a majority of the outstanding shares of common stock voting as a single class present at a meeting of stockholders at which a quorum consisting of one-third of the outstanding shares of common stock is present in person or proxy.

Subject to the prior rights of any class or series of preferred stock which may from time to time be outstanding, if any, holders of our common stock are entitled to receive ratably, dividends when, as, and if declared by our board of directors out of funds legally available for that purpose and, upon our liquidation, dissolution, or winding up, are entitled to share ratably in all assets remaining after payment of liabilities and payment of accrued dividends and liquidation preferences on the preferred stock, if any. Holders of our common stock have no preemptive rights and have no rights to convert their common stock into any other securities. The outstanding common stock is validly authorized and issued, fully-paid and nonassessable.

Warrants

The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of the warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part of. Prospective investors should carefully review the terms and provisions set forth in the form of warrant.

Exercisability. The warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. In no event shall we be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of common stock underlying the warrants.

Exercise Price. The initial exercise price per share of common stock purchasable upon exercise of the warrants is $____ per share, ____% of the public offering price of the common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock, rights or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

Fundamental Transaction. If, at any time while the warrants are outstanding, (1) we consolidate or merge with or into another corporation and we are not the surviving corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our shares of common stock are permitted to sell, tender or exchange their shares of common stock for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of common stock, (4) we effect any reclassification or recapitalization of our shares of common stock or any compulsory share exchange pursuant to which our shares of common stock are converted into or exchanged for other securities, cash or property, or (5) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding shares of common stock, each, a `Fundamental Transaction,' then upon any subsequent exercise of the warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Preferred Stock

We are authorized to issue up to 1,000,000 shares of “blank check” preferred stock. Preferred stock may be issued in one or more series and having the rights, privileges and limitations, including voting rights, conversion privileges and redemption rights, as may, from time to time, be determined by our board of directors. Preferred stock may be issued in the future in connection with acquisitions, financings, or other matters as our board of directors deems appropriate. In the event that any shares of preferred stock are to be issued, a certificate of designation containing the rights, privileges and limitations of such series of preferred stock will be filed with the Secretary of State of the State of Delaware. The effect of such preferred stock is that, subject to federal securities laws and Delaware law, our board of directors alone, may be able to authorize the issuance of preferred stock which could have the effect of delaying, deferring, or preventing a change in control of us without further action by the stockholders, and may adversely affect the voting and other rights of the holders of our common stock. The issuance of preferred stock with voting and conversion rights may also adversely affect the voting power of holders of our common stock, including the loss of voting control to others.

As of May 31, 2016, there were no shares of preferred stock issued and outstanding.

Anti-Takeover Provisions

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. This provision generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date the stockholder became an interested stockholder, unless:

- prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an “interested stockholder” as any entity or person beneficially owning 15% or more of the outstanding voting stock of a corporation, or an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of a corporation at any time within three years prior to the time of determination of interested stockholder status; and any entity or person affiliated with or controlling or controlled by such entity or person.

These statutory provisions could delay or frustrate the removal of incumbent directors or a change in control of our company. They could also discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such event would be favorable to the interests of stockholders.

Certificate of Incorporation and Bylaw Provisions

Our certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. In particular, the certificate of incorporation and bylaws, as applicable, among other things:

- provide our board of directors with the ability to alter its bylaws without stockholder approval; and

- provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum.

Such provisions may have the effect of discouraging a third-party from acquiring us, even if doing so would be beneficial to our stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by them, and to discourage some types of transactions that may involve an actual or threatened change in control of our company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage some tactics that may be used in proxy fights. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an improvement of their terms. However, these provisions could have the effect of discouraging others from making tender offers for our shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in our management.

Our certificate of incorporation provides that no director is personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty by such director as a director. Nonetheless, a director is liable to the extent provided by applicable law, (i) for breach of the director's duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL (relating to unlawful payment of dividend or unlawful stock purchase or redemption) or (iv) for any transaction from which the director derived an improper personal benefit. If the DGCL is amended to authorize the further elimination or limitation of the liability of directors, then the liability of one of our directors, in addition to the limitation on personal liability provided in our certificate of incorporation, will be limited to the fullest extent permitted by the amended DGCL. No amendment to or repeal of the relevant article of our certificate of incorporation will apply to or have any effect on the liability or alleged liability of any of our directors for or with respect to any acts or omissions of such director occurring prior to such amendment.

Our certificate of incorporation furthermore states that we shall indemnify, to the fullest extent permitted by Section 145 of the DGCL, as amended from time to time, each person that such section grants us the power to indemnify. Insofar as indemnification for liability under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, 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.

Transfer Agent and Registrar

American Stock Transfer & Trust Company, 6201 15th Avenue, Brooklyn, NY 11219, serves as the transfer agent and registrar for the common stock.

Listing

The shares of our common stock trade on the OTCQB under the symbol PRTX. We have applied to list our common stock on the NASDAQ Capital Market under the symbol "PRTX". We expect the common stock will begin trading on the NASDAQ Capital Market on the effective date of this offering. On June 2, 2016, the last reported sale price per share for our common stock as reported by the OTCQB was $3.50. We do not intend to apply for listing of the warrants on any exchange or market, and do not expect any market to develop for the warrants.

SHARES ELIGIBLE FOR FUTURE SALE

This Offering

After this offering is completed we expect to have _____ shares of common stock outstanding (_____ shares if the underwriter exercises the over-allotment option in full). Immediately after this offering is consummated, _____ shares of our common stock (_____ if the underwriters' overallotment option is exercised in full) will be freely tradeable without restrictions or further registration under the Securities Act, including the _____ shares of common stock sold in this offering (_____ shares if the underwriters' over-allotment is exercised in full), except that any shares purchased by our "affiliates," as that term is defined under the Securities Act, in this offering may generally only be sold in compliance with the limitations of Rule 144 under the Securities Act. Similarly, the _____ shares of common stock underlying the warrants sold in this offering (_____ shares of common stock if the representative's over-allotment is exercised in full) will also be freely tradable after exercise of the warrants, except for shares held by our affiliates.

Outstanding Restricted Stock

The remaining 22,615,159 outstanding shares of common stock are restricted securities within the meaning of Rule 144 and may not be sold in the absence of registration under the Securities Act unless an exemption from registration is available, including the exemption from registration offered by Rule 144, all of which are owned by officers, directors and 5% stockholders. The holders of these restricted shares have agreed not to sell or otherwise dispose of any of their shares of common stock for a period of __days after completion of this offering except with the prior written consent of the representative.

In general, under Rule 144 as currently in effect, a person who has beneficially owned restricted shares for at least six (6) months, including a person who may be deemed to be our affiliate, may sell within any three-month period a number of shares of common stock that does not exceed a specified maximum number of shares. This maximum is equal to the greater of 1% of the then outstanding shares of our common stock or the average weekly trading volume in the common stock during the four calendar weeks immediately preceding the sale. Sales under Rule 144 are also subject to restrictions relating to manner of sale, notice and availability of current public information about us.

UNDERWRITING

Chardan Capital Markets, LLC is acting as the representative of the underwriters of the offering. We have entered into an underwriting agreement dated _____ __, 2016 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock and warrants listed next to its name in the following table:

Underwriter	Number of Shares	Number of Warrants
Chardan Capital Markets, LLC		
Total		

The underwriters are committed to purchase all the shares of common stock and warrants offered by us other than those covered by the option to purchase additional shares and/or warrants described below, if they purchase any shares and warrants. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters propose to offer the shares and warrants offered by us to the public at the public offering price set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares and warrants to other securities dealers at such price less a concession of $0.__ per share. If all of the shares and warrants offered by us are not sold at the public offering price, the underwriters may change the offering price and other selling terms by means of a supplement to this prospectus.

Discounts and Commissions. The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

			Total	
	Per Share	**Per Warrant**	**Without Over-Allotment**	**With Over-Allotment**
Public offering price	$	$	$	$
Underwriting discount (8%)	$	$	$	$
Non-accountable expense allowance (1%)	$	$	$	$
Proceeds, before other expenses, to us	$	$	$	$

We have agreed to pay to the underwriters a fee equal to 8.0% of the aggregate gross proceeds of the shares and warrants sold in this offering. This fee is to be paid by means of a discount from the offering price to purchasers in the offering. In addition, we have agreed to reimburse the representatives for their reasonable out-of-pocket accountable expenses incurred in connection with this offering in an aggregate amount not to exceed 1% of the gross proceeds of this offering for all such expenses.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount, will be approximately $300,000.

Overallotment Option. We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of _____ additional shares and/or _____ additional warrants (15% of the shares and warrants sold in this offering, respectively) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase shares and/or warrants covered by the option at the public offering price that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total price to the public will be $_____ and the total net proceeds, before expenses (other than the _% non-accountable expense allowance), to us will be $_____.

Right of First Refusal. Subject to certain terms and exceptions, for a period of twelve months after the date of effectiveness of the Registration Statement of which this prospectus is a part, we have granted the representative a right of first refusal to act as co-lead book-running underwriter or co-book-running manager or financial advisor for each and every future public and private offering we do during such twelve-month period.

Discretionary Accounts. The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements. We have agreed not to offer, sell, contract to sell, pledge, grant options to purchase, or otherwise dispose of any of our shares of common stock or securities exchangeable for or convertible into our shares of common stock for a period of ___ days after the date of this prospectus without the prior written consent of the representatives. This agreement does not apply to the issuance of shares upon the exercise of rights to acquire shares of common stock pursuant to any existing stock option or similar equity incentive or compensation plan. Our directors and executive officers and any other stockholders of 5% or more of our outstanding shares of common stock expect to enter into lock up agreements with the representative prior to the commencement of this offering pursuant to which each of these persons or entities, for a period of ___ days from the effective date of the registration statement of which this prospectus is a part, without the prior written consent of the representative, agree not to (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our securities or any securities convertible into or exercisable or exchangeable for shares of our common stock owned or acquired on or prior to the closing date of this offering (including any shares of common stock acquired after the closing date of this offering upon the conversion, exercise or exchange of such securities); (2) file or caused to be filed any registration statement relating to the offering of any shares of our capital stock; or (3) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described in clause (1), (2) or (3) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, except for certain exceptions and limitations. The lock-up period described in the preceding paragraphs will be automatically extended if: (1) during the last 17 days of the restricted period, we issue an earnings release or announce material news or a material event; or (2) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the date of the earnings release.

Electronic Offer, Sale and Distribution of Securities. A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares and warrants to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.

- Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriters sell more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

- Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the s securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be effected on the NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive market making. In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the NASDAQ Capital Market or on the OTCQB in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Potential Conflicts of Interest. The underwriters and their affiliates have provided, or may in the future provide, various investment banking, commercial banking, financial advisory, brokerage and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees and expense reimbursement. We have not paid any of the underwriters any compensation in the 180 days prior to the date of this prospectus, and have no current obligations or intention to pay any of the underwriters any compensation in the 90 days after the date of this prospectus.

The underwriters and their affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers and such investment and securities activities may involve securities and/or instruments of our company. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

LEGAL MATTERS

The validity of the securities being offered by this prospectus has been passed upon for us by Morse, Zelnick, Rose & Lander, LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Loeb & Loeb LLP, New York, New York.

EXPERTS

Our financial statements included in this prospectus and registration statement as of May 31, 2015 and for each of the fiscal years in the two year period ended May 31, 2015 (as indicated in its report) have been audited by Liggett & Webb, PA, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) and is included herein in reliance upon the authority as experts in giving said report.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are a reporting company and file annual, quarterly and special reports, and other information with the Securities and Exchange Commission, or the SEC. Copies of the reports and other information may be read and copied at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You can request copies of such documents by writing to the SEC and paying a fee for the copying cost. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site at *http://www.sec.gov* that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC.

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules and regulations of the SEC. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus. For further information, you may:

- read a copy of the registration statement, including the exhibits and schedules, without charge at the SEC's Public Reference Room; or

- obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

PROTALEX, INC.

FINANCIAL STATEMENTS INDEX

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, 2015 and 2014, 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, 2015 and 2014 and the results of its operations and its cash flows for each of the years ended May 31, 2015 and 2014, in conformity with accounting principles generally accepted in the United States of America.

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

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

New York, NY
July 7, 2015

PROTALEX, INC.
BALANCE SHEETS

	May 31, 2015	May 31, 2014
CURRENT ASSETS:		
Cash and cash equivalents	$ 928,279	$ 1,614,758
Prepaid expenses	56,431	45,327
Total current assets	984,710	1,660,085
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $15,108 and $14,088 as of May 31, 2015 and May 31, 2014, respectively	4,427	5,447
Total other assets	4,427	5,447
Total Assets	$ 989,137	$ 1,665,532
LIABILITIES AND STOCKHOLDERS' (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 494,954	$ 412,718
Accrued expenses	59,701	40,135
Total current liabilities	554,655	452,853
LONG TERM LIABILITIES:		
Senior Secured Note – related party	12,524,366	9,000,000
Senior Secured Note Accrued Interest – related party	498,570	397,168
Total liabilities	13,577,591	9,850,021
STOCKHOLDERS' (DEFICIT)		
Preferred stock, par value $0.00001, 1,000,000 shares authorized; none issued and outstanding	0	0
Common stock, par value $0.00001, 100,000,000 shares authorized; 28,767,582 and 28,767,582 shares issued and outstanding, respectively	288	288
Additional paid in capital	72,618,336	65,402,505
Accumulated deficit	(85,207,078)	(73,587,282)
Total stockholders' (deficit)	(12,588,454)	(8,184,489)
Total liabilities and stockholders' (deficit)	$ 989,137	$ 1,665,532

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

PROTALEX, INC.

STATEMENTS OF OPERATIONS
Years Ended May 31,

	2015	2014
Revenues	$ 0	$ 0
Operating Expenses		
Research and development	2,989,311	3,232,321
Administrative	7,785,086	7,750,587
Professional fees	523,613	584,585
Depreciation and amortization	1,020	1,020
Operating loss	(11,299,030)	(11,568,513)
Other income (expense)		
Interest income	3	4
Interest expense	(320,769)	(283,720)
Loss before income taxes	(11,619,796)	(11,852,229)
Provision for income taxes	0	0
Net loss	$ (11,619,796)	$ (11,852,229)
Weighted average number of common shares outstanding	**28,767,582**	**26,222,563**
Loss per common share – basic and diluted	$ (0.40)	$ (0.45)

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, 2014 and May 31, 2015

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, May 31, 2013	18,926,683	$ 189	$53,237,993	$ (61,735,053)	$ (8,496,871)
June 1, 2013 – May 31, 2014 – shared-based expense	0	0	7,228,008	0	7,228,008
August 27, 2013 – issuance of 9,369,565 shares of common stock	9,369,565	94	2,154,906	0	2,155,000
January 23, 2014 – issuance of 471,334 shares of common stock	471,334	5	2,781,598	0	2,781,603
Net loss for the year ended May31, 2013	0	0	0	(11,852,229)	(11,852,229)
Balance, May 31, 2014	28,767,582	288	65,402,505	(73,587,282)	(8,184,489)
June 1, 2014 – May 31, 2015 – shared-based expense	0	0	7,215,831	0	7,215,831
Net loss for the year ended May 31, 2015	0	0	0	(11,619,796)	(11,619,796)
Balance, May 31, 2015	28,767,582	$ 288	$72,618,336	$ (85,207,078)	$(12,588,454)

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

PROTALEX, INC.

STATEMENTS OF CASH FLOWS
Years Ended May 31,

	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (11,619,796)	$ (11,852,229)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities		
Depreciation and amortization	1,020	1,020
Equity based expense	7,215,831	7,228,008
(Increase)/decrease in:		
Prepaid expenses and deposits	(11,104)	(3,008)
Increase/(decrease) in:		
Accounts payable and accrued expenses	101,801	(281,402)
Accrued interest payable	320,769	283,720
Net cash and cash equivalents used in operating activities	(3,991,479)	(4,623,891)
CASH FLOWS FROM INVESTING ACTIVITIES:	0	0
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from stock issuance, including options and warrants exercised	0	2,781,603
Issuance of note payable to related party	3,305,000	1,000,000
Net cash and cash equivalents provided by financing activities	3,305,000	3,781,603
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	(686,479)	(842,288)
Cash and cash equivalents, beginning	1,614,758	2,457,046
Cash and cash equivalents, ending	$ 928,279	$ 1,614,758
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:		
Interest paid	$ 0	$ 0
Taxes paid	$ 0	$ 0
NONCASH FINANCING ACTIVITIES:		
Conversion of debt to equity	$ 0	$ 2,155,000

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

PROTALEX, INC.
NOTES TO FINANCIAL STATEMENTS
Years Ended May 31, 2015 and 2014

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 pharmakinetics have been characterized in six 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. 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"). 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.

Pursuant to the terms and condition of the 2014 Credit Facility Agreement, as of May 31, 2015, the Company borrowed an aggregate of $3,305,000. 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, 2015, the Company has incurred an accumulated deficit of $85,207,078. For the years ended May 31, 2015 and 2014, the Company had net losses of $11,619,796 and $11,852,229, respectively. The Company utilized $3,991,479 and $4,623,891 of cash for operating activities for the years ended May 31, 2015 and 2014, respectively. As of May 31, 2015, the Company had cash and cash equivalents of $928,279 and net working capital of $430,055. 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, 2015 and 2014, the Company had a total of 3,807,543 and 4,317,543, respectively, of potentially dilutive securities comprised solely of 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 $7,215,831 and $7,228,008 and is included in operating expenses for the years ended May 31, 2015 and May 31, 2014, 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, 2015 and 2014 in connection with these compensation costs due to the uncertainty regarding ultimate realization of certain net operating loss carryforwards. The Company has also implemented the SEC interpretations in Staff Accounting Bulletin ("SAB") for "Share-Based Payments," in connection with the adoption of FASB accounting guidance.

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

As of May 31, 2015, the Company has issued 3,807,943 stock options, of which 400 were exercised. Stock options vest pursuant to the terms set forth in individual stock option agreements.

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

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

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

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

As of May 31, 2015, there were 3,807,543 stock options outstanding. At May 31, 2015, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model, was approximately $500,007 (net of estimated forfeitures) will be recognized over a weighted average remaining period of eighteen months. The remaining options will be valued once they vest upon the future events. During the year ended May 31, 2015, the Company granted an aggregate of 600,000 stock options to four consultants, one officer/director and one director, all of which have a five-year term and have an exercise price of between $8.22 and $6.00 per share, and 1,110,000 options expired or were forfeited.

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

	Year Ended May 31, 2015	Year Ended May 31, 2014
Dividends per year	0	0
Volatility percentage	570%	418% - 696%
Risk free interest rate	1.60%	4.00%
Expected life (years)	5	5-10
Weighted Average Fair Value	$ 6.74	$ 8.51

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, 2015 and 2014, 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, 2015. Amortization expense for the intellectual property will be $1,020 for each of the next four years with the remaining balance written off in the fifth 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.

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

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

In August 2014, the FASB issued Accounting Standards Update "ASU" 2014-15 on "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.

5. INCOME TAXES

For the years ended May 31, 2015 and 2014, the components of income tax benefit (expense) consist of the following:

Current:	Year Ended May 31, 2015	Year Ended May 31, 2014
Federal	$ 0	$ 0
State	0	0
Deferred:		
Federal	3,951,000	4,028,000
State	697,000	711,000
Tax credits	219,000	185,000
Permanent timing difference	(2,997,000)	(2,999,000)
Increase in valuation allowance	(1,870,000)	(1,925,000)
Income tax benefit	$ 0	$ 0

Income tax as a percentage of income for the year ended May 31, 2015 and 2014 differ from statutory federal income tax rates due to the following:

	Year Ended May 31, 2015	Year Ended May 31, 2014
Statutory federal income tax rate	(34)%	(34)%
State income taxes, net of federal income tax impact	(6)%	(6)%
Change in valuation allowance	16%	17%
Permanent timing differences	26%	25%
General business credit/other	(2)%	(2)%
	0%	0%

The components of the net deferred tax asset as of May 31, 2015 and 2014 are as follows:

Assets:	May 31, 2015	May 31, 2014
Net operating losses	$ 23,200,000	$ 21,550,000
General business credit	2,759,000	2,540,000
Deferred tax assets	25,959,000	24,090,000
Liability:		
Gross deferred tax asset	25,959,000	24,090,000
Less valuation allowance	(25,959,000)	(24,090,000)
Deferred tax asset, net of valuation allowance	$ 0	$ 0

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

Internal Revenue Code Section 382 places a limitation on the amount of taxable income that can be offset by carryforwards after a change in control. As a result of these provisions, utilization of the NOL and tax credit carryforwards may be limited. Most of the deferred tax asset of net operating loss carryforwards and tax credits are subject to a Section 382 limitation on the amount to be utilized in a given year. The years May 31, 2012 through 2015 remain subject to examination by the relevant tax authorities.

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

6. 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. 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"). 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.

Pursuant to the terms and condition of the 2014 Credit Facility Agreement, as of May 31, 2015, the Company borrowed an aggregate of $3,305,000. 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, 2014, the Company issued an option for an aggregate of 250,000 shares of Common Stock to Marco Elser, a director of the Company. This option has a ten year term, an exercise price of $9.00 per share, and vests 1/3 upon issuance, 1/3 on the 12 month anniversary date of issuance and 1/3 on May 4, 2016. This option has been valued at $2,018,000 for which $1,084,386 of compensation expense has been recorded.

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.

7. STOCK OPTIONS

Prior to January 22, 2004, all options were issued as "stand alone" options. On January 22, 2004, the Board approved the Protalex, Inc. 2003 Stock Option Plan., and on October 25, 2005, the stockholders approved an amendment to the Protalex, Inc. 2003 Stock Option Plan to increase the authorized number of shares under the Plan from 300,000 to 900,000 which provides for incentive and non-qualified stock options to purchase a total of 900,000 shares of Common Stock. Under the terms of the plan, incentive options may not be granted at exercise prices less than the fair market value of the Common Stock at the date of the grant and non-qualified options shall not be granted at exercise prices equal to less than 85% of the fair market value of Common Stock at the date of the grant. Beginning January 1, 2005, all stock options are granted at fair market value. Vesting generally occurs ratably over forty-eight months and is exercisable over a period no longer than ten years after the grant date. As of May 31, 2015, options to purchase 3,807,543 shares of Common Stock were outstanding, of which 27,000 were issued and 800 were exercised under the Company's 2003 Stock Option Plan and the remaining 3,780,543 were issued and 400 were exercised as standalone options. As of May 31, 2015, options to purchase 3,524,209 shares of Common Stock are exercisable.

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

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

A summary of the Common Stock option activity for employees, directors, officers and consultants as of May 31, 2015 and for the three years then ended is as follows:

	Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (Years)
Outstanding at May 31, 2012	2,268,927	1.27	7.65
Granted	1,000,000	1.22	10
Exercised	0	0	0
Forfeited	0	0	0
Expired	(211,385)	7.52	0
Outstanding at May 31, 2013	3,057,542	1.09	8.08
Granted	1,300,000	8.51	5.83
Exercised	0	0	0
Forfeited	0	0	0
Expired	(40,000)	7.50	0
Outstanding May 31, 2014	4,317,543	3.26	6.67
Granted	600,000	6.74	5
Exercised	0	0	0
Forfeited	(1,110,000)	2.46	0
Outstanding at May 31, 2015	3,807,543	4.04	5.76
Exercisable at May 31, 2015	3,524,209		

The outstanding and exercisable stock options as of May 31, 2015 and 2014 had an intrinsic value of $9,043,243 and $20,782,678, respectively.

The 600,000 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, 2015:

	Total			Exercisable		
Exercise Price Range	Number	Weighted Average Exercise Price	Weighted Average Remaining Life (years)	Number	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
$ 0.00 – 1.00	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

8. STOCKHOLDERS DEFICIT

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. 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.

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 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. Costs associated with this equity raise was in the amount of $46,397. 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.

9. COMMITMENTS AND CONTINGENCIES

The Company leases space on a month to month basis. Rent expense for the year ended May 31, 2015 and 2014, was $2,200 and $7,401, respectively.

10. SUBSEQUENT EVENTS

On July 1, 2015 the Company issued non-qualified stock options for an aggregate of 800,000 shares of Common Stock with an exercise price of $5.41 per share to one employee and four consultants. The option expires five years from the date of grant.

On July 1, 2015, the Company borrowed an additional $345,000 under the terms of the 2014 Credit Facility Agreement and issued Niobe a Note in the same principal amount for such loan.

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

PROTALEX, INC.

CONDENSED BALANCE SHEETS

	February 29, 2016	May 31, 2015
	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 594,701	$ 928,279
Prepaid expenses	87,836	56,431
Total current assets	682,537	984,710
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $15,873 and $15,108 as of February 29, 2016 and May 31, 2015, respectively	3,662	4,427
Total other assets	3,662	4,427
Total Assets	$ 686,199	$ 989,137
LIABILITIES AND STOCKHOLDERS' (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 780,129	$ 494,954
Accrued expenses	9,322	59,701
Total current liabilities	789,451	554,655
LONG TERM LIABILITIES:		
Senior Secured Note – related party	15,284,366	12,524,366
Senior Secured Note Accrued Interest – related party	811,917	498,570
Total liabilities	16,885,734	13,577,591
STOCKHOLDERS' (DEFICIT)		
Preferred stock, par value $0.00001, 1,000,000 shares authorized; none issued and outstanding	0	0
Common stock, par value $0.00001, 100,000,000 shares authorized; 28,767,582 and 28,767,582 shares issued and outstanding, respectively	288	288
Additional paid in capital	76,662,507	72,618,336
Accumulated deficit	(92,862,330)	(85,207,078)
Total stockholders' deficit	(16,199,535)	(12,588,454)
Total liabilities and stockholders' deficit	$ 686,199	$ 989,137

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

PROTALEX, INC.

CONDENSED STATEMENTS OF OPERATIONS

	Three Months Ended February 29, 2016	Three Months Ended February 28, 2015	Nine Months Ended February 29, 2016	Nine Months Ended February 28, 2015
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues	$ 0	$ 0	$ 0	$ 0
Operating Expenses				
Research and development	808,177	742,124	2,409,183	2,302,983
Administrative	796,624	690,259	4,395,245	7,144,472
Professional fees	122,962	158,159	536,716	373,981
Depreciation and amortization	255	255	765	765
Operating loss	(1,728,018)	(1,590,797)	(7,341,909)	(9,822,201)
Other income (expense)				
Interest income	1	1	2	2
Interest expense	(111,873)	(82,617)	(313,345)	(225,685)
Loss before income taxes	(1,839,890)	(1,673,413)	(7,655,252)	(10,047,884)
Provision for income taxes	0	0	0	0
Net loss	$ (1,839,890)	$ (1,673,413)	$ (7,655,252)	$ (10,047,884)
Weighted average number of common shares outstanding	**28,767,582**	**28,767,582**	**28,767,582**	**28,767,582**
Loss per common share – basic and diluted	$ (0.06)	$ (0.06)	$ (0.27)	$ (0.35)

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

PROTALEX, INC.

CONDENSED STATEMENTS OF CASH FLOWS

	Nine Months Ended February 29, 2016	Nine Months Ended February 28, 2015
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,655,252)	$ (10,047,884)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	765	765
Equity based expense	4,044,171	6,733,644
(Increase)/decrease in:		
Prepaid expenses and deposits	(31,405)	(44,193)
Increase/(decrease) in:		
Accounts payable and accrued expenses	548,143	282,962
Net cash and cash equivalents used in operating activities	(3,093,578)	(3,074,706)
CASH FLOWS FROM INVESTING ACTIVITIES:	0	0
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of note payable to individuals	2,760,000	1,920,000
Net cash and cash equivalents provided by financing activities	2,760,000	1,920,000
NET DECREASE IN CASH AND CASH EQUIVALENTS	(333,578)	(1,154,706)
Cash and cash equivalents, beginning of period	928,279	1,614,758
Cash and cash equivalents, ending of period	$ 594,701	$ 460,052
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:		
Interest paid	$ 0	$ 0
Taxes paid	$ 0	$ 0

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

NOTE 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, PRTX-100, is a highly-purified form of Staphylococcal protein A, a bacterial protein known to modify aspects of the human immune system.

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 and ITP. In the United States, the Company has open Investigational New Drug (IND) applications for the treatment of RA and ITP and in Europe, an open Investigational Medicinal Products Dossier (IMPD) for ITP.

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 of future human clinical trials. The safety, tolerability and pharmakinetics of PRTX-100 in humans have been characterized in six clinical studies and PRTX-100 was recently granted Orphan Drug Designation (ODD) in the United States and Europe for the treatment of ITP. The Company does not anticipate generating operating revenue for the foreseeable future and does not currently have any products that are marketable.

NOTE 2. GOING CONCERN

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

There is substantial doubt about the Company's ability to continue as a going concern. From inception through February 29, 2016, the Company has incurred an accumulated deficit of $92,862,330. For the years ended May 31, 2015 and 2014, the Company had net losses of $11,619,796 and $11,852,229, respectively, and for the nine months ended February 29, 2016, the Company had a net loss of $7,655,252. The Company utilized $3,991,479 and $4,623,891 of cash for operating activities for the years ended May 31, 2015 and 2014, respectively, and $3,093,578 during the nine months ended February 29, 2016. As of February 29, 2016, the Company had cash and cash equivalents of $594,701 and net negative working capital of $106,914. 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 the FDA approval process, its ability to sustain its operations would be significantly jeopardized.

The most likely sources of additional financing include the sale of the Company's equity or debt securities. On July 31, 2015, the Company filed a Registration Statement on Form S-1 with the U.S. Securities and Exchange Commission (SEC) (SEC File No. 333-206008) with respect to a proposed public offering of Company securities. There is no assurance that the Company will consummate a public offering of its securities, or any other offering. Accordingly, additional capital that is required by the Company may not be available on reasonable terms, or at all.

NOTE 3. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The interim financial data contained in this Report is unaudited; however in the opinion of management, the interim data includes all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of the results for the interim period. The financial statements included herein have been prepared by the Company pursuant to the rules and regulations of the SEC. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) have been omitted pursuant to such rules and regulations, although the Company believes that the disclosures included herein are adequate to make the information presented not misleading. The results of operations in interim periods are not necessarily indicative of the results that may be expected for the full year.

Information regarding the organization and business of the Company, accounting policies followed by the Company and other important information is contained in the notes to the Company's financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2015. This Report should be read in conjunction with the Company’s Annual Report.

Estimates

The preparation of financial statements in conformity with U.S. GAAP 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 guidance for “Earnings Per Share” which provides for the calculation of “Basic” and “Diluted” earnings per share. Basic earnings per share includes no dilution and is computed by dividing net loss to common stockholders by the weighted average number of common shares outstanding for the period. All potentially dilutive securities consisting of employee stock options and warrants 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 February 29, 2016 and February 28, 2015, the Company had potentially dilutive securities consisting of 4,605,543 and 3,817,543 stock options, respectively.

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 90 days or less to be cash and cash equivalents. The cash and cash equivalent deposits are not insured by The Federal Deposit Insurance Corporation.

Reclassifications

Certain reclassifications have been made to the prior periods to conform to the current presentations in the financial statements.

Research and Development

Research and development costs are expensed as incurred.

NOTE 3. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):

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 $4,044,171 and $6,733,644 and is included in operating expenses for the nine months ended February 29, 2016 and February 28, 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 February 29, 2016 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 February 29, 2016, the Company had issued 4,607,943 stock options, of which 400 were exercised and 2,000 have expired. Stock options vest pursuant to the terms set forth in individual stock option agreements.

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

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

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

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

At February 29, 2016, there were 4,605,543 stock options outstanding. At February 29, 2016, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model, was approximately $783,836 (net of estimated forfeitures) will be recognized over a weighted average period of eight months through July 2016. The remaining options will be valued once they vest upon the future events. During the nine months ended February 29, 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 an exercise price of $5.41 per share, and 2,000 options expired.

NOTE 3. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):

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

	Nine Months Ended February 29, 2016	Nine Months Ended February 28, 2015
Dividends per year	0	0
Volatility percentage	606%	696%
Risk free interest rate	4.00%	4.00%
Expected life (years)	5.00	5.00
Weighted Average Fair Value	$ 5.41	$ 6.74

NOTE 4. RECENT ACCOUNTING PRONOUNCEMENTS

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

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

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

In August 2014, the FASB issued Accounting Standards Update "ASU" 2014-15 on "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 is currently reviewing the provisions of this ASU to determine if there will be any impact on its results of operations, cash flows or financial condition.

NOTE 5. RELATED PARTIES

Niobe Ventures, LLC, a Delaware limited liability company ("Niobe"), the majority stockholder of the Company and the holder of the Consolidated Note (defined in Note 6, below), is controlled by Arnold P. Kling, the Company's president and a director.

During the fiscal year ended May 31, 2015, the Company issued an option for an aggregate of 100,000 shares of its common stock, with par value of $0.00001 per share ("Common Stock") to Marco Elser, 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, 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 nine months ended February 29, 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 $1,127,083 of compensation expense has been recorded.

NOTE 6. SENIOR SECURED NOTES - RELATED PARTY

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 outstanding secured notes then held by Niobe (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 changed to September 1, 2015, which was 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 Prepayment Amount"). 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. Effective as of October 1, 2014, the Company and Niobe agreed to extend the maturity date of the Consolidated Note until September 1, 2016. All other terms and provisions of the Consolidated Note remained unchanged and in full force and effect.

On November 4, 2014, the Company entered into a new Credit Facility Agreement (the "2014 Credit Facility Agreement") pursuant to which the Company may borrow up to an additional $5.0 Million from Niobe, in the form of secured loans, at any time prior to December 31, 2015 (the "2014 Credit Facility"). Each loan made to the Company by Niobe under the 2014 Credit Facility Agreement has been represented by a senior secured promissory note bearing interest at a rate of 3% per annum which matures on September 1, 2016 (each an "Original Note"). The obligations of the Company pursuant to each Note have been secured by a first priority perfected security interest in all of the assets of the Company 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 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.

As of February 29, 2016, the outstanding principal balance under the 2014 Credit Facility totaled $6,065,000. During the nine months ended February 29, 2016, the Company borrowed an aggregate of $2,760,000, $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, and February 1, 2016. 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, as amended.

NOTE 7. SUBSEQUENT EVENTS

On March 4, 2016 and April 1, 2016, the Company borrowed an additional $345,000, respectively, under the terms of the Amended and Restated Agreement and issued Niobe a New Note for the loan in the same principal amount.

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

_____ Shares of Common Stock
Warrants to Purchase _____ Shares of Common Stock

PROSPECTUS

Chardan

_____ __, 2016

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

Set forth below is an estimate (except for the SEC registration fees and FINRA Filing Fees, which are actual) of the approximate amount of the fees and expenses payable by us in connection with the issuance and distribution of the shares of our common stock.

EXPENSE	AMOUNT
SEC Registration Fees	$ 2,648.55
FINRA filing fees	3,376.36
Legal Fees and Expenses	170,000
Accounting Fees and Expenses	30,000
Printing Expense	10,000
Nasdaq listing Fee	75,000.00
Miscellaneous Fees and Expenses	8,975.09
Total	$ 300,000.00

* To be supplied in a subsequent amendment to this Registration Statement.

Item 14. Indemnification of Directors and Officers.

Our certificate of incorporation provides that no director is personally liable to the Company or its stockholders for monetary damages for any breach of fiduciary duty by such director as a director. Nonetheless, a director is liable to the extent provided by applicable law, (i) for breach of the director's duty of loyalty to the Company or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL (relating to unlawful payment of dividend or unlawful stock purchase or redemption) or (iv) for any transaction from which the director derived an improper personal benefit. If the DGCL is amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of the Company, in addition to the limitation on personal liability provided in our certificate of incorporation, will be limited to the fullest extent permitted by the amended DGCL. No amendment to or repeal of the relevant article of our certificate of incorporation will apply to or have any effect on the liability or alleged liability of any director of the Company for or with respect to any acts or omissions of such director occurring prior to such amendment.

Our certificate of incorporation and bylaws furthermore state that the Company shall indemnify, to the fullest extent permitted by Section 145 of the DGCL, as amended from time to time, each person that such section grants the Company the power to indemnify.

Section 145 of the DGCL provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending or completed actions, suits or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee of or agent to the Registrant. The statute provides that it is not exclusive of other rights to which those seeking indemnification may be entitled under any by-law, agreement, or vote of stockholders or disinterested directors or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of ours under Delaware law or otherwise, we have been advised the opinion of the SEC is that such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event a claim for indemnification against such liabilities (other than payment by us for expenses incurred or paid by a director, officer or controlling person of ours in successful defense of any action, suit, or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question of whether such indemnification by it is against public policy in the Securities Act and will be governed by the final adjudication of such issue.

Item 15. Recent Sales of Unregistered Securities.

On July 1, 2015 we issued non-qualified stock options for an aggregate of 800,000 shares of Common Stock with an exercise price of $5.41 per share to one employee and four consultants. The option expires five years from the date of grant.

In February 2014 we issued a non-qualified stock option for an aggregate of 250,000 shares of our Common Stock with an exercise price of $9.00 per share, to a director. The option expires 10 years from the date of grant.

In January 2014 we sold 471,334 shares of our Common Stock at $6.00 per share, yielding gross proceed of $2,828,000, in a private placement to accredited investors (the "Offering"). The Offering was exempt from the registration requirements of the Securities Act of 1933, as amended (the "Act"), pursuant to Sections 4(a)(2) and 4(a)(5) and Regulation D promulgated thereunder.

In December 2013 we issued non-qualified stock options for an aggregate of 450,000 shares of our Common Stock, each with an exercise price of $8.50 per share, to three consultants. All of the options expire 10 years from the date of grant.

In November 2013 we issued a non-qualified stock option for 100,000 shares of our Common Stock, with an exercise price of $8.40 per share, to a consultant. The option expires 10 years from the date of grant.

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

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

Item 16. Exhibits and Financial Statement Schedules.

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

EXHIBIT INDEX

1.1	Form of Underwriting Agreement	Filed herewith.
3.1	Certificate of Incorporation of the Company	Incorporated by reference, to Exhibit 3.1 to the Company's 8-K filing on December 6, 2004.
3.2	Bylaws of the Company	Incorporated by reference, to Exhibit 3.2 to the Company's 8-K filing on December 6, 2004.
3.3	State of Delaware, Certificate of Amendment of Certificate of Incorporation	Incorporated by reference, to Exhibit 3.3 to the Company 10-QSB filed on January 13, 2006.
4.1	Consolidated, Amended and Restated Promissory Note in the principal amount of $9,219,366, dated October 11, 2013	Incorporated by reference, to Exhibit 4.1 to the Company's Quarterly Report on Form 10Q filed on October 11, 2013.
4.2	Final form of Securities Purchase Agreement dated as of January 22, 2014 between the Company and certain accredited investors pursuant to which such investors were granted piggy back registration rights	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 10Q 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 10Q 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 10Q 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 10Q 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 10Q 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 the same numbered exhibit 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 the same numbered exhibit to the Company's Annual Report on Form 10-K filed on July 14, 2015.

4.11	Form of Warrant Certificate	To be filed by amendment.
4.12	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 10Q filed on October 13, 2015.
4.13	Secured Promissory Note issued to Niobe in the principal amount of $345,000 dated July 31, 2015	Incorporated by reference, to Exhibit 4.2 to the Company's Quarterly Report on Form 10Q filed on October 13, 2015.
4.14	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 10Q filed on October 13, 2015.
4.15	Secured Promissory Note issued to Niobe in the principal amount of $345,000 dated October 6, 2015	Incorporated by reference, to Exhibit 4.4 to the Company's Quarterly Report on Form 10Q filed on October 13, 2015.
4.16	Final Form of Secured Promissory Note issued to Niobe on November 10, 2015.	Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10Q filed on January 7, 2016.
4.17	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 10Q filed on January 7, 2016.
5.1	Opinion of Morse, Zelnick, Rose & Lander LLP	To be filed by amendment.
10.1	Frame Contract between the Company and Eurogentec S.A.	Incorporated by reference, to Exhibit 10.5 to the Company's 10-KSB/A filed on September 24, 2003.
10.2	Assignment of Intellectual Property from Alex LLC to the Company	Incorporated by reference, to Exhibit 10.8 to the Company's 10-KSB/A filed on September 24, 2003.
10.3	Assignment of Intellectual Property from Dr. Paul Mann to the Company	Incorporated by reference, to Exhibit 10.8 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
10.4	Protalex, Inc. 2003 Stock Option Plan Amended and Restated as of July 29, 2005	Incorporated by reference to Appendix B to the Company's Proxy Statement filed on September 23, 2005.
10.5	Service Contract with AAIPharma Inc., dated January 29, 2007	Incorporated by reference to Exhibit 10.18 to the Company's Quarterly Report on Form 10-QSB filed on April 13, 2007.
10.6	Indemnification Agreement with Directors and Executive Officers dated August 28, 2009	Incorporated by reference, to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on August 28, 2009.
10.7**	Final Form of Indemnification Agreement with current Directors, Executive Officers and the members of the Scientific Advisory Board	Incorporated by reference, to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 13, 2010.
10.8**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw December 29, 2009	Incorporate by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10Q filed on January 8, 2010.
10.9**	Form of Non-Qualified Stock Option Agreement with each of William Gannon, Edward Bernton and Valerie Jackson	Incorporated by reference, to Exhibit 4.9 to the Company's Annual Report on Form 10-K filed on August 27, 2010.
10.10**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw dated November 1, 2011.	Incorporated by reference, to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed on August 29, 2012.
10.11**	Form of Non-Qualified Stock Option Agreement with each of Edward Bernton and Valerie Jackson, dated November 1, 2011.	Incorporated by reference, to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed on August 29, 2012.
10.12**	Form of Non-Qualified Stock Option Agreement with Marco M. Elser dated February 4, 2014	Incorporate by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on February 20, 2014.
10.13**	Form of Non-Qualified Stock Option Agreement with Kirk M. Warshaw dated May 22, 2013	Incorporated by reference, to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on February 20, 2014.
10.14	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 10Q 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 10Q 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 10Q filed on October 13, 2015.
10.21	Exchange Agreement, dated June 2016, between Protalex,	Filed herewith.

	Inc. and Niobe Ventures, LLC	
10.22	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 8K filed on December 7, 2015.

10.23	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 8K filed on December 7, 2015.
23.1	Consent of Liggett & Webb, P.A.	Filed herewith.
23.2	Consent of Morse, Zelnick, Rose & Lander LLP	To be filed by amendment.
24.1	Power of Attorney	Previously filed.
99.1	Consent of Ralph Isham, Director Nominee	Filed herewith.
99.2	Consent of Doron Steger, Director Nominee	Filed herewith.
101.INS	*XBRL Instance Document*	To be filed by amendment.
101.SCH	*XBRL Taxonomy Extension Schema Document*	To be filed by amendment.
101.CAL	*XBRL Taxonomy Extension Calculation Linkbase Document*	To be filed by amendment.
101.LAB	*XBRL Taxonomy Extension Label Linkbase Document*	To be filed by amendment.
101.PRE	*XBRL Taxonomy Extension Presentation Linkbase Document*	To be filed by amendment.
101.DEF	*XBRL Taxonomy Extension Definition Linkbase Document*	To be filed by amendment.

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

Item 17. Undertakings.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, in the City of New York, State of New York on June 3, 2016.

Protalex, Inc.

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

Pursuant to the requirements of the Securities Act of 1933 this registration statement was signed by the following persons in the capacities and on the dates stated:

Signature	Title	Date
/s/ Arnold P. Kling Arnold P. Kling	President (Principal Executive Officer) and Director	June 3, 2016
* Kirk M. Warshaw	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) and Director	June 3, 2016
* Marco M. Elser	Director	June 3, 2016

* By: /s/ Arnold P. Kling
Arnold P. Kling, Attorney-in-fact

Exhibit 1.1

_____ SHARES OF COMMON STOCK AND

_____ WARRANTS OF

PROTALEX, INC.

UNDERWRITING AGREEMENT

_____, 2016

Chardan Capital Markets, LLC
As the Representative of the
Several underwriters, if any, named in Schedule I hereto
17 State Street, Suite 1600
New York, NY 10004

Ladies and Gentlemen:

The undersigned, Protalex, Inc., a company incorporated under the laws of Delaware (collectively with its subsidiaries and affiliates, including, without limitation, all entities disclosed or described in the Registration Statement as being subsidiaries or affiliates of Protalex, Inc., the "Company"), hereby confirms its agreement (this "Agreement") with the several underwriters (such underwriters, including the Representative (as defined below), the "Underwriters" and each an "Underwriter") named in Schedule I hereto for which Chardan Capital Markets, LLC is acting as representative to the several Underwriters (the "Representative" and if there are no Underwriters other than the Representative, references to multiple Underwriters shall be disregarded and the term Representative as used herein shall have the same meaning as Underwriter) on the terms and conditions set forth herein.

It is understood that the several Underwriters are to make a public offering of the Public Securities as soon as the Representative deems it advisable to do so. The Public Securities are to be initially offered to the public at the initial public offering price set forth in the Prospectus. The Representative may from time to time thereafter change the public offering price and other selling terms.

It is further understood that you will act as the Representative for the Underwriters in the offering and sale of the Closing Securities and, if any, the Option Securities in accordance with this Agreement.

ARTICLE I.
DEFINITIONS

1 . 1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

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

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

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

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

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

"Closing Date" means the hour and the date on the Trading Day on which all conditions precedent to (i) the Underwriters' obligations to pay the Closing Purchase Price and (ii) the Company's obligations to deliver the Closing Securities, in each case, have been satisfied or waived, but in no event later than 10:00 a.m. (New York City time) on the third Trading Day following the date hereof or at such earlier time as shall be agreed upon by the Representative and the Company.

"Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

"Closing Securities" shall have the meaning ascribed to such term in Section 2.1(a)(ii).

"Closing Shares" shall have the meaning ascribed to such term in Section 2.1(a)(i).

"Closing Warrants" shall have the meaning ascribed to such term in Section 2.1(a)(ii).

"Combined Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

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

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

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

"Company Auditor" means Liggett, Vogt & Webb, PA, with offices located at 432 Park Avenue South, New York, NY 10016.

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

"Debt-for-Equity Exchange" means the exchange of the outstanding principal amount of debt owed by the Company to Niobe Ventures, LLC as contemplated in the Prospectus.

"Debt Exchange Shares" means the shares of Common Stock issuable in connection with the Debt-for-Equity Exchange.

"Disclosure Schedules" means the Disclosure Schedules of the Company delivered concurrently herewith.

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

"Loeb" means Loeb & Loeb LLP, with offices located at 345 Park Avenue, New York, New York 10154.

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

"Execution Date" shall mean the date on which the parties execute and enter into this Agreement.

"Exempt Issuance" means the issuance of (a) shares of Common Stock or options to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that any such issuance shall only be to a Person (or to the equity holders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

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

"FINRA" means the Financial Industry Regulatory Authority.

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

"Indebtedness" means (a) any liabilities for borrowed money or amounts owed in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP.

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

"Lock-Up Agreements" shall mean the lock-up agreements, in the form of Exhibit D attached hereto, delivered on the date hereof by each of the Company's officers and directors holding Common Stock or Common Stock Equivalents and each holder of Common Stock and Common Stock Equivalents holding, on a fully diluted basis, more than 5% of the Company's issued and outstanding Common Stock listed in Schedule II to this Agreement.

"Material Adverse Effect" means (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document.

"Offering" shall have the meaning ascribed to such term in Section 2.1(c).

"Option Closing Date" shall have the meaning ascribed to such term in Section 2.2(c).

"Option Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.2(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

"Option Securities" shall have the meaning ascribed to such term in Section 2.2(a).

"Option Shares" shall have the meaning ascribed to such term in Section 2.2(a)(i).

"Option Warrants" shall have the meaning ascribed to such term in Section 2.2(a).

"Over-Allotment Option" shall have the meaning ascribed to such term in Section 2.2.

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

"Preliminary Prospectus" means, if any, any preliminary prospectus relating to the Securities included in the Registration Statement or filed with the Commission pursuant to Rule 424(b).

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

"Prospectus" means the final prospectus filed for the Registration Statement.

"Prospectus Supplement" means, if any, any supplement to the Prospectus complying with Rule 424(b) of the Securities Act that is filed with the Commission.

"Public Securities" means, collectively, the Closing Securities and, if any, the Option Securities.

"Registration Statement" means, collectively, the various parts of the registration statement prepared by the Company on Form S-1 (File No. 333-206008) with respect to the Securities, each as amended as of the date hereof, including the Prospectus and Prospectus Supplement, if any, the Preliminary Prospectus, if any, and all exhibits filed with or incorporated by reference into such registration statement.

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

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

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

"Securities" means the Closing Securities, the Option Securities and the Warrant Shares.

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

"Share Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Shares" means, collectively, the shares of Common Stock delivered to the Underwriters in accordance with Section 2.1(a)(i) and Section 2.2(a).

"Subsidiary" means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

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

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

"Transaction Documents" means this Agreement, the Warrants, the Underwriter's Warrant, the Lock-Up Agreements, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means the current transfer agent of the Company and any successor transfer agent of the Company.

"Underwriter's Warrant" shall have the meaning ascribed to such term in Section 2.3(viii).

"Warrant Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Warrant Shares" means the shares of Common Stock issuable upon exercise of the Warrants.

"Warrants" means, collectively, the Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a)(ii) and Section 2.2, which Warrants shall be exercisable immediately and have a term of exercise equal to five years.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing.

(a) Upon the terms and subject to the conditions set forth herein, the Company agrees to sell in the aggregate _____ shares of Common Stock and _____ Warrants, and each Underwriter agrees to purchase, severally and not jointly, at the Closing, the following securities of the Company:

(i) the number of shares of Common Stock (the "Closing Shares") set forth opposite the name of such Underwriter on Schedule I hereof; and

(ii) Warrants to purchase up to the number of shares of Common Stock set forth opposite the name of such Underwriter on Schedule I hereof (the "Closing Warrants" and, collectively with the Closing Shares, the "Closing Securities"), which Warrants shall have an exercise price of $____, subject to adjustment as provided therein, in the form of Exhibit F attached hereto.

(b) The aggregate purchase price for the Closing Securities shall equal the amount set forth opposite the name of such Underwriter on Schedule I hereto (the "Closing Purchase Price"). The combined purchase price for one Share and a Warrant to purchase [___ Warrant Share shall be $[_____ (the "Combined Purchase Price") which shall be allocated as $_____ per Share (the "Share Purchase Price") and $____ per Warrant (the "Warrant Purchase Price").

(c) On the Closing Date, each Underwriter shall deliver or cause to be delivered to the Company, via wire transfer, immediately available funds equal to such Underwriter's Closing Purchase Price and the Company shall deliver to, or as directed by, such Underwriter its respective Closing Securities and the Company shall deliver the other items required pursuant to Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4, the Closing shall occur at the offices of Loeb or such other location as the Company and Representative shall mutually agree. The Public Securities are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (the "Offering").

2.2 Over-Allotment Option.

(a) For the purposes of covering any over-allotments in connection with the distribution and sale of the Closing Securities, the Representative is hereby granted an option (the "Over-Allotment Option") to purchase, in the aggregate, up to _____ shares of Common Stock (the "Option Shares") and Warrants to purchase up to ____ shares of Common Stock (the "Option Warrants" and, collectively with the Option Shares, the "Option Securities")[1] which may be purchased in any combination of Option Shares and/or Option Warrants at the Share Purchase Price and/or Warrant Purchase Price, respectively.

[1] 15% of the Closing Shares and the Closing Warrants.

(b) In connection with an exercise of the Over-Allotment Option, (a) the purchase price to be paid for the Option Shares is equal to the product of the Share Purchase Price multiplied by the number of Option Shares to be purchased and (b) the purchase price to be paid for the Option Warrants is equal to the product of the Warrant Purchase Price multiplied by the number of Option Warrants (the aggregate purchase price to be paid on an Option Closing Date, the "Option Closing Purchase Price").

(c) The Over-Allotment Option granted pursuant to this Section 2.2 may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Securities within forty-five (45) days after the Execution Date. An Underwriter will not be under any obligation to purchase any Option Securities prior to the exercise of the Over-Allotment Option by the Representative. The Over-Allotment Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which must be confirmed in writing by overnight mail or facsimile or other electronic transmission setting forth the number of Option Shares and/or Option Warrants to be purchased and the date and time for delivery of and payment for the Option Securities (each, an "Option Closing Date"), which will not be later than three (3) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of Loeb or at such other place (including remotely by facsimile or other electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Securities does not occur on the Closing Date, each Option Closing Date will be as set forth in the notice. Upon exercise of the Over-Allotment Option, the Company will become obligated to convey to the Underwriters, and, subject to the terms and conditions set forth herein, the Underwriters will become obligated to purchase, the number of Option Shares and/or Option Warrants specified in such notice. The Representative may cancel the Over-Allotment Option at any time prior to the expiration of the Over-Allotment Option by written notice to the Company.

2.3 Deliveries. The Company shall deliver or cause to be delivered to each Underwriter (if applicable) the following:

(i) At the Closing Date, the Closing Shares and, as to each Option Closing Date, if any, the applicable Option Shares, which shares shall be delivered via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(ii) At the Closing Date, evidence of the issuance of the Closing Warrants and, as to each Option Closing Date, if any, of the applicable Option Warrants registered in the name or names and in such authorized denominations as the applicable Underwriter may request in writing at least two full Business Days prior to the Closing Date and, if any, each Option Closing Date;

(iii) [Reserved];

(iv) At the Closing Date, a legal opinion of Company Counsel addressed to the Underwriters, including, without limitation, a negative assurance letter, substantially in the form of Exhibit A attached hereto and as to the Closing Date and as to each Option Closing Date, if any, a bring-down opinion from Company Counsel in form and substance reasonably satisfactory to the Representative to the Company, including, without limitation, a negative assurance letter, addressed to the Placement Agent and in form and substance satisfactory to the Placement Agent;

(v) Contemporaneously herewith, a cold comfort letter, addressed to the Underwriters and in form and substance satisfactory in all respects to the Representative from the Company Auditor dated, respectively, as of the date of this Agreement and a bring-down letter dated as of the Closing Date and each Option Closing Date, if any;

(vi) On the Closing Date and on each Option Closing Date, the duly executed and delivered Officer's Certificate, substantially in the form required by Exhibit B attached hereto;

(vii) On the Closing Date and on each Option Closing Date, the duly executed and delivered Secretary's Certificate, substantially in the form required by Exhibit C attached hereto; and

(viii) On the Closing Date and on each Option Closing Date, the Company shall execute and deliver to the Representative or its designee a warrant in the form attached hereto as Exhibit E (the "Underwriter's Warrants"), evidencing the right to purchase a number of warrants equal to eight percent (8%) of the total number of Closing Shares or Option Shares, as the case may be, at a price per warrant equal to one hundred and ten percent (110%) of the public offering price per Closing Share as set forth in the Registration Statement. The Underwriter's Warrants shall become exercisable on the one year anniversary of the effective date of the Registration Statement, and shall expire on the five year anniversary of the effective date of the Registration Statement.

(ix) Contemporaneously herewith, the duly executed and delivered Lock-Up Agreements.

2 . 4 Closing Conditions. The respective obligations of each Underwriter hereunder in connection with the Closing and each Option Closing Date are subject to the following conditions being met:

(i) the accuracy in all material respects when made and on the date in question (other than representations and warranties of the Company already qualified by materiality, which shall be true and correct in all respects) of the representations and warranties of the Company contained herein (unless as of a specific date therein);

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

(iii) the delivery by the Company of the items set forth in Section 2.3 of this Agreement;

(iv) the Registration Statement shall be effective on the date of this Agreement and at each of the Closing Date and each Option Closing Date, if any, no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been instituted or shall be pending or contemplated by the Commission and any request on the part of the Commission for additional information shall have been complied with to the reasonable satisfaction of the Representative;

(v) by the Execution Date the Underwriters shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement;

(vi) the Closing Shares, the Option Shares and the Warrant Shares have been approved for listing on the Nasdaq Capital Market upon notice of issuance or another national securities exchange acceptable to the Representative; and

(vii) prior to and on each of the Closing Date and each Option Closing Date, if any: (i) there shall have been no material adverse change or development involving a prospective material adverse change in the condition or prospects or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement and Prospectus; (ii) no action suit or proceeding, at law or in equity, shall have been pending or threatened in writing against the Company or any Affiliate of the Company before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding may materially adversely affect the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement and Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; and (iv) the Registration Statement and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the rules and regulations thereunder and shall conform in all material respects to the requirements of the Securities Act and the rules and regulations thereunder, and neither the Registration Statement nor the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. Except as set forth in the Disclosure Schedules, which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules, the Company represents and warrants to the Underwriters as of the Execution Date, as of the Closing Date and as of each Option Closing Date, if any, as follows:

(a) Subsidiaries. All of the direct and indirect Subsidiaries of the Company are set forth in the SEC Reports. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no Subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in a Material Adverse Effect and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

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

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

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filing with the Commission of the Prospectus and (ii) such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").

(f) Registration Statement. The Company has filed with the Commission the Registration Statement, including any related Prospectus or Prospectuses, for the registration of the Securities under the Securities Act, which Registration Statement has been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act. The Registration Statement has been declared effective by the Commission on the date hereof (the "Effective Date"). The Company has filed with the Commission a Form 8-A (File Number 000-_____) providing for the registration under the Exchange Act of Closing Shares, the Option Shares and the Warrant Shares. The Company has advised the Representative of all further information (financial and other) with respect to the Company required to be set forth therein in the Registration Statement and Prospectus Supplement. Any reference in this Agreement to the Registration Statement, the Prospectus or the Prospectus Supplement shall be deemed to refer to and include the documents incorporated by reference therein pursuant to Items 11A and 12 of Form S-1 which were filed under the Securities Exchange Act, on or before the date of this Agreement, or the issue date of the Prospectus or the Prospectus Supplement, as the case may be; and any reference in this Agreement to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement, the Prospectus or the Prospectus Supplement shall be deemed to refer to and include the filing of any document under the Exchange Act after the date of this Agreement, or the issue date of the Prospectus or the Prospectus Supplement, as the case may be, deemed to be incorporated therein by reference. All references in this Agreement to financial statements and schedules and other information which is "contained," "included," "described," "referenced," "set forth" or "stated" in the Registration Statement, the Prospectus or the Prospectus Supplement (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Prospectus or the Prospectus Supplement, as the case may be. No stop order suspending the effectiveness of the Registration Statement or the use of the Prospectus or the Prospectus Supplement has been issued, and no proceeding for any such purpose is pending or has been initiated or, to the Company's knowledge, is threatened by the Commission. For purposes of this Agreement, "free writing prospectus" has the meaning set forth in Rule 405 under the Securities Act. The Company will not, without the prior consent of the Representative, prepare, use or refer to, any free writing prospectus.

(g) Issuance of Securities. The Securities and the Underwriter's Warrants are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Warrant Shares, when issued in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The shares of Common Stock underlying the Underwriter's Warrant, when issued in accordance with the terms of the Underwriter's Warrant, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement, the Warrants and the Underwriter's Warrant. The holder of the Securities and the Underwriter's Warrants will not be subject to personal liability by reason of being such holders. The Securities and the Underwriter's Warrants are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. All corporate action required to be taken for the authorization, issuance and sale of the Securities and the Underwriter's Warrants has been duly and validly taken. The Securities and the Underwriter's Warrants conform in all material respects to all statements with respect thereto contained in the Registration Statement.

(h) Capitalization. The capitalization of the Company is as set forth in the SEC Reports. Other than the Debt Exchange Shares, the Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. Except as a result of the purchase and sale of the Securities, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents. The issuance and sale of the Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Underwriters) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. The authorized shares of the Company conform in all material respects to all statements relating thereto contained in the Registration Statement and the Prospectus. The offers and sales of the Company's securities were at all relevant times either registered under the Securities Act and the applicable state securities or Blue Sky laws or, based in part on the representations and warranties of the purchasers, exempt from such registration requirements. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholder agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(i) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Prospectus and the Prospectus Supplement, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments. The agreements and documents described in the Registration Statement, the Prospectus, the Prospectus Supplement and the SEC Reports conform to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the rules and regulations thereunder to be described in the Registration Statement, the Prospectus, the Prospectus Supplement or the SEC Reports or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Prospectus, the Prospectus Supplement or the SEC Reports, or (ii) is material to the Company's business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefore may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the best of the Company's knowledge, any other party is in default thereunder and, to the best of the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder. To the best of the Company's knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses, including, without limitation, those relating to environmental laws and regulations.

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

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

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect (each, a "Material Permit"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit. The disclosures in the Registration Statement concerning the effects of Federal, State, local and all foreign regulation on the Company's business as currently contemplated are correct in all material respects.

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

(p) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(q) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(r) Transactions with Affiliates and Employees. Except as set forth in the SEC Reports, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from, any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $100,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

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

(t) Certain Fees. Except as set forth in the Prospectus, no brokerage or finder's fees or commissions are or will be payable by the Company, any Subsidiary or Affiliate of the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. To the Company's knowledge, there are no other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its stockholders that may affect the Underwriter's compensation, as determined by FINRA. The Company has not made any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member, other than a $10,000 payment made to Drexel Hamilton, LLC in February 2015; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the twelve (12) months prior to the Execution Date. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

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

(v) Registration Rights. No Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration. The Company has not, in the twelve (12) months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements.

(x) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable as a result of the Underwriters and the Company fulfilling their obligations or exercising their rights under the Transaction Documents.

(y) Disclosure; 10b-5. The Registration Statement (and any further documents to be filed with the Commission) contains all exhibits and schedules as required by the Securities Act. Each of the Registration Statement and any post-effective amendment thereto, if any, at the time it became effective, complied in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations under the Securities Act and did not and, as amended or supplemented, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus and the Prospectus Supplement, each as of its respective date, comply in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations. Each of the Prospectus and the Prospectus Supplement, as amended or supplemented, did not and will not contain as of the date thereof any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The SEC Reports, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, and none of such documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (with respect to the SEC Reports incorporated by reference in the Prospectus or Prospectus Supplement), in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Prospectus or Prospectus Supplement, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made not misleading. No post-effective amendment to the Registration Statement reflecting any facts or events arising after the date thereof which represent, individually or in the aggregate, a fundamental change in the information set forth therein is required to be filed with the Commission. There are no documents required to be filed with the Commission in connection with the transaction contemplated hereby that (x) have not been filed as required pursuant to the Securities Act or (y) will not be filed within the requisite time period. There are no contracts or other documents required to be described in the Prospectus or Prospectus Supplement, or to be filed as exhibits or schedules to the Registration Statement, which have not been described or filed as required. The press releases disseminated by the Company during the twelve (12) months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading.

(z) No Integrated Offering. Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(a a) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. The SEC Reports sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments.

(bb) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. The term "taxes" mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatsoever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(cc) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA. The Company has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the FCPA.

(dd) Accountants. To the knowledge and belief of the Company, the Company Auditor (i) is an independent registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending May 31, 2016. The Company Auditor has not, during the periods covered by the financial statements included in the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

(ee) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration (" FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a "Pharmaceutical Product"), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(ff) *Consents to Conduct Business*. Except as disclosed in the Registration Statement, the Prospectus Supplement and the Prospectus, the Company has all consents, approvals, authorizations, orders, registrations, qualifications, licenses, filings and permits of, with and from all judicial, regulatory and other legal or governmental agencies and bodies and all third parties, foreign and domestic, including, without limitation, FDA or equivalent in non-U.S. jurisdictions (collectively, the " Consents"), to own, lease and operate its properties and conduct its business as it is now being conducted and as disclosed in the Registration Statement, the Prospectus Supplement and the Prospectus, and each such Consent is valid and in full force and effect, except which (individually or in the aggregate), in each such case, would not reasonably be expected to have a Material Adverse Effect. The Company has not received notice of any investigation or proceedings which, if decided adversely to the Company, could reasonably be expected to result in, the revocation of, or imposition of a materially burdensome restriction on, any Consent. No Consent contains a materially burdensome restriction not adequately disclosed in the Registration Statement, the Prospectus Supplement and the Prospectus.

(g g) *Clinical, Pre-clinical and Other Studies*. The clinical, pre-clinical and other studies and tests ("Studies") conducted by or on behalf of or sponsored by the Company that are described or referred to in the Registration Statement, the General Disclosure Package and the Prospectus were and, if still pending, are, being conducted in accordance with all applicable statutes, laws, rules and regulations (including, without limitation, those administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA), as well as the protocols, procedures and controls designed and approved for such Studies and with standard medical and scientific research procedures, except where the failure to be so conducted would not have a Material Adverse Effect. The descriptions of the results of such Studies that are described or referred to in the Registration Statement, the Prospectus Supplement and the Prospectus are accurate and complete in all material respects and fairly present the data derived from such Studies. Except as disclosed in the Registration Statement, the Prospectus Supplement and the Prospectus, the Company has not received any notices or other correspondence from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA requiring the termination or suspension of such Studies, other than ordinary course communications with respect to modifications in connection with the design and implementation of such Studies.

(h h) *No Failure to File with a Governmental Authority; Governmental Permits*. Except as would not result in a Material Adverse Effect, the Company has not failed to file with the applicable regulatory authorities (including the FDA or any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA and having jurisdiction over the Company) any filing, declaration, listing, registration, report or submission that is required to be so filed for the Company's business operation as currently conducted. All such filings complied in all material respects with applicable laws when filed and no deficiencies have been asserted in writing by any applicable regulatory authority (including, without limitation, the FDA or any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) with respect to any such filings, declarations, listings, registrations, reports or submissions. The Company holds, and is in material compliance with, all franchises, grants, authorizations, licenses, permits, easements, consents, certificates and orders ("Permits") of any governmental or self-regulatory agency, authority or body (including, without limitation, those administered by FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA and having jurisdiction over the Company) required for the conduct of the Company's business as currently conducted, and all such Permits are in full force and effect, in each case except where the failure to hold, or comply with, any of them is not reasonably likely to result in a Material Adverse Effect.

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

(jj) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon the Representative's request.

(kk) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

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

(mm) D&O Questionnaires. To the Company's knowledge, all information contained in the questionnaires completed by each of the Company's directors and officers immediately prior to the Offering as well as in the Lock-Up Agreement provided to the Underwriters is true and correct in all respects and the Company has not become aware of any information which would cause the information disclosed in such questionnaires become inaccurate and incorrect.

(nn) FINRA Affiliation. No officer, director or any beneficial owner of five (5%) or more of the Company's unregistered securities has any direct or indirect affiliation or association with any FINRA member (as determined in accordance with the rules and regulations of FINRA). The Company will advise the Representative and Loeb if it learns that any officer, director or owner of 5% or more of the Company's outstanding shares of Common Stock or Common Stock Equivalents is or becomes an affiliate or associated person of a FINRA member firm.

(oo) Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to you or to Loeb shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

(pp) Lock-up Period. The Company agrees with the Underwriters that the Company will not, for a period of __ days from the date of this Agreement (the "Lock-Up Period"), without the prior written consent of the Representative, directly or indirectly offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, other than the Company's sale of the Public Securities hereunder and the issuance of options to acquire Common Stock pursuant to the Company's employee benefit plans, qualified stock option plans or other employee compensation plans consistent with past practice, and the issuance of Common Stock pursuant to the valid exercises of options, warrants or rights outstanding on the date hereof. The Company will cause each officer, director and shareholder listed in Schedule II to furnish to the Representative, prior to the date hereof, a letter, substantially in the form of Exhibit D hereto, pursuant to which each such person shall agree, among other things, not to directly or indirectly offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, not to engage in any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, directly or indirectly, the economic risk of ownership of Common Stock or any such securities during the Lock-Up Period, without the prior written consent of the Representative. The Company also agrees that during such period, other than for the sale of the Public Securities hereunder, the Company will not file any registration statement, preliminary prospectus or prospectus, or any amendment or supplement thereto, under the Securities Act for any such transaction or which registers, or offers for sale, Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, except for registration statements on Form S-8 relating to employee benefit plans. Notwithstanding the foregoing, if (x) during the last 17 days of the initial Lock-Up Period, the Company releases earnings results or material news or a material event relating to the Company occurs or (y) prior to the expiration of the initial Lock-Up Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the initial Lock-Up Period, then in each case the Lock-Up Period will be extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the occurrence of the material news or material event, as applicable, unless the Representative waives, in writing, such extension.

(qq) Board of Directors. The Board of Directors is comprised of the persons set forth under the heading of the Prospectus captioned "Management." The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder applicable to the Company and the rules of the Trading Market. At least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and the rules of the Trading Market. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent" as defined under the rules of the Trading Market.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4 . 1 Amendments to Registration Statement. The Company has delivered, or will as promptly as practicable deliver, to the Underwriters complete conformed copies of the Registration Statement and of each consent and certificate of experts, as applicable, filed as a part thereof, and conformed copies of the Registration Statement (without exhibits), the Prospectus and the Prospectus Supplement, as amended or supplemented, in such quantities and at such places as an Underwriter reasonably requests. Neither the Company nor any of its directors and officers has distributed and none of them will distribute, prior to the Closing Date, any offering material in connection with the offering and sale of the Securities other than the Prospectus, the Prospectus Supplement, the Registration Statement, and copies of the documents incorporated by reference therein. The Company shall not file any such amendment or supplement to which the Representative shall reasonably object in writing.

4.2 Federal Securities Laws.

(a) Compliance. During the time when a Prospectus is required to be delivered under the Securities Act, the Company will use its best efforts to comply with all requirements imposed upon it by the Securities Act and the rules and regulations thereunder and the Exchange Act and the rules and regulations thereunder, as from time to time in force, so far as necessary to permit the continuance of sales of or dealings in the Securities in accordance with the provisions hereof and the Prospectus. If at any time when a Prospectus relating to the Securities is required to be delivered under the Securities Act, any event shall have occurred as a result of which, in the opinion of counsel for the Company or counsel for the Underwriters, the Prospectus, as then amended or supplemented, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, or if it is necessary at any time to amend the Prospectus to comply with the Securities Act, the Company will notify the Underwriters promptly and prepare and file with the Commission, subject to Section 4.1 hereof, an appropriate amendment or supplement in accordance with Section 10 of the Securities Act.

(b) Exchange Act Registration. For a period of three years from the Execution Date, the Company will use its best efforts to maintain the registration of the Common Stock and Warrants under the Exchange Act. The Company will not deregister the Common Stock or the Warrants under the Exchange Act without the prior written consent of the Representative.

(c) Free Writing Prospectuses. The Company represents and agrees that it has not made and will not make any offer relating to the Securities that would constitute an issuer free writing prospectus, as defined in Rule 433 of the rules and regulations under the Securities Act, without the prior written consent of the Representative. Any such free writing prospectus consented to by the Representative is hereinafter referred to as a **"**Permitted Free Writing Prospectus." The Company represents that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus" as defined in rule and regulations under the Securities Act, and has complied and will comply with the applicable requirements of Rule 433 of the Securities Act, including timely Commission filing where required, legending and record keeping.

4.3 Delivery to the Underwriters of Prospectuses. The Company will deliver to the Underwriters, without charge, from time to time during the period when the Prospectus is required to be delivered under the Securities Act or the Exchange Act such number of copies of each Prospectus as the Underwriters may reasonably request and, as soon as the Registration Statement or any amendment or supplement thereto becomes effective, deliver to you two original executed Registration Statements, including exhibits, and all post-effective amendments thereto and copies of all exhibits filed therewith or incorporated therein by reference and all original executed consents of certified experts.

4.4 Effectiveness and Events Requiring Notice to the Underwriters. The Company will use commercially reasonable best efforts to cause the Registration Statement to remain effective with a current prospectus until nine (9) months from the Execution Date, and will notify the Underwriters and holders of the Warrants immediately and confirm the notice in writing: (i) of the effectiveness of the Registration Statement and any amendment thereto; (ii) of the issuance by the Commission of any stop order or of the initiation, or the threatening, of any proceeding for that purpose; (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iv) of the mailing and delivery to the Commission for filing of any amendment or supplement to the Registration Statement or Prospectus; (v) of the receipt of any comments or request for any additional information from the Commission; and (vi) of the happening of any event during the period described in this Section 4.4 that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement or the Prospectus untrue or that requires the making of any changes in the Registration Statement or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company will make every reasonable effort to obtain promptly the lifting of such order.

4.5 Review of Financial Statements. For a period of five (5) years from the Execution Date, the Company, at its expense, shall cause its regularly engaged independent registered public accountants to review (but not audit) the Company's financial statements for each of the first three fiscal quarters prior to the announcement of quarterly financial information.

4.6 Reports to the Underwriters.

(a) Periodic Reports, etc. For a period of three years from the Execution Date, the Company will furnish to the Underwriters copies of such financial statements and other periodic and special reports as the Company from time to time furnishes generally to holders of any class of its securities and also promptly furnish to the Underwriters: (i) a copy of each periodic report the Company shall be required to file with the Commission; (ii) a copy of every press release and every news item and article with respect to the Company or its affairs which was released by the Company; (iii) a copy of each Form 8-K prepared and filed by the Company; (iv) a copy of each registration statement filed by the Company under the Securities Act; (v) such additional documents and information with respect to the Company and the affairs of any future Subsidiaries of the Company as the Representative may from time to time reasonably request; provided that the Underwriters shall each sign, if requested by the Company, a Regulation FD compliant confidentiality agreement which is reasonably acceptable to the Representative in connection with such Underwriter's receipt of such information. Documents filed with the Commission pursuant to its EDGAR system shall be deemed to have been delivered to the Underwriters pursuant to this Section.

(b) Transfer Sheets. For a period of three (3) years from the Execution Date, the Company shall retain the Transfer Agent or a transfer and registrar agent acceptable to the Representative and will furnish to the Underwriters at the Company's sole cost and expense such transfer sheets of the Company's securities as an Underwriter may reasonably request, including the daily and monthly consolidated transfer sheets of the Transfer Agent and the DTC.

(c) Trading Reports. During such time as the Closing Shares, Option Shares and Warrant Shares are listed on the Trading Market, the Company shall provide to the Underwriters, at the Company's expense, such reports published by the Trading Market relating to price and trading of such shares, as the Underwriters shall reasonably request.

(d) General Expenses Related to the Offering. The Company hereby agrees to pay all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the Securities to be sold in the Offering (including the Option Securities) with the Commission; (b) all FINRA Public Offering Filing System fees associated with the review of the Offering by FINRA; (c) all fees and expenses relating to the listing of such Closing Shares, Option Shares and Warrant Shares on the Trading Market and such other stock exchanges as the Company and the Representative together determine; (d) all fees, expenses and disbursements relating to the registration or qualification of such Securities under the "blue sky" securities laws of such states and other foreign jurisdictions as the Representative may reasonably designate (including, without limitation, all filing and registration fees, if any), provided, however, that a budget for "blue sky" fees and expenses shall be pre-approved in writing by the Company; (e) the costs of printing the underwriting documents (including, without limitation, the Underwriting Agreement, and, if appropriate, any Agreement Among Underwriters, Selected Dealers' Agreement, Underwriter's Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (f) the costs of preparing, printing and delivering the Securities; (g) fees and expenses of the Transfer Agent for the Securities (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company); (h) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriter; (i) the fees and expenses of the Company's accountants; (j) the fees and expenses of the Company's legal counsel and other agents and representatives; (k) the Underwriters' costs of mailing prospectuses to prospective investors; and (l) other reasonable out-of-pocket expenses of the Representative incurred as a result of performing its services in connection with the Offering, subject to presentation of appropriate documentations evidencing such out-of-pocket expenses, which amount shall not exceed a maximum of 1% of the gross proceeds of the Offering. The Company has paid the Representative monthly retainer fees in the aggregate amount of [$90,000] (the "Advance"). The Advance paid will be credited against underwriting discounts and commissions payable to the Representative hereunder.

4.7 Application of Net Proceeds. The Company will apply the net proceeds from the Offering received by it in a manner consistent with the application described under the caption "Use of Proceeds" in the Prospectus.

4.8 Delivery of Earnings Statements to Security Holders. The Company will make generally available to its security holders as soon as practicable, but not later than the first day of the fifteenth full calendar month following the Execution Date, an earnings statement (which need not be certified by independent public or independent certified public accountants unless required by the Securities Act or the Rules and Regulations under the Securities Act, but which shall satisfy the provisions of Rule 158(a) under Section 11(a) of the Securities Act) covering a period of at least twelve consecutive months beginning after the Execution Date.

4.9 Stabilization. Neither the Company, nor, to its knowledge, any of its employees, directors or shareholders (without the consent of the Representative) has taken or will take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

4.10 Internal Controls. The Company will maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

4.11 Accountants. The Company shall continue to retain a nationally recognized independent certified public accounting firm for a period of at least three years after the Execution Date. The Underwriters acknowledge that the Company Auditor is acceptable to the Underwriters.

4.12 FINRA. The Company shall advise the Underwriters (who shall make an appropriate filing with FINRA) if it is aware that any five percent (5%) or greater shareholder of the Company becomes an affiliate or associated person of a FINRA member firm.

4.13 No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual and commercial in nature, based on arms-length negotiations and that neither the Underwriters nor their affiliates or any selected dealer shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement. Notwithstanding anything in this Agreement to the contrary, the Company acknowledges that the Underwriters may have financial interests in the success of the Offering that are not limited to the difference between the price to the public and the purchase price paid to the Company by the Underwriters for the shares and the Underwriters have no obligation to disclose, or account to the Company for, any of such additional financial interests. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any breach or alleged breach of fiduciary duty.

4.14 Warrant Shares. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance of the Warrant Shares or if the Warrant is exercised via cashless exercise at a time when such Warrant Shares would be eligible for resale under Rule 144 by a non-affiliate of the Company, the Warrant Shares issued pursuant to any such exercise shall be issued free of all restrictive legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Warrant Shares) is not effective or is not otherwise available for the sale of the Warrant Shares, the Company shall immediately notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any holder thereof to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws).

4.15 Board Composition and Board Designations. The Company shall ensure that: (i) the qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and with the listing requirements of the Trading Market and (ii) if applicable, at least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder.

4.16 Securities Laws Disclosure; Publicity. At the request of the Representative, by 9:00 a.m. (New York City time) on the date hereof, the Company shall issue a press release disclosing the material terms of the Offering. The Company and the Representative shall consult with each other in issuing any other press releases with respect to the Offering, and neither the Company nor any Underwriter shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of such Underwriter, or without the prior consent of such Underwriter, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. The Company will not issue press releases or engage in any other publicity, without the Representative's prior written consent, for a period ending at 5:00 p.m. (New York City time) on the first business day following the 40th day following the Closing Date, other than normal and customary releases issued in the ordinary course of the Company's business.

4.17 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Underwriter of the Securities is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Underwriter of Securities could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities.

4.18 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Option Shares pursuant to the Over-Allotment Option and Warrant Shares pursuant to any exercise of the Warrants.

4.19 Listing of Common Stock. The Company hereby agrees to use best efforts to maintain the listing or quotation of the Common Stock on a national securities exchange for the life of the Warrants, and concurrently with the Closing, the Company shall apply to list or quote all of the Closing Shares, Option Shares and Warrant Shares on the Nasdaq Global Market and promptly secure the listing of all of the Closing Shares, Option Shares and Warrant Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Closing Shares, Option Shares and Warrant Shares, and will take such other action as is necessary to cause all of the Closing Shares, Option Shares and Warrant Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market.

4.20 Right of First Refusal.

Effective upon the Closing of the Offering, if the Offering results in gross proceeds to the Company of at least $7.0 million, then, for a period of twelve (12) months following the Effective Date, the Company hereby grants the Representative a right of first refusal to act as the lead or co-lead book-running manager, placement agent or financial advisor for each and every future offering during such period (each a "Subject Transaction"). The Company shall notify the Representative of its intention to pursue a Subject Transaction, including the material terms thereof, by providing written notice thereof by registered mail or overnight courier service addressed to the Representative. If the Representative fails to exercise its right of first refusal with respect to any Subject Transaction within five (5) business days after transmittal of such notice, then the Representative shall have no further claim or right with respect to the Subject Transaction. The Representative may elect, in its sole and absolute discretion, not to exercise its right of first refusal with respect to any Subject Transaction; provided that any such election by a Representative shall not adversely affect the Representative's right of first refusal with respect to any other Subject Transaction. The terms and conditions of any such engagements shall be set forth in separate agreements and may be subject to, among other things, satisfactory completion of due diligence by the Representative, market conditions, the absence of a material adverse change to the Company's business, financial condition and prospects, approval of the Representative's internal committee and any other conditions that the Representative may deem appropriate for transactions of such nature. The Representative will not have more than one opportunity to waive or terminate the right of first refusal in consideration of any payment or fee.

4.21 Subsequent Equity Sales.

(a) From the date hereof until no Warrants are outstanding, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. "Variable Rate Transaction" means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price; provided, nothing herein shall prohibit the company from conducting a registered at-the-market offering in compliance with Rule 415. Any Underwriter shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages.

(b) Notwithstanding the foregoing, this Section 4.21 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.22 Research Independence. In addition, the Company acknowledges that each Underwriter's research analysts and research departments, if any, are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriter's research analysts may hold and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the offering that differ from the views of its investment bankers. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against such Underwriter with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by such Underwriter's investment banking divisions. The Company acknowledges that the Representative is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short position in debt or equity securities of the Company.

ARTICLE V.
DEFAULT BY UNDERWRITERS

If on the Closing Date or any Option Closing Date, if any, any Underwriter shall fail to purchase and pay for the portion of the Closing Securities or Option Securities, as the case may be, which such Underwriter has agreed to purchase and pay for on such date (otherwise than by reason of any default on the part of the Company), the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, shall use their reasonable efforts to procure within thirty-six (36) hours thereafter one or more of the other Underwriters, or any others, to purchase from the Company such amounts as may be agreed upon and upon the terms set forth herein, the Closing Securities or Option Securities, as the case may be, which the defaulting Underwriter or Underwriters failed to purchase. If during such thirty-six (36) hours the Representative shall not have procured such other Underwriters, or any others, to purchase the Closing Securities or Option Securities, as the case may be, agreed to be purchased by the defaulting Underwriter or Underwriters, then (a) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur does not exceed ten percent (10%) of the Closing Securities or Option Securities, as the case may be, covered hereby, the other Underwriters shall be obligated, severally, in proportion to the respective numbers of Closing Securities or Option Securities, as the case may be, which they are obligated to purchase hereunder, to purchase the Closing Securities or Option Securities, as the case may be, which such defaulting Underwriter or Underwriters failed to purchase, or (b) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur exceeds ten percent (10%) of the Closing Securities or Option Securities, as the case may be, covered hereby, the Company or the Representative will have the right to terminate this Agreement without liability on the part of the non-defaulting Underwriters or of the Company except to the extent provided in Article VI hereof. In the event of a default by any Underwriter or Underwriters, as set forth in this Article V, the applicable Closing Date may be postponed for such period, not exceeding seven (7) days, as the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, may determine in order that the required changes in the Prospectus or in any other documents or arrangements may be effected. The term "Underwriter" includes any person substituted for a defaulting Underwriter. Any action taken under this Section shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

ARTICLE VI.
INDEMNIFICATION

6 . 1 Indemnification of the Underwriters. Subject to the conditions set forth below, the Company agrees to indemnify and hold harmless the Underwriters, and each dealer selected by each Underwriter that participates in the offer and sale of the Securities (each a "Selected Dealer") and each of their respective directors, officers and employees and each Person, if any, who controls such Underwriter or any Selected Dealer ("Controlling Person") within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any and all loss, liability, claim, damage and expense whatsoever (including but not limited to any and all legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between such Underwriter and the Company or between such Underwriter and any third party or otherwise) to which they or any of them may become subject under the Securities Act, the Exchange Act or any other statute or at common law or otherwise or under the laws of foreign countries, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) any Preliminary Prospectus, if any, the Registration Statement or the Prospectus (as from time to time each may be amended and supplemented); (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically); or (iii) any application or other document or written communication (in this Article VI, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, Trading Market or any securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon and in conformity with written information furnished to the Company with respect to the applicable Underwriter by or on behalf of such Underwriter expressly for use in any Preliminary Prospectus, if any, the Registration Statement or Prospectus, or any amendment or supplement thereto, or in any application, as the case may be. With respect to any untrue statement or omission or alleged untrue statement or omission made in the Preliminary Prospectus, if any, the indemnity agreement contained in this Section 6.1 shall not inure to the benefit of an Underwriter to the extent that any loss, liability, claim, damage or expense of such Underwriter results from the fact that a copy of the Prospectus was not given or sent to the Person asserting any such loss, liability, claim or damage at or prior to the written confirmation of sale of the Securities to such Person as required by the Securities Act and the rules and regulations thereunder, and if the untrue statement or omission has been corrected in the Prospectus, unless such failure to deliver the Prospectus was a result of non-compliance by the Company with its obligations under this Agreement. The Company agrees promptly to notify each Underwriter of the commencement of any litigation or proceedings against the Company or any of its officers, directors or Controlling Persons in connection with the issue and sale of the Public Securities or in connection with the Registration Statement or Prospectus.

6.2 Procedure. If any action is brought against an Underwriter, a Selected Dealer or a Controlling Person in respect of which indemnity may be sought against the Company pursuant to Section 6.1, such Underwriter, such Selected Dealer or Controlling Person, as the case may be, shall promptly notify the Company in writing of the institution of such action and the Company shall assume the defense of such action, including the employment and fees of counsel (subject to the reasonable approval of such Underwriter or such Selected Dealer, as the case may be) and payment of actual expenses. Such Underwriter, such Selected Dealer or Controlling Person shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such Underwriter, such Selected Dealer or Controlling Person unless (i) the employment of such counsel at the expense of the Company shall have been authorized in writing by the Company in connection with the defense of such action, or (ii) the Company shall not have employed counsel to have charge of the defense of such action, or (iii) such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from or additional to those available to the Company (in which case the Company shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events the reasonable fees and expenses of not more than one additional firm of attorneys selected by such Underwriter (in addition to local counsel), Selected Dealer and/or Controlling Person shall be borne by the Company. Notwithstanding anything to the contrary contained herein, if any Underwriter, Selected Dealer or Controlling Person shall assume the defense of such action as provided above, the Company shall have the right to approve the terms of any settlement of such action which approval shall not be unreasonably withheld.

6.3 Indemnification of the Company. Each Underwriter severally and not jointly agrees to indemnify and hold harmless the Company, its directors, officers and employees and agents who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the foregoing indemnity from the Company to such Underwriter, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, written information furnished to the Company with respect to such Underwriter by or on behalf of such Underwriter expressly for use in such Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any such application. In case any action shall be brought against the Company or any other Person so indemnified based on any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or any application, and in respect of which indemnity may be sought against such Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other Person so indemnified shall have the rights and duties given to such Underwriter by the provisions of this Article VI. Notwithstanding the provisions of this Section 6.3, no Underwriter shall be required to indemnify the Company for any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriter's obligations in this Section 6.3 to indemnify the Company are several in proportion to their respective underwriting obligations and not joint.

6.4 Contribution.

(a) Contribution Rights. In order to provide for just and equitable contribution under the Securities Act in any case in which (i) any Person entitled to indemnification under this Article VI makes a claim for indemnification pursuant hereto but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Article VI provides for indemnification in such case, or (ii) contribution under the Securities Act, the Exchange Act or otherwise may be required on the part of any such Person in circumstances for which indemnification is provided under this Article VI, then, and in each such case, the Company and each Underwriter, severally and not jointly, shall contribute to the aggregate losses, liabilities, claims, damages and expenses of the nature contemplated by said indemnity agreement incurred by the Company and such Underwriter, as incurred, in such proportions that such Underwriter is responsible for that portion represented by the percentage that the underwriting discount appearing on the cover page of the Prospectus bears to the initial offering price appearing thereon and the Company is responsible for the balance; provided, that, no Person guilty of a fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. For purposes of this Section, each director, officer and employee of such Underwriter or the Company, as applicable, and each Person, if any, who controls such Underwriter or the Company, as applicable, within the meaning of Section 15 of the Securities Act shall have the same rights to contribution as such Underwriter or the Company, as applicable. Notwithstanding the provisions of this Section 6.4, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriter's obligations in this Section 6.4 to contribute are several in proportion to their respective underwriting obligations and not joint.

(b) Contribution Procedure. Within fifteen (15) days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made against another party ("contributing party"), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid fifteen days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 6.4 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available.

ARTICLE VII.
MISCELLANEOUS

7.1 Termination.

(a) Termination Right. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or, in its reasonable opinion, will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on any Trading Market shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction, or (iii) if the United States shall have become involved in a new war or an increase in major hostilities, or (iv) if a banking moratorium has been declared by a New York State or federal authority, or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets, or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in the Representative's reasonable opinion, make it inadvisable to proceed with the delivery of the Securities, or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder, or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Securities or to enforce contracts made by the Underwriters for the sale of the Securities.

(b) Expenses. In the event this Agreement shall be terminated pursuant to Section 7.1(a), within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Representative its actual and accountable out of pocket expenses related to the transactions contemplated herein then due and payable, including the fees and disbursements of Loeb.

(c) Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Article VI shall not be in any way effected by such election or termination or failure to carry out the terms of this Agreement or any part hereof.

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

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

7.4 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Representative. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

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

7.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

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

7.8 Survival. The representations and warranties contained herein shall survive the Closing and the Option Closing, if any, and the delivery of the Securities.

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

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

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

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

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

7.14 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVE FOREVER ANY RIGHT TO TRIAL BY JURY.**

(Signature Pages Follow)

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among the Company and the several Underwriters in accordance with its terms.

Very truly yours,

PROTALEX, INC.

By: _____
Name:
Title:

Address for Notice:
131 Columbia Turnpike, Suite 1,
Florham Park NJ 07932
Attention: President

Copy to:
Morse, Zelnick, Rose & Lander, LLP
825 Third Avenue, 16th Floor
New York, NY 10022
Attention: Kenneth S. Rose, Esq.

Accepted on the date first above written.
Chardan Capital Markets, LLC
As the Representative of the several
Underwriters listed on Schedule I
By: Chardan Capital Markets, LLC

By: _____
Name: Jonas Grossman
Title: President and Head of Capital Markets

SCHEDULE I

Schedule of Underwriters

Underwriters	Closing Shares	Closing Purchase Price
Total		

Schedule II
Parties Subject to Lock-up

Arnold P. Kling
Kirk M. Warshaw
Marco Elser
Niobe Ventures LLC

EXHIBIT A

FORM OF LEGAL OPINION

[Intentionally omitted]

EXHIBIT B

FORM OF OFFICER'S CERTIFICATE

[Intentionally omitted]

EXHIBIT C

FORM OF SECRETARY'S CERTIFICATE

[Intentionally omitted]

EXHIBIT D

LOCK-UP LETTER AGREEMENT

Chardan Capital Markets, LLC
As Representative of the several underwriters, if any, named in the Underwriting Agreement referenced below
17 State Street
Suite 1600
New York, NY 10004

Ladies and Gentlemen:

The undersigned understands that you and certain other firms, if any, (the "***Underwriters***") propose to enter into an Underwriting Agreement (the "***Underwriting Agreement***") providing for the purchase by the Underwriters of shares (the "***Shares***") of common stock, par value $0.00001 per share (the "***Common Stock***") and warrants to purchase Common Stock (the "***Warrants***" and, together with the Shares, the "***Securities***"), of Protalex, Inc., a Delaware corporation (the "***Company***"), and that the Underwriters propose to reoffer the Shares and Warrants to the public (the "***Offering***").

In consideration of the execution of the Underwriting Agreement by the Underwriters, and for other good and valuable consideration, the undersigned hereby irrevocably agrees that, without the prior written consent of the Representative, on behalf of the Underwriters, the undersigned will not, directly or indirectly, (1) offer for sale, sell, pledge, or otherwise transfer or dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the transfer or disposition by any person at any time in the future of) any shares of Common Stock (including, without limitation, shares of Common Stock that may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and shares of Common Stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for Common Stock, (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, (3) except as provided for below, make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock or any other securities of the Company, or (4) publicly disclose the intention to do any of the foregoing for a period commencing on the date hereof and ending on the __day after the date of the Prospectus relating to the Offering (such __day period, the "***Lock-Up Period***").

The foregoing paragraph shall not apply to (a) transactions relating to shares of Common Stock or other securities acquired in the open market after the completion of the Offering, *provided* that no filing under Section 16(a) of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***), shall be required or shall be voluntarily made in connection with such transfers; (b) bona fide gifts, sales or other dispositions of shares of any class of the Company's capital stock or any security convertible into Common Stock, in each case that are made exclusively between and among the undersigned or members of the undersigned's family, or affiliates of the undersigned, including its partners (if a partnership) or members (if a limited liability company); (c) any transfer of shares of Common Stock or any security convertible into Common Stock by will or intestate succession upon the death of the undersigned; (d) transfer of shares of Common Stock or any security convertible into Common Stock to an immediate family member (for purposes of this Lock-Up Letter Agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin) or any trust, limited partnership, limited liability company or other entity for the direct or indirect benefit of the undersigned or any immediate family member of the undersigned; *provided* that, in the case of clauses (b)- (d) above, it shall be a condition to any such transfer that (i) the transferee/donee agrees to be bound by the terms of this Lock-Up Letter Agreement (including, without limitation, the restrictions set forth in the preceding sentence) to the same extent as if the transferee/donee were a party hereto, (ii) each party (donor, donee, transferor or transferee) shall not be required by law (including without limitation the disclosure requirements of the Securities Act of 1933, as amended, (the "***Securities Act***") and the Exchange Act) to make, and shall agree to not voluntarily make, any filing or public announcement of the transfer or disposition prior to the expiration of the __day period referred to above, and (iii) the undersigned notifies the Representative at least two business days prior to the proposed transfer or disposition; (e) the transfer of shares to the Company to satisfy withholding obligations for any equity award granted pursuant to the terms of the Company's stock option/incentive plans, such as upon exercise, vesting, lapse of substantial risk of forfeiture, or other similar taxable event, in each case on a "cashless" or "net exercise" basis (which, for the avoidance of doubt shall not include "cashless" exercise programs involving a broker or other third party), *provided* that as a condition of any transfer pursuant to this clause (e), that if the undersigned is required to file a report under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock during the Lock-Up Period, the undersigned shall include a statement in such report, and if applicable an appropriate disposition transaction code, to the effect that such transfer is being made as a share delivery or forfeiture in connection with a net value exercise, or as a forfeiture or sale of shares solely to cover required tax withholding, as the case may be; (f) transfers of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock pursuant to a bona fide third party tender offer made to all holders of the Common Stock, merger, consolidation or other similar transaction involving a change of control (as defined below) of the Company, including voting in favor of any such transaction or taking any other action in connection with such transaction, *provided* that in the event that such merger, tender offer or other transaction is not completed, the Common Stock and any security convertible into or exercisable or exchangeable for Common Stock shall remain subject to the restrictions set forth herein; (g) the exercise of warrants or the exercise of stock options granted pursuant to the Company's stock option/incentive plans or otherwise outstanding on the date hereof; *provided*, that the restrictions shall apply to shares of Common Stock issued upon such exercise or conversion; (h) the establishment of any contract, instruction or plan that satisfies all of the requirements of Rule 10b5-1 (a "***Rule 10b5-1 Plan***") under the Exchange Act; *provided*, *however*, that no sales of Common Stock or securities convertible into, or exchangeable or exercisable for, Common Stock, shall be made pursuant to a Rule 10b5-1 Plan prior to the expiration of the Lock-Up Period; *provided further*, that the Company is not required to report the establishment of such Rule 10b5-1 Plan in any public report or filing with the Commission under the Exchange Act during the lock-up period and does not otherwise voluntarily effect any such public filing or report regarding such Rule 10b5-1 Plan; and (i) any demands or requests for, exercise of any right with respect to, or taking any action in preparation of, the registration by the Company under the Act of the undersigned's shares of Common Stock, provided that no transfer of the undersigned's shares of Common Stock registered pursuant to the exercise of any such right and no registration statement shall be filed under the Act with respect to any of the undersigned's shares of Common Stock during the Lock-Up Period. For purposes of clause (f) above, "change of control" shall mean the consummation of any bona fide third party tender offer, merger, purchase, consolidation or other similar transaction the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of a majority of total voting power of the voting stock of the Company.

The Lock-Up Period will commence on the date of this Lock-Up Letter Agreement and continue and include the date __ days after the date of the Prospectus relating to the Offering, provided, however, if (1) during the last 17 days of the initial Lock-Up Period, the Company releases earnings results or material news or a material event relating to the Company occurs or (2) prior to the expiration of the initial Lock-Up Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the initial Lock-Up Period, then in each case the Lock-Up Period will be extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the occurrence of the material news or material event, as applicable, unless the Representative waives, in writing, such extension.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's securities subject to this Lock-Up Letter Agreement except in compliance with this Lock-Up Letter Agreement.

It is understood that, if the Company notifies the Underwriters that it does not intend to proceed with the Offering, if the Underwriting Agreement does not become effective, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Securities, the undersigned will be released from its obligations under this Lock-Up Letter Agreement.

The undersigned understands that the Company and the Underwriters will proceed with the Offering in reliance on this Lock-Up Letter Agreement.

Whether or not the Offering actually occurs depends on a number of factors, including market conditions. Any Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

This Lock-Up Letter Agreement shall automatically terminate upon the earliest to occur, if any, of (1) the termination of the Underwriting Agreement before the sale of any Securities to the Underwriters, or (2) _____, 2016, in the event that the Underwriting Agreement has not been executed by that date.

This Lock-Up Letter Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof.

[Signature page follows]

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Lock-Up Letter Agreement and that, upon request, the undersigned will execute any additional documents necessary in connection with the enforcement hereof. Any obligations of the undersigned shall be binding upon the heirs, personal representatives, successors and assigns of the undersigned.

Very truly yours,

By: _____
Name:

Title:

Dated: _____, 2016

Exhibit E

Form of Underwriter's Warrant

[Intentionally omitted]

Exhibit F
Form of Warrant

[Intentionally omitted]

EXHIBIT 10.21

EXCHANGE AGREEMENT

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

June 3, 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 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 all 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, all accrued and unpaid interest on 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.

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.*

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Amendment No. 1 to Form S-1 Registration Statement of our report dated July 7, 2015, relating to the financial statements of Protalex, Inc. appearing in the prospectus, which is part of this registration statement. Our report includes an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern. We also consent to the reference to us under the heading "Experts" in such prospectus.

/s/ Liggett & Webb, P.A.
Liggett & Webb, P.A.

New York, New York
June 2, 2016

EXHIBIT 99.1

DIRECTOR NOMINEE CONSENT

The undersigned hereby consents to being named as a director nominee in the Registration Statement on Form S-1 (SEC File No. 333-206008) under the Securities Act of 1933, as amended (the "Act"), filed by Protalex, Inc., a Delaware corporation (the "Company"), with the U.S. Securities and Exchange Commission (the "Registration Statement") and to being appointed as a director to serve on the Company's Board of Directors commencing on the effective date of the Registration Statement.

Dated: June 2, 2016

/s/ Ralph H. Isham

Ralph H. Isham

EXHIBIT 99.2

DIRECTOR NOMINEE CONSENT

The undersigned hereby consents to being named as a director nominee in the Registration Statement on Form S-1 (SEC File No. 333-206008) under the Securities Act of 1933, as amended (the "Act"), filed by Protalex, Inc., a Delaware corporation (the "Company"), with the U.S. Securities and Exchange Commission (the "Registration Statement") and to being appointed as a director to serve on the Company's Board of Directors commencing on the effective date of the Registration Statement.

Dated: June 2, 2016

/s/ Doron Steger

Doron Steger