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

FORM 10-Q

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended August 31, 2018

OR

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

Commission File Number: **000-28385**

Protalex, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**91-2003490**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

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

215-862-9720
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Number of shares outstanding of the issuer's Common Stock, par value $0.00001 per share, as of October 12, 2018: 47,325,387 shares.

PROTALEX, INC.

Quarterly Report on Form 10-Q
For the Period Ended August 31, 2018

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

Certain statements made in this Quarterly Report on Form 10-Q are "forward-looking statements" regarding the plans and objectives of management for future operations and market trends and expectations. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements included herein are based on current expectations that involve numerous risks and uncertainties. Our plans and objectives are based, in part, on assumptions involving the continued expansion of our business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond our control. Although we believe that our assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there can be no assurance that the forward-looking statements included in this Report will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that our objectives and plans will be achieved. We undertake no obligation to revise or update publicly any forward-looking statements for any reason. The terms "we", "our", "us", or any derivative thereof, as used herein refer to Protalex, Inc., a Delaware corporation, and its predecessors.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PROTALEX, INC.

CONDENSED BALANCE SHEETS

	August 31, 2018 (Unaudited)	May 31, 2018
CURRENT ASSETS:		
Cash and cash equivalents	$ 114,876	$ 555,411
Prepaid expenses	40,082	74,386
Total current assets	154,958	629,797
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $18,423 and $18,168 as of August 31, 2018 and May 31, 2018, respectively	1,112	1,367
Total other assets	1,112	1,367
Total Assets	$ 156,070	$ 631,164
LIABILITIES AND STOCKHOLDERS' (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 468,467	$ 428,383
Accrued expenses	146,577	200,752
Total current liabilities	615,044	629,135
LONG TERM LIABILITIES:		
Note Payable – related party	2,004,408	1,989,322
Senior Convertible Debt - net of discount ($1,475,000 face value less Senior Convertible Debt Discount of $1,324,382 at August 31, 2018 and $1,399,873 at May 31, 2018)	150,618	75,127
Senior Secured Convertible Note – Accrued Interest	75,747	37,514
Total liabilities	2,845,817	2,731,098
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; 47,325,387 and 47,325,387 shares issued and outstanding, respectively	473	473
Additional paid in capital	102,308,325	102,122,025
Accumulated deficit	(104,998,545)	(104,222,432)
Total stockholders' (deficit)	(2,689,747)	(2,099,934)
Total liabilities and stockholders' (deficit)	$ 156,070	$ 631,164

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

PROTALEX, INC.

CONDENSED STATEMENTS OF OPERATIONS

	Three Months Ended August 31, 2018 (Unaudited)	Three Months Ended August 31, 2017 (Unaudited)
Revenues	$ 0	$ 0
Operating Expenses		
Research and development	248,933	681,829
Administrative	297,730	142,390
Professional fees	100,386	182,943
Depreciation and amortization	255	255
Operating loss	(647,304)	(1,007,417)
Other income (expense)		
Interest income	1	1
Interest expense	(128,810)	(157,561)
Loss before income taxes	(776,113)	(1,164,977)
Provision for income taxes	0	0
Net loss	$ (776,113)	$ (1,164,977)
Weighted average number of common shares outstanding	**47,325,387**	**28,767,582**
Loss per common share – basic and diluted	$ (0.02)	$ (0.04)

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

PROTALEX, INC.

CONDENSED STATEMENTS OF CASH FLOWS

	Three Months Ended August 31, 2018 (Unaudited)	Three Months Ended August 31, 2017 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (776,113)	$ (1,164,977)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Amortization of debt discount	75,491	0
Depreciation and amortization	255	255
Equity based expense	186,300	0
(Increase)/decrease in:		
Prepaid expenses and deposits	34,304	49,076
Increase/(decrease) in:		
Accounts payable and accrued expenses	(14,091)	77,960
Accrued interest payable	53,319	157,561
Net cash and cash equivalents used in operating activities	(440,535)	(880,125)
CASH FLOWS FROM INVESTING ACTIVITIES:	0	0
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of note payable to individuals	0	870,000
Net cash and cash equivalents provided by financing activities	0	870,000
NET DECREASE IN CASH AND CASH EQUIVALENTS	(440,535)	(10,125)
Cash and cash equivalents, beginning of period	555,411	487,383
Cash and cash equivalents, ending of period	$ 114,876	$ 477,258
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.

PROTALEX, INC.

NOTES TO 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 has been 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 August 31, 2018, the Company has incurred an accumulated deficit of $104,998,545. For the years ended May 31, 2018 and 2017 and three months ended August 31, 2018, the Company had net losses of $5,036,183, $4,563,721 and $776,113, respectively. The Company utilized $3,376,972, $3,936,796 and $440,535 of cash for operating activities for the years ended May 31, 2018 and 2017, and three months ended August 31, 2018, respectively. As of August 31, 2018, the Company had cash and cash equivalents of $114,876 and net negative working capital of $460,086. 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. Although the Company is exploring all options to raise working capital, if it is not successful in imminently raising additionally working capital, it will be forced to substantially scale back, suspend or discontinue operations.

The Company does not anticipate generating operating revenue for the foreseeable future and do not currently have any products that are marketable. In order to continue its research and development program and commercialization efforts the Company will require substantial additional working capital. The Company currently has no agreements or commitments with respect to raising the working capital necessary to continue its research and development program and commercialization efforts. Although the Company is exploring all options to raise working capital, if it is not successful in imminently raising additionally working capital, it will be forced to substantially scale back, suspend or discontinue operations.

PROTALEX, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

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, 2018. 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 August 31, 2018 and August 31, 2017, the Company had a total of 5,560,543 and 3,980,543, respectively, of Common Stock underlying exercisable stock options and shares from convertible debt of $1,475,000 as of August 31, 2018 of potentially dilutive securities.

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.

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 $186,300 and $0 and is included in operating expenses for the three months ended August 31, 2018 and August 31, 2017, 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 August 31, 2018 in connection with these compensation

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

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 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 August 31, 2018, there were 6,940,543 stock options outstanding, of which 5,560,543 were exercisable. At August 31, 2018, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model, was $372,600. The remaining options will be valued once they vest upon the future events. The Company did not grant any options during the three months ended August 31, 2018, and no options expired.

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.

The amendments in ASU 2017-11 change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. ASU 2017-11 defines down round feature as: "A feature in a financial instrument that reduces the strike price of an issued financial instrument if the issuer sells shares of its stock for an amount less than the currently stated strike price of the issued financial instrument or issues an equity-linked financial instrument with a strike price below the currently stated strike price of the issued financial instrument. A down round feature may reduce the strike price of a financial instrument to the current issuance price, or the reduction may be limited by a floor or on the basis of a formula that results in a price that is at a discount to the original exercise price but above the new issuance price of the shares, or may reduce the strike price to below the current issuance price. A standard antidilution provision is not considered a down round feature"

Early Adoption ASU 2017-11 - For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period prior to ASU 2017-11. The Company has elected to early adopt this standard and has no other instruments from prior periods that are affected by this adoption.

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 director.

NOTE 6. SENIOR SECURED NOTES - RELATED PARTY

As of May 31, 2018, as a result of the Exchange Agreement, described below, the outstanding principal balance under the Senior Secured Debt to Niobe totaled $0.

On February 28, 2018, the Company raised an aggregate of $1.425 million from eight accredited investors in a private placement financing (the "Offering") of 10% Senior Convertible Notes, due on February 28, 2023 (the "Senior Notes"). No commissions were paid in connection with the Offering which was principally sold to certain existing stockholders of the Company. Proceeds of the Offering have been used for working capital purposes, principally to fund ongoing clinical trials and studies and related activities. No registration rights were granted to the investors in the Offering.

The Senior Notes are convertible into shares of Common Stock at a price of $0.20 per share at the option of the holder prior to maturity or earlier prepayment, accrue interest at the rate of 10% per annum and are due on February 28, 2023. Upon conversion, the note holder will receive 5,000 shares of the common stock of the Company for each $1,000 of principal or accrued interest converted. Two-thirds of the shares issuable upon any conversion of the Senior Notes will be acquired by the Company from Niobe for nominal consideration ($.01 per share) pursuant to a mandatory call agreement entered into in connection with the Offering (the "Call Agreement"). As a result, for each $1,000 of principal or interest converted, the Company will issue approximately 1,667 new shares. Accordingly, the Company's effective conversion price will be approximately $0.60 per share of Common Stock, with Niobe incurring substantially all of the associated dilution. The closing price per share of Common Stock on the date of the Offering was $0.45.

On March 13, 2018, the Company raised an additional $50,000 in the Offering and issued a Senior Note in the principal amount of $50,000 to an accredited investor. In connection with the foregoing, on March 13, 2018, the Call Agreement was amended and restated to also include two-thirds of the shares issuable upon the conversion of this Senior Note.

The Company evaluated the conversion feature of the Senior Notes and determined that under the accounting guidance for "Accounting for Convertible Securities with Beneficial Conversion Features" that a value should be attributed to the embedded conversion feature. The Company determined the allocation to the conversion feature to be $1.475 million, which reduced the face amount of the Senior Notes carried on its balance sheet to -$0-. This discount will be amortized over 60 months and will serve to increase the interest expense of the Senior Notes during the term of such notes. During the year ended May 31, 2018, $75,127 of the discount was amortized and increased interest expense by that amount. As of August 31, 2018, $1,324,382 of the original discount remained resulting in the net amount of the debt being $150,618 as of August 31, 2018.

As a condition to the consummation of the Offering, on February 28, 2018, the Company entered into an Exchange Agreement with Niobe (the "Exchange Agreement") pursuant to which Niobe converted $22,269,367, the aggregate outstanding principal balance of the Senior Secured Debt due to Niobe, into 18,557,805 shares of Common Stock at a conversion price of $1.20 per share. This resulted in a gain on conversion of $13,918,354, which was recognized against equity and had no impact on the Statement of Operations. The Company also issued a promissory note, dated February 28, 2018, to Niobe in the principal amount of $1,974,349 bearing interest at a rate of 3% per annum and maturing on March 31, 2023 (the "Niobe Note"), for the accrued but unpaid interest on the notes converted by Niobe. At August 31, 2018, $2,004,408 was outstanding under the Niobe Note.

NOTE 7. SUBSEQUENT EVENTS

In September 2018, the Company borrowed $250,000 from Niobe and issued a promissory note to Niobe in the principal amount of $250,000 bearing interest at a rate of 3% per annum and maturing on March 31, 2023 (the "September 2018 Note"). The September 2018 Note is subordinate to the Senior Notes.

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

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 eight clinical studies and was granted Orphan Drug Designation (ODD) in the United States and Europe for the treatment of ITP.

We do not anticipate generating operating revenue for the foreseeable future and do not currently have any products that are marketable. In order to continue our research and development program and commercialization efforts we will require substantial additional working capital. We currently have no agreements or commitments with respect to raising the working capital necessary to continue our research and development program and commercialization efforts. Although we are exploring all options to raise working capital, if we are not successful in imminently raising additionally working capital, we will be forced to substantially scale back, suspend or discontinue operations.

In March 2015, the FDA accepted our Investigational New Drug (IND) application for a Phase I/II open-label, dose-escalating study of PRTX-100 in adults with persistent/chronic ITP (the "PRTX-100-202 Study"). In June 2015, the U.S. Food and Drug Administration (FDA) granted ODD to PRTX-100 for the treatment of ITP. In July 2015, the European Medicines Agency (EMA) granted approval for a Phase 1b open-label, dose-escalating study of PRTX-100 in adult patients with persistent/chronic ITP (the "PRTX-100-203 Study"). In September 2015, the EMA Committee for Orphan Medicinal Products (COMP) issued a positive opinion recommending PRTX-100 for designation as an orphan medicinal product for the treatment of ITP. In November 2015, we enrolled our first patient in the PRTX-100-202 Study in the United States and in January 2016 we enrolled our first patient in the PRTX-100-203 Study in Europe. Enrollment has been completed in both the PRTX-100-202 Study in the U.S. and the United Kingdom (UK) and in the PRTX-100-203 Study in the UK during the past quarter. In August 2017, the FDA's Office of Orphan Product Development (OOPD) awarded us a grant of $403,000 to support the future clinical development of PRTX-100 as a treatment for ITP.

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

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

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

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

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

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

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

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

In November 2015, we commenced enrollment and enrolled our first patient in the PRTX-100-202 Study. The PRTX-100-202 Study may enroll up to 36 patients in as many as six cohorts. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoint of the PRTX-100-202 Study is a platelet response to PRTX-100. Secondary endpoints include safety, immunogenicity, and pharmacokinetics. Enrollment was completed in the PRTX-100-202 Study last quarter. A total of 13 patients completed the PRTX-100-202 Study up through the fourth dosage cohort (12 mg/kg) with 2 patients having had a platelet response per protocol. Preliminary analysis of the PRTX-100-202 Study data showed that PRTX-100 had an acceptable safety profile across the dose range studied and that platelet counts were elevated in most patients that received four weeks of treatment.

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. 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. Enrollment was completed in the PRTX-100-203 Study earlier this year. A total of 15 patients completed the PRTX-100-203 Study up through the fifth dosage cohort (24 mg/kg) with 3 patients having had a platelet response per protocol. Preliminary analysis of the PRTX-100-203 Study data showed that PRTX-100 had an acceptable safety profile across the dose range studied and that platelet counts were elevated in most patients that received four weeks of treatment.

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.

Change in Control and Incremental Financing Transactions

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.

On November 11, 2009 (the "Effective Date"), we consummated a financing transaction (the "Financing") in which we raised $3 million 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 our common stock.

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

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 our common stock after taking into account all outstanding shares of our 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 our common stock.

In 2012, from February 1, 2012 through December 3, 2012, we raised an aggregate of $3.5 million of additional working capital pursuant to four loans from Niobe and issued to Niobe four secured promissory notes in the same aggregate principal amount, hereinafter referred to as the "2012 Secured Notes."

In 2013, from January 18, 2013 through August 27, 2013, we raised an aggregate of $5.5 million of additional working capital pursuant to three loans from Niobe and issued to Niobe three secured promissory notes in the same aggregate principal amount, hereinafter referred to as the "2013 Secured Notes."

Collectively, the 2012 Secured Notes and the 2013 Secured Notes represented a total of $9 million of loans from Niobe, 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 which bore interest at a rate of 3% per annum and, as amended, was due to mature on September 1, 2018 (the "Consolidated Note"). The face amount of the Consolidated Note reflects the $9 million aggregate principal amount of the Secured Notes plus interest accrued at 3% per annum on the notes from their respective dates of issuance.

On January 23, 2014, we consummated a private placement financing to accredited investors of 471,334 shares of our 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 were 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, as amended and restated through January 2018, we borrowed an aggregate of an additional $13.05 million from Niobe (the "2014 Credit Facility"). Each loan made under the 2014 Credit Facility was represented by a senior secured promissory note which bore interest at a rate of 3% per annum and was due to mature on September 1, 2018. Our obligations under the 2014 Credit Facility were secured by a first priority perfected security interest in all of our assets.

On February 28, 2018, we raised an aggregate of $1.425 million from eight accredited investors in a private placement financing (the "Offering") of 10% Senior Convertible Notes, due on February 28, 2023 (the "Senior Notes"). No commissions were paid in connection with the Offering which was principally sold to certain of our existing stockholders. Proceeds of the Offering have been used for working capital purposes, principally to fund ongoing clinical trials and studies and related activities. No registration rights were granted to the investors in the Offering.

The Senior Notes are convertible into shares of our common stock at a price of $0.20 per share at the option of the holder prior to maturity or earlier prepayment, accrue interest at the rate of 10% per annum and are due on February 28, 2023. Upon conversion, the note holder will receive 5,000 shares of our common stock for each $1,000 of principal or accrued interest converted. Two-thirds of the shares issuable upon any conversion of the Senior Notes will be acquired by us from Niobe for nominal consideration ($.01 per share) pursuant to a mandatory call agreement entered into in connection with the Offering (the "Call Agreement"). As a result, for each $1,000 of principal or interest converted, we will issue approximately 1,667 new shares. Accordingly, our effective conversion price will be approximately $0.60 per share of our common stock, with Niobe incurring substantially all of the associated dilution. The closing price per share of our common stock on the date of the Offering was $0.45.

On March 13, 2018, we raised an additional $50,000 in the Offering and issued a Senior Note in the principal amount of $50,000 to an accredited investor. In connection with the foregoing, on March 13, 2018, the Call Agreement was amended and restated to also include two-thirds of the shares issuable upon the conversion of this Senior Note.

As a condition to the consummation of the Offering, on February 28, 2018, we entered into an Exchange Agreement with Niobe (the "Exchange Agreement") pursuant to which Niobe converted the $22,269,367 aggregate outstanding principal balance under the Consolidated Note and the 2014 Credit Facility, as of February 28, 2018, into 18,557,805 shares of our common stock at a conversion price of $1.20 per share. This resulted in a gain on conversion of $13,918,354, which was recognized against equity and had no impact on the Statement of Operations. We also issued a promissory note, dated February 28, 2018, to Niobe in the principal amount of $1,974,349 bearing interest at a rate of 3% per annum and maturing on March 31, 2023, for the accrued but unpaid interest on the notes converted by Niobe.

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 Sections 4(a)(2) and/or 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 five clinical trials under this IND. Our first Phase I single-dose clinical trial commenced in December 2005 and was completed in March 2006. This trial was performed in healthy volunteers and was designed primarily to assess the safety and tolerability of a single intravenous dose of PRTX-100. This study demonstrated that PRTX-100 appears safe and well-tolerated at the doses administered. There were no deaths or serious adverse events. The PK profile was determined and found consistent with that projected from pre-clinical models.

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

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

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

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

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

In March 2015, the FDA accepted our IND application for a Phase I/II open-label, dose-escalating study of PRTX-100 in adults with persistent/chronic ITP (the "PRTX-100-202 Study"). In June 2015, the FDA granted ODD to PRTX-100 for the treatment of ITP. In July 2015, the EMA granted approval for a Phase 1b open-label, dose-escalating study of PRTX-100 in adult patients with persistent/chronic ITP (the "PRTX-100-203 Study"). In September 2015, COMP issued a positive opinion recommending PRTX-100 for designation as an orphan medicinal product for the treatment of ITP. In November 2015, we enrolled our first patient in the PRTX-100-202 Study in the United States and in January 2016 enrolled our first patient in the PRTX 100-203 Study in Europe. Enrollment was completed in both studies at different dosage cohorts earlier this year. In August 2017, OOPD awarded us a grant of $403,000 to support the future clinical development of PRTX-100 as a treatment for ITP.

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

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

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

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

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

The PRTX-100-105 Study

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

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

The PRTX-100-202 Study

In November 2015, we commenced enrollment and enrolled our first patient in the PRTX-100-202 Study. The PRTX-100-202 Study may enroll up to 36 patients in as many as six cohorts. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoint of the PRTX-100-202 Study is a platelet response to PRTX-100. Secondary endpoints include safety, immunogenicity, and pharmacokinetics. Enrollment was completed in the PRTX-100-202 Study last quarter. A total of 13 patients completed the PRTX-100-202 Study up through the fourth dosage cohort (12 mg/kg) with 2 patients having had a platelet response per protocol. Preliminary analysis of the PRTX-100-202 Study data showed that PRTX-100 had an acceptable safety profile across the dose range studied and that platelet counts were elevated in most patients that received four weeks of treatment.

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. 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. Enrollment was completed in the PRTX-100-203 Study earlier this year. A total of 15 patients completed the PRTX-100-203 Study up through the fifth dosage cohort (24 mg/kg) with 3 patients having had a platelet response per protocol. Preliminary analysis of the PRTX-100-203 Study data showed that PRTX-100 had an acceptable safety profile across the dose range studied and that platelet counts were elevated in most patients that received four weeks of treatment.

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

Markets

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

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

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

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

ITP has no known cure, and relapses may occur years after seemingly successful medical or surgical management. If the patient's condition does not improve with the use of prednisone, a corticosteroid drug that is the first line therapy for ITP, other treatments may include: danazol (Danocrine), a drug taken by mouth; infusions of high-dose gamma globulin (an immune factor); drugs that suppress the immune system; anti-RhD therapy for people with certain blood types; and newer agents like romiplostim (Nplate) and eltrombopag (Promacta) that stimulate the bone marrow to make more platelets. Global sales of Nplate and Promacta were approximately $642 million and $867 million, respectively, in 2017. 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. Tavalisse (fostamatinib disodium hexahydrate) is most recent new agent approved for the treatment of adult patients with chronic ITP who have an insufficient response to a previous treatment. Approved by the FDA in April 2018, Rigel's Tavalisse is an oral spleen tyrosine kinase (SYK) inhibitor.

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 (MG), chronic idiopathic demyelinating polyneuropathy, and pemphigus. We recently completed a second confirmatory study of PRTX-100 in an animal model of MG with promising results. MG is an autoimmune disorder caused by anti-self antibodies that react with the neuromuscular junction causing muscle weakness and fatigability.

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

Competition

We believe, based on the pre-clinical trials and the results to date of our five Phase I RA clinical studies, that PRTX-100 has a potential competitive advantage as it may be safer and more efficacious than existing RA therapies, and may cost less to manufacture than competing biologic-based therapies. Current RA treatments are characterized by complex manufacturing methods and, in 2016, 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. Several 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 2017 annual report, Enbrel generated revenues of approximately $7.9 billion combined for Amgen and Pfizer, Remicade generated revenues of more than $7.2 billion combined for Johnson & Johnson and Merck, and AbbVie reported generated revenues of over $18.4 billion for Humira. For other TNF inhibitors, Cimzia generated revenues of $1.7 billion for UCB; Simponi generated revenues of $2.7 billion for Johnson & Johnson and Merck; and Orencia generated revenues of $2.5 billion for Bristol Myers Squibb. Kineret generated revenues of $126 million in sales for SOBI, which acquired from Amgen the rights to develop and commercialize Kineret in 2014. Actemra generated revenues of $1.97 billion for Roche. Also for Roche, Rituxan earned $7.5 billion total for multiple indications. Xeljanz had the largest increase for Pfizer from $927 million in 2016 to almost $1.4 billion in 2017. Revenue figures above reflect the use of these drugs for RA, other indications and off label uses.

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

Government Regulation and Product Approval

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

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

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

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

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

Clinical Trials

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

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

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

Biological License Application

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

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

Fast Track Designation

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

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

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

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

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

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

Regulatory Requirements

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

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

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

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

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

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

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

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

In August 2017, the OOPD awarded us a grant of $403,000 to support the future clinical development of PRTX-100 as a treatment for ITP.

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
Protein A Compositions and Methods of Use	U.S. Patent No. 9,370,552	November 6, 2022
Protein A Compositions and Methods of Use	European Patent No. 2,206,511	September 13, 2025
Protein A Compositions and Methods of Use	Canadian Patent No. 2,894,098	March 6, 2023
Protein A Compositions and Methods of Use	Canadian Patent No. 2,481,282	March 6, 2023
Protein A Compositions and Methods of Use	European Patent No. 1,499,345	March 6, 2023
Protein A Compositions and Methods of Use	Hong Kong Patent No. 1145805B	September 13, 2025

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

Employees

We have two employees, our president and our chief financial officer. 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.

Critical Accounting Policies

Our financial statements are prepared in conformity with accounting principles generally accepted in the United States of America. Note 3 to the financial statements describes the significant accounting policies and methods used in the preparation of our financial statements.

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

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

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

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

Results of Operations

For the Three Months Ended August 31, 2018 and August 31, 2017

Research and Development Expenses - Research and Development expenses ("R&D Expenses") were $248,933 and $681,829 for the three months ended August 31, 2018 and August 31, 2017, respectively. The decrease in R&D expenses for the three month period ended August 31, 2018 compared to the same prior year period was due to a decrease in clinical activities and a decrease in drug material and drug product related activities.

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 $297,730 and $142,390 for the three months ended August 31, 2018 and August 31, 2017, respectively. The increase in administrative expenses for the three month period ended August 31, 2018 compared to the same prior year period was due to an increase in stock compensation expense.

Professional Fees - Professional expenses were $100,386 and $182,943 for the three months ended August 31, 2018 and August 31, 2017, respectively. The decrease for the three month period ended August 31, 2018 was principally due to the non-recurring nature of fundraising expenses incurred in the three months ended August 31, 2017.

Net Loss Outlook

We have not generated any operating revenues, have incurred operating losses since inception and have not achieved profitable operations. Our accumulated deficit from inception through August 31, 2018 was approximately $105 million 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.

We do not anticipate generating operating revenue for the foreseeable future and do not currently have any products that are marketable. In order to continue our research and development program and commercialization efforts we will require substantial additional working capital. We currently have no agreements or commitments with respect to raising the working capital necessary to continue our research and development program and commercialization efforts. Although we are exploring all options to raise working capital, if we are not successful in imminently raising additionally working capital, we will be forced to substantially scale back, suspend or discontinue operations.

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.

As of August 31, 2018, we had cash and cash equivalents of $114,876 and net negative working capital of $460,086, which, based on our current "burn" rate, is insufficient to sustain our ongoing operations. In order to sustain our operations through the end of the current fiscal year in a manner consistent with past practice we require a working capital infusion of at least $3.0 million. We currently have no agreements or commitments with respect to raising the working capital necessary to continue our research and development program and commercialization efforts. Although we are exploring all options to raise working capital, if we are not successful in imminently raising additionally working capital, we will be forced to substantially scale back, suspend or discontinue operations.

On February 28, 2018, pursuant to the Exchange Agreement and as a condition to the consummation of the Offering (more fully described above), Niobe converted the $22,269,367 aggregate outstanding principal balance under the Consolidated Note and the 2014 Credit Facility, as of February 28, 2018, into 18,557,805 shares of our common stock at a conversion price of $1.20 per share. This resulted in a gain on conversion of $13,918,354, which was recognized against equity and had no impact on the Statement of Operations. We also issued a promissory note, dated February 28, 2018, to Niobe in the principal amount of $1,974,349 bearing interest at a rate of 3% per annum and maturing on March 31, 2023, for the accrued but unpaid interest on the notes converted by Niobe.

On February 28, 2018 and March 13, 2018, we raised an aggregate of $1.475 million from nine accredited investors in the Offering of Senior Notes. No commissions were paid in connection with the Offering which was principally sold to certain of our existing stockholders. Proceeds of the Offering have been used for working capital purposes, principally to fund ongoing clinical trials and studies and related activities. No registration rights were granted to the investors in the Offering.

Subsequent Event

In September 2018, we borrowed $250,000 from Niobe and issued a promissory note to Niobe in the principal amount of $250,000 bearing interest at a rate of 3% per annum and maturing on March 31, 2023 (the "September 2018 Note"). The September 2018 Note is subordinate to the Senior Notes.

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

Our operating cash outflows for the three months ended August 31, 2018 and 2017 were primarily attributable to research and development expenditures associated for PRTX-100 and administrative purposes. We expect to continue to use cash resources to fund operating losses and expect to continue to incur operating losses in fiscal 2018 and beyond due to continuing research and development activities.

Net Cash From 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.

Net Cash Provided by Financing Activities and Financing Requirements Outlook

We did not have any cash flow from financing activities for the three months ended August 31, 2018 and our cash flow from financing activities for the three months ended August 31, 2017 was primarily attributable to our borrowings under the 2014 Credit Facility as described above. We continue to actively seek sources of financing to fund our continuing operations and development programs. To raise additional capital, we may sell equity or debt securities. There can be no assurance that we will be able to complete any future financing transaction in a timely manner or on acceptable terms or otherwise. If we are not able to raise additional cash, we may be forced to delay, curtail, or cease our operations.

Off-Balance Sheet Arrangements

As of August 31, 2018, we had no off-balance sheet arrangements such as guarantees, retained or contingent interest in assets transferred, obligation under a derivative instrument and obligation arising out of or a variable interest in an unconsolidated entity.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company we are not required to provide the information required by this Item.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of both of our president and chief financial officer, carried out an evaluation of the effectiveness of our "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"), Rules 13a-15(e) and 15-d-15(e)) as of the end of the period covered by this Report (the "Evaluation Date"). Based upon that evaluation, both of our president and chief financial officer concluded that as of the Evaluation Date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) is accumulated and communicated to our management, including our president and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting

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

PART II – OTHER INFORMATION

ITEM 6. EXHIBITS

Exhibit No.	Description	
4.1	Promissory Note issued to Niobe in the principal amount of $250,000, dated as of September 20, 2018.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act	Filed herewith.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith in accordance with Item 601 (32) (ii) of Regulation S-K.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith in accordance with Item 601 (32) (ii) of Regulation S-K.
101.INS	XBRL Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: October 12, 2018 PROTALEX, INC.

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

Date: October 12, 2018

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

Exhibit 4.1

PROMISSORY NOTE

$250,000 September 20, 2018
New York, New York

FOR VALUE RECEIVED, PROTALEX, INC., a Delaware corporation ("Protalex"), having an address at 131 Columbia Turnpike, Suite 1, Florham Park, NJ 07932 (the "Company"), unconditionally promise to pay to the order of NIOBE VENTURES, LLC, a Delaware limited liability company (hereinafter referred to as the "Holder"), at the offices of Morse, Zelnick, Rose & Lander LLP, 825 Third Avenue, 16th floor, New York, New York 10022, or at such other place as Holder may designate in writing, the principal sum of Two Hundred Fifty Thousand and 00/100 Dollars ($250,000) (the "Principal Sum"), with interest thereon computed from the date hereof until maturity, whether on the Maturity Date (as hereinafter defined), by acceleration, or otherwise, at the rate of three percent (3.00%) per annum (the "Interest Rate"), and thereafter, in accordance with the terms of this Note, at the Default Rate (as hereinafter defined and governed), together with any costs, expenses and attorneys' fees incurred by Holder pursuant to the provisions hereof. Any amounts that remain unpaid after the Maturity Date shall thereafter bear interest at the rate of twelve percent (12%) per annum (the "Default Rate"). Interest as aforesaid shall be calculated on the basis of actual number of days elapsed over a year of 360 days.

The Principal Sum and all accrued interest on this Note shall be due on March 31, 2023 (the "Maturity Date"). The Maturity Date is subject to acceleration in accordance with Section 4 hereof.

Section 1. Promissory Note. This Note is a direct debt obligation of the Company to the Holder and is subordinate to the Senior Convertible Notes due February 28, 2023 issued by the Company.

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

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

"Event of Default" shall have the meaning set forth in Section 5.

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

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

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

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

Section 3. Registration of Transfers and Exchanges.

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

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

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

Section 5. Events of Default.

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

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

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

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

Section 6. Miscellaneous.

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

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

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

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

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

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

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

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

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

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

PROTALEX, INC.

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

Exhibit 31.1

CERTIFICATION

I, Arnold P. Kling, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protalex, Inc.;

2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Report based on such evaluation; and

    d) Disclosed in this Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 12, 2018

/s/ Arnold P. Kling

Arnold P. Kling
President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Kirk M. Warshaw, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protalex, Inc.;

2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Report based on such evaluation; and

    d) Disclosed in this Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 12, 2018

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

Exhibit 32.1

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

In connection with the quarterly report of Protalex, Inc. (the "Company") on Form 10-Q for the period ending August 31, 2018 as filed with the Securities and Exchange Commission (the "Report"), I, Arnold P. Kling, President of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: October 12, 2018

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

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

Exhibit 32.2

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

In connection with the quarterly report of Protalex, Inc. (the "Company") on Form 10-Q for the period ending August 31, 2018 as filed with the Securities and Exchange Commission (the "Report"), I, Kirk M. Warshaw, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: October 12, 2018

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

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